Pan American Health Organization
World Health Organization
REGIONAL OFFICE FOR THE Americas

170th SESSION OF THE EXECUTIVE COMMITTEE

Washington, D.C., USA (hybrid session), 20-24 June 2022

Provisional Agenda Item 7.12-E

CE170/INF/12
20 April 2022
Original: Spanish

E. ACCESS AND RATIONAL USE OF STRATEGIC AND HIGH-COST MEDICINES AND OTHER HEALTH TECHNOLOGIES: PROGRESS REPORT

Background

1. The purpose of this document is to present a progress report on the implementation of the policy on Access and Rational Use of Strategic and High-Cost Medicines and Other Health Technologies (Document CD55/10, Rev. 1 and Resolution CD55.R12) *(1, 2)* to the Governing Bodies of the Pan American Health Organization (PAHO). This policy presents recommendations, policy options, legal and regulatory frameworks, and comprehensive multisectoral interventions that can help improve access to and rational use of medicines and other health technologies (MHTs).

2. The safety, efficacy, affordability, availability, and rational use of strategic and high-cost MHTs are necessary requirements for universal access to health and universal health coverage. Since the adoption of Resolution CD55.R12 in 2016, Member States have taken a number of actions in line with the recommendations; however, the adoption of comprehensive measures that address the determinants of access and rational use of strategic and high-cost MHTs continues to be a challenge for health systems.

Analysis of Progress Achieved

3. The COVID-19 pandemic redefined work priorities and focused the efforts of Member States and the Pan American Sanitary Bureau (PASB) on the response to the health emergency. As a result, in 2021, Member States were not consulted to formally assess progress on the recommendations and policy options contained in Document CD55/10, Rev. 1 and Resolution CD55.R12. Nevertheless, since its adoption, significant progress has been made, although many challenges persist. Recognizing this, the recommendations and policy options stated in Document CD55/10, Rev. 1 remain valid.

4. The following are some of the policies and actions implemented in the Region of the Americas, structured according to the policy options presented in Document CD55/10, Rev. 1.

Policy option A: Comprehensive national health and pharmaceutical and other health technology policies

5. Member States have promoted dialogue and information exchange at the regional and subregional levels. Some Member States adopted or updated their policies according to their national context, updated their national lists of essential medicines, and fostered collaboration between the health sector and the judicial sector *(3-6)*. Member States also made progress in strengthening national regulatory systems, seeking to meet the needs of the health system through continuous improvements.

6. Document CD58/INF/14(E) on Strengthening National Regulatory Authorities for Medicines and Biologicals (2020) *(7)* presented some of the progress made on this issue over the past decade. These include strengthening initiatives at the national, subregional, and regional levels, and the creation of regulatory convergence networks, as well as platforms for discussion and exchange on the challenges associated with the regulation and oversight of other health technologies not covered by previous mandates. Countries also worked to expand access to MHTs through increased use of centralized national, subregional, and regional negotiation and procurement processes, such as PAHO's Regional Revolving Fund for Strategic Public Health Supplies (the Strategic Fund) and the Revolving Fund for Access to Vaccines (the Revolving Fund) *(8-10)*.

7. In 2021, recognizing the importance of regional production as a strategic element to meet health needs, especially in emergency situations, Member States adopted Resolution CD59.R3 on Increasing Production Capacity for Essential Medicines and Health Technologies, which promotes a multisectoral and comprehensive approach aimed at improving access *(11)*.

Policy option B: Strategies that improve transparency and knowledge for decision making

8. Improving transparency in markets continues to be a major challenge in the Region of the Americas and around the world, particularly in relation to the transparency of costs along the supply chain and the impact on the final price of MHTs. Member States have made progress in publishing national databases with the sales prices of medicines, and they continue to work on options for exchanging information on public procurement prices at the subregional level.

9. Through the Regional Initiative for the Exchange of Information on Prices, Coverage and Economic Regulation of Health Technologies, 11 Member States have promoted transparency and the exchange of information and experiences in collaboration with PASB *(12)*. Member States have also made progress in using health technology assessments (HTAs) for decision-making and have actively participated in the Health Technology Assessment Network of the Americas (known as RedETSA). They have also

progressively advanced in the exchange of HTA reports through the Regional Database of HTA Reports of the Americas (known as BRISA).[1]

10. In an annex module of the Regional Platform on Access and Innovation for Health Technologies (known as PRAIS), 14 Member States have provided information on their national lists of essential medicines, the World Health Organization (WHO) Model List of Essential Medicines, the PAHO Strategic Fund list of medicines, and lists of medical devices. Currently, they are adding evidence briefs *(13)*.

Policy option C: Strategies that improve pricing outcomes and efficiency

11. Through the Regional Initiative for the Exchange of Information on Prices, Coverage and Economic Regulation of Health Technologies, Member States have exchanged information, and workshops have been organized to implement policies that promote competition, the use of generic and biosimilar drugs, and pricing policies. Argentina collaborated with WHO and PAHO in organizing the third Fair Pricing Forum (2021) *(14, 15)*.

12. Policies on intellectual property and public health have been implemented in the Region *(16-18)*. Member States have promoted debate and actions on public health and intellectual property issues in international initiatives and forums, and have participated in workshops organized by the World Trade Organization and the Inter-American Development Bank with the support of PAHO/WHO and the World Intellectual Property Organization.

13. In May 2020, the government of Costa Rica and WHO launched the COVID-19 Technology Access Pool initiative, issuing a call for WHO Member States and other stakeholders to join and support the initiative in solidarity *(19)*.

Policy option D: Strategies that promote the rational use of medicines and other health technologies

14. Some Member States, with the support of PASB, developed a working proposal with an integrated approach to the assessment, selection, incorporation, prescription, dispensing, and monitoring of the use of MHTs. Member States have continued to update their procedures for assessing and selecting MHTs, and for exchanging information and proposals for their rational use through the Network of Pharmacotherapeutic Committees and RedETSA. Also, a pilot study has been prepared and published to evaluate indicators of rational use of medicines in health services, which will serve as a monitoring tool for the countries of the Region. However, it remains a challenge to reach the level of priority

[1] Additional information on progress made in the assessment and incorporation of health technologies into health systems can be found in the document Health Technologies Assessment and Incorporation into Health Systems: Final Report (Document CE170/INF/11).

and integration required so that policies and strategies promoting cost-effective and evidence-based use of MHTs can produce tangible results.[2]

15. Some Member States have made progress with operational measures to oversee the dispensing of prescription antimicrobials, an effort that should be extended to other countries in the Region. In relation to the dispensing of medications and the integration of primary-health-care-based pharmaceutical services into health systems, national groups have been formed on this issue, with work plans in 14 Member States. Health authorities and experts addressed the functions of these services in the Charter of Brasilia, and proposed indicators for their evaluation through pilot testing in Brazil and Peru.

16. The Pan American Pharmaceutical Education Network, in which 23 Member States participate, is updating a proposal for a basic plan to address interprofessional work. Periodic information on evaluation, guidelines, and rational use has also been collected every five years.

Lessons Learned

17. Access to strategic, high-cost MHTs continues to be a challenge for health systems. Since the adoption of Resolution CD55.R12, Member States have made significant efforts and adopted a variety of policies and actions according to their national context. Regardless of the particular characteristics of the policies and actions adopted, comprehensiveness, multisectoral coordination, and international collaboration remain essential elements in ensuring their effectiveness.

Action Needed to Improve the Situation

18. Improving access to strategic and high-cost MHTs requires ongoing monitoring, evaluation, sustainability, and adaptation of multisectoral policies and actions, consistent with evolving innovation, changing health needs, and market dynamics. Strengthening cooperation between countries is essential in order to find common solutions to consolidate actions such as joint procurement and negotiations, and to undertake other actions aimed at improving the position of Member States in the MHTs market.

19. The COVID-19 pandemic redefined work priorities and focused the efforts of Member States and PASB on the response to the health emergency. For this reason, in 2021, progress was not assessed in accordance with Annex B of Document CD55/10, Rev. 1. Considering this, it is proposed to assess progress in 2023 and submit a report to the Executive Committee in 2024. The mandates and recommendations of Resolution CD55.R12 remain in force; it is therefore recommended to continue implementing them in coordination with other related current mandates for increasing the

[2] An example of this was the use of COVID-19 treatments that lacked proven efficacy and were even harmful to health in some countries of the Region.

production capacity of MHTs and strengthening regulatory systems, and for the evaluation, incorporation, and rational use of MHTs, among others.

Action by the Executive Committee

20. The Executive Committee is invited to take note of this report and provide any comments it deems pertinent.

References

1. Pan American Health Organization. Access and Rational Use of Strategic and High-cost Medicines and Other Health Technologies [Internet]. 55th Directing Council, 68th session of the Regional Committee of WHO for the Americas; 26-30 September 2016; Washington, DC. Washington, DC: PAHO; 2016 (Document CD55/10, Rev. 1) [cited 2022 Feb 10]. Available from: https://www.paho.org/hq/dmdocuments/2016/CD55-10-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, 68th session of the Regional Committee of WHO for the Americas; 26-30 September 2016; Washington, DC. Washington, DC: PAHO; 2016 (Resolution CD55.R12) [cited 2022 Feb 10]. Available from: https://www.paho.org/hq/dmdocuments/2016/CD55-R12-e.pdf.

3. World Health Organization. WHO Global Essential Medicines Lists dashboard [Internet] [cited 2022 Feb 11]. Available from: https://www.who.int/groups/expert-committee-on-selection-and-use-of-essential-medicines/essential-medicines-lists.

4. Ministry of Health of the Republic of Argentina [Internet]. Salud participó de la reunión de la Comisión Intergubernamental de Políticas de Medicamentos [cited 2022 Feb 11]. Available from: https://www.argentina.gob.ar/noticias/salud-participo-de-la-reunion-de-la-comision-intergubernamental-de-politicas-de.

5. Pan American Health Organization. Judicialización de los medicamentos de alto precio en Uruguay – Conversatorio Interinstitucional [Internet] [cited 2022 Feb 11]. Available from: https://www.paho.org/es/documentos/judicializacion-medicamentos-alto-precio-uruguay-conversatorio-interinstitucional.

6. Ministry of Health of Paraguay [Internet]. Precautelar acceso equitativo de la salud de todas las personas [cited 2022 Feb 11]. Available from: https://www.mspbs.gov.py/portal/19268/precautelar-acceso-equitativo-de-la-salud-de-todas-las-personas.html.

7. Pan American Health Organization. Strengthening National Regulatory Authorities for Medicines and Biologicals: Progress Report [Internet]. 58th Directing Council, 72nd session of the Regional Committee of WHO for the Americas. Virtual session, 28-29 September 2020; Washington, DC. Washington, DC: PAHO; 2020 [Document CD58/INF/14(E)] [cited 2022 Feb 11]. Available from: https://www.paho.org/en/documents/cd58inf14-progress-reports-technical-matters-strengthening-national-regulatory.

8. Executive Secretariat of the Council of Ministers of Health of Central America and the Dominican Republic [Internet]. Negociación conjunta COMISCA [cited 2022 Feb 11]. Available from: https://www.sica.int/comisca/n_conjunta.aspx.

9. Southern Common Market [Internet]. Países del Mercosur se unen para adquirir medicamentos de alto costo [cited 2022 Feb 11]. Available from: https://www.mercosur.int/paises-del-mercosur-se-unen-para-adquirir-medicamentos-de-alto-costo/.

10. Preston, C. et al. [Internet]. Pharmaceutical procurement among public sector procurers in CARICOM. Rev. Panam. Salud Pública 45, 2021 [cited 2022 Feb 11]. Available from: https://iris.paho.org/handle/10665.2/53910.

11. Pan American Health Organization. Increasing Production Capacity for Essential Medicines and Health Technologies [Internet]. 59th Directing Council, 73rd session of the Regional Committee of WHO for the Americas. Virtual session, 20-24 September 2021; Washington, DC. Washington, DC: PAHO; 2021 (Resolution CD59.R3) [cited 2022 Feb 11]. Available from: https://www.paho.org/en/documents/cd59r3-increasing-production-capacity-essential-medicines-and-health-technologies.

12. Pan American Health Organization [Internet]. PAHO and ANVISA organize training on medicine pricing policies and regulation [cited 2022 Feb 11]. Available from: https://www3.paho.org/hq/index.php?option=com_content&view=article&id=15378:paho-and-anvisa-organize-training-on-medicine-pricing-policies-and-regulation&Itemid=39594&lang=en.

13. Pan American Health Organization [Internet]. Annotated Medicine and Device Lists, PAHO [cited 2022 Feb 16]. Available from: https://medlistapp.paho.org/en/list/compare.

14. World Health Organization [Internet]. Fair Pricing Forum 2021 [cited 2022 Feb 11]. Available from: https://www.who.int/news-room/events/detail/2021/04/13/default-calendar/fair-pricing-forum-2021.

15. World Health Organization [Internet]. Fair Pricing Forum 2021: meeting report [cited 2022 Feb 11]. Available from: https://www.who.int/publications/i/item/9789240038585.

16. Ministry of Industry, Ministry of Health, and National Institute of Industrial Property [Internet]. Patentes de invención y modelos de utilidad. Resolución Conjunta 118/2012, 546/2012 y 107/2012 [cited 2022 Feb 11]. Available from: https://www.argentina.gob.ar/normativa/nacional/resolución-118-2012-196991/texto.

17. National Health Surveillance Agency [Internet]. Manual 4 – Exame de patenteabilidade na anuência prévia dos pedidos de patentes de produtos e processos farmacêuticos [cited 2022 Feb 11]. Available from: https://www.gov.br/anvisa/pt-br/setorregulado/regularizacao/medicamentos/propriedade-intelectual/manual-de-exame-de-pedidos-de-patente/manual-4/view.

18. Presidency of the Republic of Brazil [Internet]. Sancionada lei sobre licença compulsória de patentes no caso de emergência de saúde pública. 2021 [cited 2022 Feb 11]. Available from: https://www.gov.br/secretariageral/pt-br/noticias/2021/setembro/presidente-bolsonaro-sanciona-lei-sobre-licenca-compulsoria-de-patentes-no-caso-de-emergencia-de-saude-publica.

19. World Health Organization [Internet]. WHO COVID-19 Technology Access Pool [cited 2022 Feb 11]. Available from: https://www.who.int/initiatives/covid-19-technology-access-pool.

- - -