

168th SESSION OF THE EXECUTIVE COMMITTEE

Virtual session, 21-25 June 2021

Provisional Agenda Item 4.5

CE168/12
18 May 2021
Original: Spanish

INCREASING PRODUCTION CAPACITY FOR ESSENTIAL MEDICINES AND HEALTH TECHNOLOGIES

Introduction

1. The COVID-19 pandemic has led to shortages and inequities in access to essential medicines¹ (pharmaceuticals and vaccines) and other health technologies², hampering the response capacity of health systems and limiting or jeopardizing the delivery of essential health services.³ The health crisis 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 COVID-19 vaccine research, development, and production capacity.

2. This policy paper aims to promote intersectoral action and an increase in regional capacities for the development and production of medicines and other health technologies to improve their access and better respond to the health priorities and needs of the Region. Increasing regional production capacities can help to increase access to essential medicines and other health technologies, protect national security, and stimulate economic recovery in the Region. Implementing comprehensive intersectoral policies on essential medicines and other health technologies is useful for lending coherence to sectoral policies and

¹ The term *medicines and other health technologies* employed in this document includes products used in traditional and complementary medicine.

² In this document, the concept of essential medicines and other health technologies (pharmaceuticals and vaccines) used by the World Health Organization extends to other health technologies; *other essential health technologies* are understood as those that meet the priority health care needs of the population. Their selection is based on disease prevalence and the comparative safety, efficacy, and cost-effectiveness of these products, which should be quality-assured and available in the existing health systems at all times in sufficient quantities and in the appropriate pharmaceutical forms at affordable prices for individuals and the community.

³ Other affected medicines and technologies include oxygen, mechanical ventilators, diagnostic tests, sedatives and analgesics for intubating patients, and personal protective equipment.

facilitating effective coordination among sectors to increase development and production capacities.

Background

3. This policy is preceded by various global and regional agreements that serve as its framework. At the regional level, the *Strategy for Universal Access to Health and Universal Health Coverage* (Document CD53.R14 [2014]) (1), and the resolutions *Access and Rational Use of Strategic and High-cost Medicines and Other Health Technologies* (Resolution CD55.R12 [2016]) (2), *Public Health, Innovation and Intellectual Property: A Regional Perspective* (Resolution CD48.R15 [2008]) (3) and *COVID-19 Pandemic in the Region of the Americas* (Resolution CD58.R9 [2020]) (4) reaffirm the commitment to advancing in different dimensions to improve access to essential medicines and other health technologies. The Sustainable Health Agenda for the Americas 2018-2030 (5), the *Plan of Action on Health in All Policies* (Resolution CD53.R2 [2014]) (6), and the Strategic Plan of the Pan American Health Organization 2020-2025 (7) also provide a framework for this document.

4. Significant at the global level is the draft resolution *Strengthening local production of medicines and other health technologies to improve access*, presented at the 74th World Health Assembly in May 2021,⁴ as well as the resolutions *COVID-19 Response* (WHA73.1 [2020]) (8), also of the World Health Assembly, and *International cooperation to ensure global access to medicines, vaccines and medical equipment to face COVID-19* (A/RES/74/274 [2020]) (9), of the United Nations General Assembly, which call on Member States, United Nations agencies, international financial institutions, and other stakeholders to collaborate, including through coordination with the private sector, to improve equitable and timely access to quality-assured, safe, effective, and affordable medicines and other health technologies to fight COVID-19 by strengthening the coordination, financing, development, testing, manufacture, supply, and distribution of these products and technologies.

5. Other examples of global consensus that provide a framework for this policy are the Sustainable Development Goals (10), the World Health Assembly resolution *Improving the transparency of markets for medicines, vaccines, and other health products* (WHA72.8 [2019]) (11), and the *Global strategy and plan of action on public health, innovation and intellectual property* (WHA61.21 [2008]) (12) and its Implementation Plan 2020-2022 (13).

Situation analysis

6. As countries declared the COVID-19 health emergency, the unexpected, precipitous, and synchronous increase in demand for certain medical products led almost immediately to severe shortages and excessive price increases (14). The scarcity of

⁴ Draft resolution presented at the 74th World Health Assembly, held 24-31 May 2021 in Geneva, Switzerland.

personal protective equipment⁵ and disinfectant products was one of the first consequences of the pandemic (15), preceding even its impact in terms of health service disruptions, and morbidity and mortality. Shortages of other health technologies, such as mechanical ventilators, oxygen production technologies, oximeters, and certain medicines used in intensive care units progressively emerged.

7. Spurred by the need to meet the domestic demand for medicines and other health technologies, many countries began to adopt international trade measures. According to the World Trade Organization (WTO), many of the measures adopted to facilitate trade involved facilitating imports, nearly two-thirds of them corresponding to tariff reduction or elimination (16). Furthermore, more than 90% of the restrictive trade measures introduced during the pandemic involved restrictions on exports (17), largely those of medicines and other health technologies. According to the Economic Commission for Latin America and the Caribbean (ECLAC), in May 2020, more than 70 countries, including four of the Region's five principal suppliers, had restricted exports of some of the health technologies employed in the COVID-19 response (18).

8. The restrictions on exports of finished and intermediate products caused disruptions in the already geographically concentrated global value chains. This, combined with other factors that affected domestic supply, as well as supply chains, exacerbated shortages and impacted the countries' COVID-19 response capacity, as well as the delivery of essential health services.⁶

9. According to a 2020 survey of 122 countries conducted by the World Health Organization (WHO), 20% reported shortages or unavailability of medicines and 33% reported shortages of personal protective equipment as the leading causes of disruptions in health services for the treatment of noncommunicable chronic diseases (19). According to the Pan American Health Organization (PAHO), in August 2020, at least 11 countries in the Americas had less than a three-month supply of antiretrovirals, critically affecting the administration of HIV/AIDS prevention and control programs and the achievement of their targets (20).

10. In a joint declaration issued on 14 August 2020, the International Narcotics Control Board (INCB), WHO, and the United Nations Office on Drugs and Crime (UNODC) noted the need "to ensure access to controlled medicines such as sedatives and analgesics for intubation protocols for the treatment of patients with COVID-19" and stated that countries "should ease COVID-19-related transport restrictions for controlled medicines and consider local production solutions when feasible, to meet the COVID-19-driven demand" (21).

⁵ For example, gloves, surgical masks, safety goggles, face shields, gowns, and aprons.

⁶ Although the procurement of specific products remains a challenge for some developing countries, the WTO observed that, compared to the early phases of the pandemic, chronic shortages of personal protective equipment were diminishing as production ramped up to meet demand. According to the preliminary data from 41 countries, the WTO estimated that trade in medical goods rose by 38.7% in the first semester of 2020 (16).

11. Since the pandemic was declared, the global community has rapidly advanced many projects for the development of COVID-19 candidate vaccines. Initiatives in the Region include projects in Argentina, Brazil, Canada, Cuba, Mexico, and the United States, that have already obtained authorization from national regulatory agencies or are conducting clinical trials prior to authorization (22). Furthermore, both developed and developing countries have participated in several clinical trials of medicines and other health technologies in the Americas.

12. Nevertheless, while these projects are extremely valuable, as of this writing, they have not reached the production levels necessary to meet regional and global demand. Global production of COVID-19 vaccines authorized for distribution and administration is still concentrated in a few manufacturers, which, moreover, are facing obstacles to accelerating and expanding production due to global constraints in the manufacture of materials and inputs for vaccine production (for example, biological excipients and vials).

13. In order to accelerate development and promote the fair distribution of COVID-19 vaccines, WHO, in conjunction with Gavi, The Vaccine Alliance, and the Coalition for Epidemic Preparedness Innovations (CEPI), created the COVAX Facility for global access to COVID-19 vaccines (23). After overcoming a series of obstacles, COVAX has begun to fulfill its mission, yet continues to require support from countries and manufacturers to equitably increase access to vaccines worldwide based on public health criteria that maximize the effect of immunization. In order to accelerate technology transfer, WHO and the Government of Costa Rica have launched a platform that provides open access to the technology to fight COVID-19 (the COVID-19 Technology Access Pool or C-TAP), which facilitates the voluntary exchange of knowledge, intellectual property, data, regulatory information, and manufacturing processes, among other things (24). WHO will also facilitate the creation of technology transfer hubs (one or more, as appropriate) to transfer the whole technology package and provide training to manufacturers in middle- and low-income countries, initially prioritizing mRNA vaccine technology (25). Furthermore, to promote the global effort, WTO and other competent international organizations are discussing innovative options for the production and equitable distribution of medicines and other health technologies to fight COVID-19 through local production.

Situation prior to the COVID-19 pandemic

14. Latin America and the Caribbean are characterized by a high dependence on imports of raw materials, medicines, and other health technologies from other regions. In a recently published study, ECLAC estimated that in 2018, only 4% of Latin American and Caribbean imports of a strategic group of health technologies⁷ came from the subregion itself (18). Furthermore, while PAHO has been ramping up its efforts and participating in regional forums with the industry to increase the participation of regional manufacturers, in 2019-2020 the participation of Latin American and Caribbean manufacturers in the

⁷ ECLAC calculated the estimate by observing Latin American and Caribbean pre-pandemic imports of a series of health products used to fight COVID-19 (2018, the last year with available information).

international public procurement activities of the Revolving Fund for Vaccine Procurement (the Revolving Fund) and the Regional Revolving Fund for Strategic Public Health Supplies (the Strategic Fund) was barely 0.63% (US\$ 8.8 million)⁸ for vaccines and 2.4% (\$6.9 million) for medicines.⁹

15. Prior to the pandemic, the supply of medicines from domestic industry was increasing in several Latin American and Caribbean countries; however growing imports of innovative medicines and active ingredients exacerbated the subregion's negative balance of trade with the rest of the world. Although domestic and foreign companies that produce locally supplied more than 50% of the market, the pharmaceutical industry's share of Latin America's regional gross domestic product (GDP) in 2014 (0.37%) was low in comparison to the share of the countries of the Organisation for Economic Co-operation and Development (OECD) (0.83%) (26). The manufacture of medicines of biological origin (biotherapeutics) has grown worldwide in recent decades and, while it is heavily concentrated in developed countries, there has also been a decentralization of manufacturing, with a growing share of participation by Asian and some Latin American countries, mainly in the market for biosimilars (27, 28).

16. The balance of trade between the Latin America and Caribbean region and the rest of the world in the pharmaceutical sector also illustrates the situation in this group of countries in the Americas, which in 2018 had imports of \$23.795 billion and exports of only \$2.312 billion. Meanwhile, the medical devices and equipment industry showed large trade deficits in every Latin American and Caribbean country except Costa Rica, the Dominican Republic, and Mexico (26).¹⁰

17. While recognizing the strategic importance of vaccine production for public health and national health security (29, 30), the Latin America and Caribbean region has not succeeded in overcoming some of its long-standing challenges to increasing research, development, and the production of these products (31). With the exception of a number of successful production activities (public and private) in some Latin American countries, the subregion has been characterized by its dependence on imports to meet the needs of its expanded programs on immunization (32).

18. Furthermore, average gross spending on health research and development in the Region of the Americas (0.03% of GDP) has been much lower than that of high-income countries (0.19% of GDP). This is reflected in the low number of health researchers per

⁸ Unless otherwise indicated, all monetary figures in this document are expressed in United States Dollars.

⁹ This refers to the procurement of finished products manufactured in Latin America and the Caribbean in 2019 and 2020. It does not include the procurement of products imported through suppliers, representatives, or distributors legally operating in Latin America and the Caribbean.

¹⁰ These three countries account for almost 99% of Latin American and Caribbean exports of medical devices and equipment, which are destined mainly for the U.S. market (27).

million inhabitants (24 per million in the Americas versus 363 per million in high-income countries) (33).¹¹

Opportunities

19. During the pandemic, different areas of government and the private sector in Latin America and the Caribbean have collaborated to compensate, to some extent, the unmet needs for health supplies. Effective coordination, the presence of a pre-existing production and science and technology base, and the existence of a mature regulatory system are essential for promoting development projects and producing a wide range of health technologies (from personal protective equipment, diagnostic tests, and mechanical ventilators to vaccine production projects) (34-36).

20. The strategic importance of geographically diversifying global value chains and, above all, the need to reduce the region's dependence on the rest of the world and increase intraregional trade, offer opportunities to strengthen the industries that produce raw materials, medicines, and other health technologies, as well as strengthening economic and social integration and improving access to health in Latin America and the Caribbean (26).

21. However, 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. Under the right conditions (37), domestic production of raw materials, medicines, and other health technologies can increase their availability and accessibility. It should be noted, however, that not all local production projects meet this objective (38).¹²

22. The objective of reducing dependence and ensuring the sustainability of the supply chain in Latin America and the Caribbean is related, among other things, to the added value generated by manufacturing in the subregion (ranging from the production of active ingredients and inputs to the labeling of finished products). For production projects to contribute to access, including access in emergencies, they must have the capacity to meet health needs in an affordable and timely manner.

23. To be sustainable, projects must be technologically feasible and viable from a public health, economic, environmental, and social standpoint. Important factors include coherent design of government incentives (including public investment in research,

¹¹ Data for the most recent year since 2010. Some 83% of the data on gross spending on research and development in the medical sciences and health, and 77% of the data on investigators in the same area (full-time equivalents) correspond to 2015. The results should be analyzed with caution due to the number of missing observations (33).

¹² A literature review published by WHO yielded inconclusive results on the relationship between access to medical products and local production; it identified cases in which these objectives were aligned and others in which they were not (38).

development, and innovation; promotion of multisource generic medicines¹³; and other direct measures to promote scientific, technological, and industrial activity), as well as intellectual property,¹⁴ health, and tax regulatory frameworks that lead to the creation of an enabling environment for increased research and development, and production of raw materials, medicines, and other health technologies to address national and regional health priorities (37, 42, 43). Strengthening basic infrastructure, developing innovation clusters, and increasing the capacities of skilled human resources are also fundamental for creating the conditions for sustainable projects.

Proposal

24. Access to essential medicines and other health technologies requires, among other elements, ensuring their safety, quality, and effectiveness, as well as making them affordable and available in a timely manner and in forms that meet the needs, while including comprehensive services that promote their rational use.

25. Capacity building in research, development, innovation, and regional production of raw materials and essential medicines and other health technologies can help improve access to these medicines and technologies, while simultaneously contributing to national and regional security, and to equity and economic and social development in the countries. To accomplish this, intersectoral collaboration must be strengthened through policies to boost the regional production of medicines and other health technologies as part of a renewed comprehensive policy approach to improve access to them.

26. For the transformation process to be effective, it is strategic to engage interest and enlist political support at the highest level in each country, and to actively involve health authorities in advocacy and coordination with other sectors and stakeholders, both domestic and international, to evaluate capacities and develop policies, considering the national context. Other key elements include implementation of effective governance and leadership mechanisms (including ethical governance of data), availability of adequate resources and financial mechanisms, clearly defined public health objectives in coherent intersectoral policies, collaboration with academia and industry, and participation of civil society.

¹³ As stated in Resolution CD55.R12 (2016) of the 55th Directing Council of PAHO (2), WHO defines *multisource pharmaceutical products*” as “pharmaceutically equivalent or pharmaceutically alternative products that may or may not be therapeutically equivalent. Multisource pharmaceutical products that are therapeutically equivalent are interchangeable” (39).

¹⁴ This is in accordance with the amended version of the WTO Agreement on Aspects of Trade-related Intellectual Property Rights (TRIPS Agreement) and the Declaration on the TRIPS Agreement and Public Health, issued by the WTO Member States in Doha in 2001, the latter of which states that the agreement should be interpreted and implemented in a manner supportive of WTO Members’ right to protect public health and, in particular, to promote access to medicines for all, while recognizing the importance of intellectual property protection for the development of new medicines and the concerns about its effects on prices (40, 41).

27. This policy provides a sustainable common framework with priority strategic lines of action to orient and guide the countries of the Region in their work.

Strategic line of action 1: Strengthen coherence in intersectoral action and governance in health, science and technology, and industry

28. Defining a strategic direction for regional development of the medicines and other health technologies sector requires the development of a roadmap and setting intersectoral priorities in national policy in this area that are explicitly and coherently reflected in policies on health, science and technology, and industrial production. The achievement of public health goals and targets, as well as transparency in sectoral policies and incentives, should be explicitly stated in order to monitor and evaluate the social return on public investment.

29. The development of an environment in which health regulations are aligned with international standards and consistent with the regulatory frameworks of the science and technology, industry, and trade sectors is also essential in order to create an ecosystem that promotes research, development, and innovation, technology transfer under voluntary and mutually agreed terms, and the production of quality-assured raw materials, medicines, and other technologies, while at the same time promoting equitable access, effectiveness, competitiveness, environmental protection, project sustainability, transparency, and access to timely comprehensive information, including information on the total cost of research and development, as well as policies and pricing structures.

30. Equally relevant is the creation of intersectoral governance mechanisms to strengthen national capacity in research, development, innovation, and production of medicines and other health technologies, defining roles and respecting sectoral competencies, strengthening the leadership of national authorities and collaboration with academia and the private sector, and prioritizing the development and manufacture of raw materials, medicines, and other health technologies to meet domestic health needs, including in health emergencies.

Strategic line of action 2: Strengthen research, development, production, and logistical capacity

31. The sustainable growth of an industry devoted to innovation and the production of raw materials, medicines, and other health technologies requires strengthening various capacities. Worth mentioning in this regard are the training of different types of human resources to meet needs at the different stages of the value chain (e.g., in engineering and the biomedical, pharmaceutical, and biological sciences), as well as the development of domestic infrastructure; clusters to support research, development, innovation, and production activities; and institutions with enabling functions, such as universities, public health institutes, national institutes for science and technology development, and national health regulatory authorities.

32. In addition, to improve access to raw materials, medicines, and other health technologies in emergencies, it is also essential to strengthen and expand logistical capacity in health at the regional, national, and subnational levels through partnerships for coordination and cooperation in the management of funds and strategic national reserves, and harmonization of standards that allow for mutual support during health crises.¹⁵

Strategic line of action 3: Strengthening regional and subregional collaboration and strategic partnerships

33. Optimizing installed capacity requires strengthening intraregional technical cooperation in health, innovation, and productive development through dialogue among government authorities, networks for institutional research, development, and innovation, and collaboration with regional industrial associations and other relevant stakeholders.

34. International cooperation is essential for the coordinated and coherent design of incentives to optimize regional and domestic supply chains and decentralize value chains, and to increase the supply of raw materials and intermediate inputs for the production of priority essential medicines and other health technologies. The Latin America and Caribbean region has experience with good practices in cooperation among countries and can further the implementation of activities that contribute to human resources education, joint research (research, development, and innovation), and technology transfer under voluntary and mutually agreed terms. Moreover, collaboration through mechanisms for the consolidation of regional demand, among them the PAHO Revolving Fund and Strategic Fund, could help generate the necessary scale to ensure the feasibility of projects for the development and production of strategic medicines and other health technologies in Latin America and the Caribbean.

35. Subregional integration mechanisms, United Nations agencies, and international financial institutions for development are also key to supporting and coordinating international cooperation, forging strategic partnerships, and sharing information and capacities among the Member States.

Action by the Executive Committee

36. The Executive Committee is requested to review the policy *Increasing Production Capacity for Essential Medicines and Health Technologies*, issue the recommendations it deems pertinent, and consider adopting the proposed resolution presented in Annex A.

Annexes

¹⁵ Initiative consistent with the PAHO *Plan of Action for the Coordination of Humanitarian Assistance* (Document CD53/12 and Resolution CD53.R9), which includes technical cooperation and the coordination of humanitarian assistance in the Region through the interconnection of logistical systems and Pan American cooperation (44, 45).

References

1. Pan American Health Organization. Strategy for Universal Access to Health and Universal Health Coverage [Internet]. 53rd Directing Council of PAHO, 66th Session of the Regional Committee of WHO for the Americas; 2014 September 29 to October 3; Washington, DC. Washington, DC: PAHO; 2014 (Resolution CD53.R14) [cited 2021 March 5]. Available from: <https://iris.paho.org/bitstream/handle/10665.2/7652/CD53-R14-e.pdf>
2. Pan American Health Organization. Access and Rational Use of Strategic and High-cost Medicines and Other Health Technologies [Internet]. 55th Directing Council of PAHO, 68th Session of the Regional Committee of WHO for the Americas; 2016 September 26-30; Washington, DC. Washington, DC: PAHO; 2016 (Resolution CD55.R12) [cited 2021 March 5]. Available from: <https://www.paho.org/en/documents/cd55r12-access-and-rational-use-strategic-and-high-cost-medicines-and-other-health>
3. Pan American Health Organization. Public Health, Innovation and Intellectual Property: A Regional Perspective [Internet]. 48th Directing Council of PAHO, 60th Session of the Regional Committee of WHO for the Americas; 2008 September 3 to October 3; Washington, DC. Washington, DC: PAHO; 2008 (Resolution CD48.R15) [cited 2021 March 5]. Available from: <https://www.paho.org/en/documents/cd48r15-public-health-innovation-and-intellectual-property-regional-perspective>
4. Pan American Health Organization. COVID-19 Pandemic in the Region of the Americas [Internet]. 58th Directing Council of PAHO, 72nd Session of the Regional Committee of WHO for the Americas; 2020 September 28-29; virtual session. Washington, DC: PAHO; 2020 (Resolution CD58.R9) [cited 2021 March 5]. Available from: <https://www.paho.org/en/documents/cd58-r9-e-covid-19>
5. Pan American Health Organization. Sustainable Health Agenda for the Americas 2018-2030: A Call to Action for Health and Well-being in the Region [Internet]. 29th Pan American Sanitary Conference, 69th Session of the Regional Committee of WHO for the Americas; 2017 September 25-29; Washington, DC. Washington, DC: PAHO; 2017 (CSP29/6, Rev. 3) [cited 2021 March 5]. Available from: <https://iris.paho.org/handle/10665.2/49170>
6. Pan American Health Organization. Plan of Action on Health in All Policies [Internet]. 53rd Directing Council of PAHO, 66th Session of the Regional Committee of WHO for the Americas; 2014 September 29 to October 3; Washington, DC. Washington, DC: PAHO; 2014 (Resolution CD53.R2) [cited 2021 March 5]. Available from: <https://www.paho.org/hq/dmdocuments/2014/CD53-R2-e.pdf>

7. Pan American Health Organization. Strategic Plan of the Pan American Health Organization 2020-2025 [Internet]. 57th Directing Council of PAHO, 71st Session of the Regional Committee of WHO for the Americas; 2019 September 30 to October 4; Washington, DC. Washington, DC: PAHO; 2019 (Official Document 359) [cited 2021 March 5]. Available from: https://www3.paho.org/hq/index.php?option=com_docman&view=download&alias=50316-cd57-od359-e-add-i-strategic-plan-paho&category_slug=cd57-en&Itemid=270&lang=en
8. World Health Organization. COVID-19 Response [Internet]. 73rd World Health Assembly; 2020 May 18-19 and November 9-13; Geneva, Switzerland. Geneva: WHO; 2020 (Resolution WHA73.1) [cited 2021 March 5]. Available from: https://apps.who.int/gb/ebwha/pdf_files/WHA73/A73_R1-en.pdf
9. United Nations. International cooperation to ensure global access to medicines, vaccines and medical equipment to face COVID-19 [Internet]. Seventy-fourth session of the United Nations General Assembly; 2019 September 17 to 2020 September 14; New York, United States. New York: United Nations; 2020 (Resolution A/RES/74/274) [cited 2021 March 5]. Available from: <https://undocs.org/en/A/RES/74/274>
10. United Nations. Transforming our world: the 2030 Agenda for Sustainable Development [Internet]. Seventieth session of the United Nations General Assembly; 2015 September 15 to 2016 September 12; New York, United States. New York: United Nations; 2015 (Resolution A/RES/70/1) [cited 2021 March 5]. Available from: <https://sdgs.un.org/2030agenda>
11. World Health Organization. Improving the transparency of markets for medicines, vaccines, and other health technologies [Internet]. 72nd World Health Assembly; 2019 May 20-28; Geneva, Switzerland. Geneva: WHO; 2019 (Resolution WHA72.8) [cited 2021 March 5]. Available from: https://apps.who.int/gb/ebwha/pdf_files/WHA72/A72_R8-en.pdf
12. World Health Organization. Global strategy and plan of action on public health, innovation and intellectual property [Internet]. 61st World Health Assembly; 2008 May 19-24; Geneva, Switzerland. Geneva: WHO; 2008 (Resolution WHA61.21) [cited 2021 March 5]. Available from: https://www.who.int/medicines/technical_briefing/tbs/A61_R21-en.pdf
13. World Health Organization. Global strategy and plan of action on public health, innovation and intellectual property. Report by the Director-General [Internet]. 148th meeting of the WHO Executive Board; 2021 January 18-26; Geneva, Switzerland. Geneva: WHO; 2021 (Document EB148/10) [cited 2021 March 5]. Annex, Implementation Plan 2020-2022 to guide further action on the prioritized recommendations of the review panel addressed to the Secretariat; pp. 3-20. Available from: https://apps.who.int/gb/ebwha/pdf_files/EB148/B148_10-en.pdf

14. Organisation for Economic Co-operation and Development. Exploitative pricing in the time of COVID-19 [Internet]. Paris: OECD; 2020 [cited 2021 March 5]. Available from: <https://www.oecd.org/competition/Exploitative-pricing-in-the-time-of-COVID-19.pdf>
15. World Health Organization [Internet]. Shortage of personal protective equipment endangering health workers worldwide. Geneva: WHO; 2020 March 3 [cited 2021 March 5]. Available from: <https://www.who.int/news/item/03-03-2020-shortage-of-personal-protective-equipment-endangering-health-workers-worldwide>
16. World Trade Organization. How WTO members have used trade measures to expedite access to COVID-19 critical medical goods and services. Information note [Internet]. Geneva: WTO; 2020 [cited 2021 March 5]. Available from: https://www.wto.org/english/tratop_e/covid19_e/services_report_16092020_e.pdf
17. World Trade Organization. Overview of Developments in the International Trading Environment. Annual Report of the Director-General [Internet]. Geneva; WTO; 2020 (Document WT/TPR/OV/23) [cited 2021 March 5]. Available from: <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename-q:/WT/TPR/OV23.pdf>
18. Economic Commission for Latin America and the Caribbean. Restrictions on the export of medical products hamper efforts to contain coronavirus disease (COVID-19) in Latin America and the Caribbean [Internet]. Santiago, Chile: United Nations; 2020 [cited 2021 March 5]. Available in Spanish from: <https://www.cepal.org/en/publications/45511-restrictions-export-medical-products-hamper-efforts-contain-coronavirus-disease>
19. World Health Organization. The impact of the COVID-19 pandemic on noncommunicable disease resources and services: results of a rapid assessment [Internet]. Geneva: WHO; 2020 [cited 2021 March 5]. Available from: <https://apps.who.int/iris/handle/10665/334136>
20. Pan American Health Organization [Internet]. Washington, DC: OPS. PAHO Director warns of disruptions in regular health services due to COVID-19. 2020 August 4 [cited 2021 March 5]. Available from: <https://www.paho.org/en/news/4-8-2020-paho-director-warns-disruptions-regular-health-services-due-covid-19>
21. World Health Organization [Internet]. INCB, WHO and UNODC statement on access to internationally controlled medicines during the COVID-19 pandemic. Geneva: WHO; 2020 August 14 [cited 2021 March 5]. Available from: <https://www.who.int/en/news/item/14-08-2020-incb-who-and-unodc-statement-on-access-to-internationally-controlled-medicines-during-covid-19-pandemic>

22. World Health Organization [Internet]. Draft landscape and tracker of COVID-19 candidate vaccines. Geneva: WHO; c2021 [cited 2021 March 5]. Available from: <https://www.who.int/publications/m/item/draft-landscape-of-covid-19-candidate-vaccines>
23. World Health Organization [Internet]. COVAX: Working for global equitable access to COVID-19 vaccines. Geneva: WHO; c2021 [cited 2021 March 5]. Available from: <https://www.who.int/initiatives/act-accelerator/covax>
24. World Health Organization. Operating the COVID-19 Technology Access Pool (C-TAP): A concept paper [Internet]. Geneva: WHO; 2020 [cited 2021 March 5]. Available from: <https://www.who.int/publications/m/item/c-tap-a-concept-paper>
25. World Health Organization [Internet]. Establishment of a COVID-19 mRNA vaccine technology transfer cluster to scale up global manufacturing. Geneva: WHO; 2021 April 16 [cited 2021 June 3]. Available from: <https://www.who.int/news-room/articles-detail/establishment-of-a-covid-19-mrna-vaccine-technology-transfer-cluster-to-scale-up-global-manufacturing>
26. Economic Commission for Latin America and the Caribbean. Building a New Future: Transformative Recovery with Equality and Sustainability [Internet]. Santiago, Chile: United Nations; 2020 (Document LC/SES.38/3-P/Rev.1) [cited 2021 March 5]. Available from: <https://www.cepal.org/en/publications/46228-building-new-future-transformative-recovery-equality-and-sustainability>
27. International AIDS Vaccine Initiative. Expanding access to monoclonal antibody-based products: A global call to action [Internet]. New York: IAVI; 2020 [cited 2021 March 5]. Available from: <https://www.iavi.org/news-resources/expanding-access-to-monoclonal-antibody-based-products-a-global-call-to-action>
28. Baaj A, Kaitin K, Serebrov M. Manufacturing strategy for diverse biologic pipelines of the future [Internet]. Boston, MA: Tufts University School of Medicine; 2017 [cited 2021 March 5]. Available from: <https://www.fdanews.com/ext/resources/files/2017/11/11-20-17-Tufts.pdf>
29. World Health Organization. Increasing access to vaccines through technology transfer and local production [Internet]. Geneva: WHO; 2011 [cited 2021 March 5]. Available from: https://apps.who.int/iris/bitstream/handle/10665/44714/9789241502368_eng.pdf

30. Francis DP, Du Y-P, Precioso A. Global vaccine supply. The increasing role of manufacturers from middle income countries. *Vaccine* [Internet]. 2014 September 15 [cited 2021 March 5];32(41):5259-65. Available from: <https://doi.org/10.1016/j.vaccine.2014.07.069>
31. Homma A, di Fabio JL, de Quadros C. Los laboratorios públicos productores de vacunas: el nuevo paradigma. *Rev Panam Salud Publica* [Internet]. 1998 [cited 2021 March 5];4(4):223-32. Available in Spanish from: <https://iris.paho.org/bitstream/handle/10665.2/8529/4n4a1.pdf>
32. Cortes MA, Cardoso D, Fitzgerald J, DiFabio JL. Public vaccine manufacturing capacity in the Latin American and Caribbean region: Current status and perspectives. *Biologicals* [Internet]. January 2012 [cited 2021 March 5];40(1):3-14. Available from: <https://doi.org/10.1016/j.biologicals.2011.09.013>
33. World Health Organization [Internet]. Global Observatory on Health R&D. Indicators from the Observatory; Geneva: WHO; January 2020 [cited 2021 March 5]. Available from: <https://www.who.int/observatories/global-observatory-on-health-research-and-development/indicators>
34. Organisation for Economic Co-operation and Development. COVID-19 in Latin America and the Caribbean: An overview of government responses to the crisis [Internet]. Paris: OECD; 2020 [cited 2021 March 5]. Available from: https://read.oecd-ilibrary.org/view/?ref=129_129907-eae84sciov&title=COVID-19-in-Latin-America-and-the-Caribbean_An-overview-of-government-responses-to-the-crisis
35. Torrico B, Castillo R, Castillo A. Respuestas innovadoras de América Latina y el Caribe a los desafíos de la pandemia de COVID-19 [Internet]. Washington, DC: Inter-American Development Bank; 2020 [cited 2021 March 5]. Available in Spanish from: <https://publications.iadb.org/publications/spanish/document/Respuestas-innovadoras-de-America-Latina-y-el-Caribe-a-los-desafios-de-la-pandemia-de-COVID-19.pdf>
36. Inter-American Development Bank. Responding to COVID-19 with Science, Innovation, and Productive Development [Internet]. Washington, DC: IDB; 2020 [cited 2021 March 5]. Available from: <https://publications.iadb.org/en/responding-to-covid-19-with-science-innovation-and-productive-development>
37. World Health Organization. Local production for access to medical products. Developing a framework to improve public health [Internet]. Geneva: WHO; 2011 [cited 2021 March 5]. Available from: https://www.who.int/phi/publications/Local_Production_Policy_Framework.pdf

38. World Health Organization. Local production and access to medicines in low- and middle-income countries: a literature review and critical analysis. Geneva: WHO; 2011 [cited 2021 March 5]. Available from:
https://www.who.int/phi/publications/Local_Production_Literature_Review.pdf
39. World Health Organization. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fortieth Report [Internet]. Geneva: WHO; 2006 (WHO Technical Report Series 937) [cited 2021 March 5]. Available from:
http://apps.who.int/iris/bitstream/handle/10665/43443/WHO_TRS_937_eng.pdf
40. World Trade Organization. Annex 1C. Trade-related Aspects of Intellectual Property Rights [Internet]. Final Meeting of the ministerial Trade Negotiations Committee; 1994 April 12-15; Marrakech, Morocco. Geneva: WTO; 1994 [cited 2021 March 5]. Text amended on 2017 January 23. Available from:
https://www.wto.org/english/docs_e/legal_e/27-trips.pdf
41. World Trade Organization. Declaration on the TRIPS Agreement and Public Health [Internet]. Fourth Session of the Ministerial Conference of the WTO; 2001 November 9-14; Doha, Qatar. Geneva: WTO; 2001 (Document WT/MIN(01)/DEC/2) [cited 2021 March 5]. Available from:
https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.pdf
42. World Health Organization. The role of intellectual property in local production in developing countries: opportunities and challenges [Internet]. Geneva: WHO; 2016 [cited 2021 March 5]. Available from:
https://www.who.int/phi/publications/int_prop_role_local_prod_opportunities-challenges.pdf
43. World Health Organization; United Nations Industrial Development Organization; United Nations Conference on Trade and Development; Joint UN Programme on HIV/AIDS; United Nations Children's Fund; The Global Fund. Interagency statement on promoting local production of medicines and other health technologies [Internet]. Geneva, 2019 May 24 [cited 2021 March 5]. Available from:
https://www.who.int/phi/implementation/tech_transfer/Interagency-statement-on-promoting-local-production.pdf
44. Pan American Health Organization. Plan of Action for the Coordination of Humanitarian Assistance [Internet]. 53rd Directing Council of PAHO, 66th Session of the Regional Committee of WHO for the Americas; 2014 September 29 to October 3; Washington, DC. Washington, DC: PAHO; 2014 (Document CD53/12) [cited 2021 March 5]. Available from:
<https://www.paho.org/hq/dmdocuments/2014/CD53-12-e.pdf>

45. Pan American Health Organization. Plan of Action for the Coordination of Humanitarian Assistance [Internet]. 53rd Directing Council of PAHO, 66th Session of the Regional Committee of WHO for the Americas; 2014 September 29 to October 3; Washington, DC. Washington, DC: PAHO; 2014 (Resolution CD53.R9) [cited 2021 March 5]. Available from:
<https://iris.paho.org/bitstream/handle/10665.2/7647/CD53-R9-e.pdf>

168th SESSION OF THE EXECUTIVE COMMITTEE

Virtual session, 21-25 June 2021

CE168/12
Annex A
Original: Spanish

PROPOSED RESOLUTION

INCREASING PRODUCTION CAPACITY FOR ESSENTIAL MEDICINES AND HEALTH TECHNOLOGIES

THE 168th SESSION OF THE EXECUTIVE COMMITTEE,

(PP) Having reviewed the policy *Increasing Production Capacity for Essential Medicines and Health Technologies* (Document CE168/12),

RESOLVES:

(OP) To recommend that the 59th Directing Council adopt a resolution in the following terms:

INCREASING PRODUCTION CAPACITY FOR ESSENTIAL MEDICINES AND HEALTH TECHNOLOGIES

THE 59th DIRECTING COUNCIL,

(PP1) Having reviewed the policy *Increasing Production Capacity for Essential Medicines and Health Technologies* (Document CD59/ ____);

(PP2) Considering that one of the basic principles enshrined in the Constitution of the World Health Organization (WHO) is that “enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, or economic or social condition” and that the “health of all peoples is a fundamental to the attainment of peace and security and is dependent upon the fullest co-operation of individuals and States”;

(PP3) Recognizing that access to essential medicines and other health technologies is a global priority and fundamental to universal access to health and universal health coverage, and that some countries face access barriers due to factors such as limited manufacturing capacity and high prices, and that these problems may be exacerbated during public health emergencies or situations of overwhelming demand, such as during the COVID-19 pandemic;

(PP4) Observing with concern the impact of transport and international trade restrictions on access to raw materials, intermediate inputs, and medicines and other health technologies, including access to substances subject to international control, such as sedatives and analgesics for intubation protocols during the treatment of patients with COVID-19;

(PP5) Considering Resolution A/RES/74/274 of the United Nations General Assembly, the resolutions *Access and Rational Use of Strategic and High-cost Medicines and Other Health Technologies* (CD55.R12 [2016]), *Public Health, Innovation, and Intellectual Property: A Regional Perspective* (CD48.R15 [2008]), and *COVID-19 Pandemic in the Region of the Americas* (CD58.R9 [2020]) of PAHO, and draft resolution *Strengthening local production of medicines and other health technologies to improve access* (74th World Health Assembly, May 2021),¹ resolutions *COVID-19 response* (WHA73.1 [2020]) and *Improving the transparency of markets for medicines, vaccines, and other health products* (WHA72.8 [2019]) of the World Health Assembly, together with the adoption of the *Global strategy and plan of action on public health, innovation and intellectual property* (WHA61.21 [2008]) and its priority actions;

(PP6) Recalling the Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS Agreement), in its amended version, and also the Declaration on the TRIPS Agreement and Public Health, issued by the World Trade Organization (WTO) in Doha in 2001, which states that intellectual property rights can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all, and which recognizes the importance of intellectual property protection for the development of new medicines and the concerns about its effects on prices;

(PP7) Recognizing that health is a precondition and result of sustainable development and calling for the participation of all relevant sectors in coordinated multisectoral action to urgently address the health needs of the population;

(PP8) Recognizing that the creation and strengthening of national and regional capacity for the development and production of raw materials and essential medicines and other health technologies is important for improving their affordability and accessibility,

¹ Draft resolution presented to the 74th World Health Assembly, held from 24-31 May 2021 in Geneva, Switzerland.

and adequately responding to regional health needs, especially during health emergencies, and that this also contributes to health security and economic and social development;

(PP9) Recognizing the importance of promoting competition to improve the availability and affordability of medicines and other health technologies consistent with public health policies and needs through, *inter alia*, the manufacture and introduction of generic versions, and especially of essential medicines, in developing countries;

(PP10) Recognizing the importance of transparency, access to sustainable financing, strengthening of research, and development and transfer of technology under voluntary and mutually agreed terms, as well as the importance of initiatives such as the COVID-19 Technology Access Pool (C-TAP) and Medicines Patent Pool as mechanisms for building and strengthening national and regional capacity for the development and production of raw materials and essential medicines and other health technologies;

(PP11) Recognizing the need for strengthened national regulatory systems convergent with international standards to help ensure appropriate oversight of the quality, safety, and efficacy of the raw materials, medicines, and other health technologies produced in the Region;

(PP12) Recognizing that regional and subregional integration can stimulate production through the development of sustainable demand, including the needs of Member States with small markets, and reaffirming the importance of international cooperation and collaboration with regional agencies of the United Nations system and other international and domestic financial institutions,

RESOLVES:

(OP1) To urge the Member States, considering their contexts, needs, vulnerabilities, and priorities, to:

- a) promote the implementation of comprehensive national intersectoral policies on essential medicines and other health technologies that include roadmaps for their implementation and the explicit statement of intersectoral priorities for development, production, and equitable universal access;
- b) create or strengthen intersectoral governance mechanisms with health sector participation to increase national research, development, innovation, and production capacity, defining roles, respecting sector competencies, and prioritizing attention to regional health needs, with the leadership of national authorities and the collaboration of academia, the private sector, civil society, and international organizations;
- c) strengthen national capacity for the development and production of raw materials and essential medicines and other health technologies, including the training of skilled human resources and, where applicable, the strengthening or development

- of national infrastructure and clusters that support research, development, innovation, and production activities to better meet health needs and priorities;
- d) strengthen the capacity of institutions with enabling and oversight functions for the medicines and other health technologies sector, including the strengthening of national health regulatory systems;
 - e) develop or strengthen, as appropriate, a coherent policy environment for the health sector and the science and technology, industry, and trade sectors to encourage the promotion of research, development, innovation, technology transfer under voluntary and mutually agreed terms, and the production of quality raw materials, essential medicines, and other health technologies, promoting affordability and accessibility, transparency, effectiveness, and competitiveness, environmental protection, and the sustainability of projects;
 - f) increase investment in science and technology for the production of raw materials, essential medicines, and other health technologies, and strengthen the incentives for industrial promotion and the use of public procurement that simultaneously fosters affordability, sustainability, competitiveness, development, and regional production;
 - g) promote international dialogue and collaboration to make progress toward timely, universal, and equitable access to quality-assured, safe, effective, and affordable essential medicines and other health technologies, including their components and precursors, that are necessary for public health emergencies and long-term planning, while ensuring their fair distribution and eliminating unjustifiable access barriers.

(OP2) To request the Director to:

- a) provide technical cooperation to the Member States in developing and implementing comprehensive policies on essential medicines and other health technologies to strengthen national capacity, meet intersectoral objectives, and improve access to essential medicines and other health technologies;
- b) collaborate with the Member States in promoting technology transfer under voluntary and mutually agreed terms, as well as intraregional activities in science, technology, and innovation, including networks of institutions devoted to research, development, and innovation, and collaboration with regional industrial associations and international financial institutions for economic and social development;
- c) promote collaboration and the exchange of information and experiences among Member States, and prepare model lists to prioritize the needs for medicines and other health technology in the Region in order to guide investment and other incentives for increasing regional development and production;
- d) continue to support the Member States by strengthening the capacity of national health regulatory systems to help ensure appropriate oversight of the safety, quality,

- and efficacy of medicines and other health technologies, including those produced in the Region, by promoting convergence, regulatory harmonization, and networks of national health regulatory authorities;
- e) continue promoting transparency of prices and economic data along the value chain of medicines and other health technologies, including those produced locally, in order to foster affordability and access;
 - f) continue providing technical support—as appropriate and when requested, in collaboration with the principal relevant actors, including support for policy processes—to countries that intend to make use of the provisions of the TRIPS Agreement, including the flexibilities recognized by the Doha Declaration on the TRIPS Agreement and Public Health, in order to promote access to pharmaceutical products.

Report on the Financial and Administrative Implications of the Proposed Resolution for PASB

1. **Agenda item:** 4.5 Increasing Production Capacity for Essential Medicines and Health Technologies

2. **Linkage to [PAHO Program Budget of the Pan American Health Organization 2020-2021](#):**

Intermediate outcome 8: Increased equitable access to essential medicines, vaccines, and other health technologies that are safe, affordable, clinically effective, cost-effective, and quality assured, and rational use of medicines, with strengthened regulatory systems that contribute to achieving universal access to health and universal health coverage

3. **Financial implications:**

a) **Total estimated cost for implementation over the life cycle of the resolution (including staff and activities):**

The resolution does not have a life cycle. The estimates covered the four years from the start of implementation (2022) until the end of the life cycle of the PAHO Strategic Plan 2020-2025.

Areas	Estimated cost (in US\$)
Human resources	595,000
Training	150,000
Consultants/service contracts	130,000
Travel and meetings	500,000
Publications	215,000
Supplies and other expenses	115,000
Total	1,705,000

b) **Estimated cost for the 2020-2021 biennium (including staff and activities):**

Implementation of the resolution would begin once it is adopted. The expenditures corresponding to the estimated incremental costs would begin in 2022.

- c) **Of the estimated cost noted in b), what can be subsumed under existing programmed activities?** Only incremental costs were calculated.

4. Administrative implications:

- a) **Indicate the levels of the Organization at which the work will be undertaken:**

All levels of the Organization will be involved: programmatic, country, regional, and subregional. Active participation by the ministries of health of the Member States and subregional organizations and mechanisms will also be needed.

- b) **Additional staffing requirements (indicate additional required staff full-time equivalents, noting necessary skills profile):**

One staff member will be needed for technical assistance to the Member States and support for working in a network on the formulation, implementation, and evaluation of comprehensive policies (P3 or equivalent); one staff member for the preparation of model lists and technical support to the Member States (P3 or equivalent); and one staff member for technical assistance and support for regulatory strengthening activities (P3 or equivalent, 50%).

- c) **Time frames (indicate broad time frames for implementation and evaluation):**

Implementation of the policy will begin in 2022. A progress report will be submitted in 2025.

Analytical Form to Link Agenda Item with Organizational Mandates

1. **Agenda item:** 4.5 Increasing Production Capacity for Essential Medicines and Health Technologies

2. **Responsible unit:** Health Systems and Services (HSS)

3. **Preparing officer:** Dr. James Fitzgerald and Dr. Analía Porrás

4. **Link between Agenda item and [Sustainable Health Agenda for the Americas 2018-2030](#):**

Goal 5: Ensure access to essential medicines and vaccines, and to other priority health technologies, according to available scientific evidence and the national context.

Target:

5.1: Ensure timely access to medicines on the national medicines list, and to priority health technologies, without any payment at the point of care, service, or dispensing of the medicine, according to the national context (revised PAHO Strategic Plan, outcome 4.3).

5.3: Have in place a national regulatory authority for medicines rated at level-3 capacity based on the WHO global benchmarking tool (Adapted from PAHO Strategic Plan, outcome 4.3).

5.4: Implement health technology assessment methodologies in the decision-making process for incorporation in health systems (PAHO Report *Health Technology Assessment and Incorporation into Health Systems*, PAHO Document CSP28/11 [2012]).

5.7: Strengthen national, subregional, and regional mechanisms for negotiation and purchasing to improve the capacity of countries to obtain more affordable and equitable prices for medicines, vaccines, and other health technologies (policy on Access and Rational Use of Strategic and High-cost Medicines and Other Health Technologies, PAHO Document CD55/10, Rev. 1 [2016]).

5.8: Taking into account public health perspectives, strengthen the capacity to implement intellectual property policies and health policies that promote research and development of medicines, vaccines, and other health technologies for communicable and noncommunicable diseases that primarily affect developing countries and that promote access to affordable medicines, vaccines, and other health technologies (adapted from SDG 3.b and the policy paper *Access and Rational Use of Strategic and High-cost Medicines and Other Health Technologies* PAHO Document CD55/10, Rev. 1 [2016]).

5. Link between Agenda Item and the [Strategic Plan of the Pan American Health Organization 2020-2025](#):

Intermediate outcome 8: Access to health technologies. Increased equitable access to essential medicines, vaccines, and other health technologies that are safe, affordable, clinically effective, cost-effective, and quality-assured, and rational use of medicines, with strengthened regulatory systems that contribute to achieving universal access to health and universal health coverage

6. List of collaborating centers and national institutions linked to this Agenda item:

- Ministries of health, science and technology, and industry and trade. National health regulatory authorities, national institutes of health, institutes of science and technology.
- Other government agencies and entities linked to the promotion of research, development, innovation, production, trade, and access to medicines and other health technologies.
- PAHO/WHO Collaborating Centers.
- Civil society and charitable organizations that promote access to medicines and other health technologies.
- Industrial associations linked to the development and manufacture of medicines and other health technologies.
- Universities, schools of health public, and other research and academic institutions.
- United Nations agencies.
- National and international development banks.
- Subregional agencies and integration mechanisms.

7. Best practices in this area and examples from countries within the Region of the Americas

Although various challenges persist, the Region of the Americas has made progress in improving access to safe, effective, and affordable quality medicines and other health technologies, incorporating, among other aspects, the promotion of comprehensive policies on medicines and other health technologies that promote access and research and development. For example, it has made progress in the use of health technology assessments, in decisions on the selection and incorporation of national health technologies, and in the strengthening of health regulatory systems (Brazil, Argentina, Chile, Colombia).

PAHO has promoted networks to share experiences and information on health technology assessment, good practices, and lessons learned in promoting regulatory convergence, formulating comprehensive medicines policies, and combatting substandard and falsified medicines.
