
ACCESS AND RATIONAL USE OF STRATEGIC AND HIGH-COST MEDICINES AND OTHER HEALTH TECHNOLOGIES: FINAL REPORT

Background

1. In 2016, the 55th Directing Council of the Pan American Health Organization (PAHO), through Resolution CD55.R12, adopted the policy document Access and Rational Use of Strategic and High-Cost Medicines and Other Health Technologies (Document CD55/10) (1, 2), containing policy options and strategies to improve access to and rational use of strategic and high-cost medicines and other health technologies (MHTs) from a comprehensive perspective. In 2022, a progress report was submitted to the 30th Pan American Sanitary Conference (Document CSP30/INF/12) (3), noting that country consultations could not be held in 2021 due to the COVID-19 pandemic.
2. This policy is in line with Resolution CD45.R7 on Access to Medicines, adopted in 2004 by the 45th Directing Council of PAHO (4). The purpose of this document is to report to the Governing Bodies of PAHO on the results achieved in the implementation of both resolutions.

Analysis of Progress Achieved

3. This report presents the progress achieved and challenges faced by Member States regarding access to and rational use of MHTs in light of the proposed policy options and strategies, using data from a country consultation on strategic and high-cost technologies held at the end of 2023, to which 20 countries in the Region of the Americas responded. The information thus obtained was supplemented with experiences from technical cooperation, follow-up consultations with Member States, literature reviews, and a desk review of publicly available documents.

Comprehensive national policies on health, pharmaceutical products, and other health technologies

4. Member States have made substantial efforts to design and implement comprehensive policies or strategies, with varying levels of development. A total of 15 countries stated that they have comprehensive policies, while five have strategies in place for specific areas. Several countries have made progress in developing policies on access in recent years.
5. Among the policies developed, implemented, or updated by Member States in the last decade are policies concerning access to high-cost technologies (many of them linked to the prevention and control of cancer and rare diseases) and medical devices, as well as national policies on medicines and

health technology management. Two countries created specific agencies within ministries to address issues related to high-cost medicines.

6. The COVID-19 pandemic shed light on the extent to which Latin America and the Caribbean are dependent on imports of health technologies, as well as on the vulnerability of global supply chains. Fostering regional research and development (R&D), innovation, and manufacturing is key to addressing future pandemics and other public health priorities, including the need to increase access to high-cost single-source or limited-source technologies. In this regard, some Member States have made progress in developing strategies to incentivize and encourage innovation, including the use of non-refundable tax benefits and grant programs. Nevertheless, 65% of countries stated that they did not have any incentives in place for MHT innovation.

7. Overall, 90% of Member States report having intellectual property legislation that considers the public health perspective and includes some or all of the flexibilities under the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) (5).¹ According to publicly available data, 14 countries in the Region have used at least one of these flexibilities (6). Actual use, according to information provided by countries which responded to the PAHO survey, was limited to 15%. The most recent experience is that of Colombia, which granted a compulsory license for non-commercial use of the medicine dolutegravir for reasons of public interest (7). During the COVID-19 pandemic, several countries in the Region discussed or approved legislative measures to facilitate the use of the TRIPS flexibilities in cases of international public health emergencies.

8. A total of 13 Member States reported having mechanisms in place to review patent quality. Argentina has rigorous guidelines for examination of the patentability of chemical and pharmaceutical inventions and has made significant advances in access to high-cost medicines in the country. For example, domestically manufactured generic elexacaftor/tezacaftor/ivacaftor, a combination medicine for cystic fibrosis, is priced 45 times lower than the brand-name medicine purchased in Uruguay (8, 9).

9. In May 2020, the government of Costa Rica and the World Health Organization (WHO) launched the COVID-19 Technology Access Pool (C-TAP) initiative, issuing a call for WHO Member States and other stakeholders to join the initiative in solidarity and voluntarily license their patents and technical knowledge. During the pandemic, the U.S. National Institutes of Health (NIH) granted several voluntary licenses to the C-TAP initiative, which were implemented through the Medicines Patent Pool (10). In 2024, WHO announced the establishment of the Health Technology Access Pool (HTAP) initiative, to expand beyond COVID-19 (11, 12).

10. PAHO Member States have made progress in increasing their productive capacity through strategic partnerships with private-sector and public-sector MHT manufacturers. In terms of public manufacturing, at least six countries² in the Region have state laboratories with a focus on different stages of production. Countries have also made progress in the implementation of mechanisms for

¹ Ratified in the Declaration of the Fourth WTO Ministerial Conference, held in Doha (Qatar), November 2001, better known as the Doha Declaration.

² Argentina, Brazil, Colombia, Cuba, Mexico and the Bolivarian Republic of Venezuela.

coordination between the health system, academia, and the industrial sector. Overall, 60% of the countries reported that they had cooperation channels for this purpose, with different degrees of interaction. Other experiences regarding incentives for productive capacity entail strengthening legal frameworks to encourage domestic manufacturing of MHTs. Despite advances, MHT manufacturing remains a regional challenge; 60% of Member States responded that they do not participate in any such initiative.

11. To support the development of regional innovation and production capacities, in 2023 the Pan American Sanitary Bureau (PASB) created the Innovation and Regional Production Platform. Its initiatives include regional implementation of the WHO/Medicines Patent Pool project for technology transfer of messenger RNA (mRNA) vaccine manufacturing in two Member States (13). In Argentina, a public-private partnership was established to integrate strategic components of the value chain, including a mechanism that will provide equitable access during public health emergencies and will allow countries in the Region to procure the vaccine at reduced prices and bound to the cost of production, through PAHO's Revolving Fund for Access to Vaccines. In Brazil, clinical trials to develop an mRNA vaccine are being supported (14, 15). These two experiences are examples of how to explore new R&D-linked access strategies, with the inclusion of certain conditions as contractual clauses in publicly funded projects.

12. If strategies to expand access to health technologies are to be successful, mature regulatory systems must be in place. The Region has implemented a pioneering program in which more than 75% of the Region's regulatory systems were evaluated and institutional development plans were established in 32 countries. Despite these advances, challenges and asymmetries persist, and regulatory systems are not always able to cope with the growing market demand. The eight national regulatory authorities of regional reference³ have yet to adopt continuous improvement plans to meet new demands and achieve international recognition as WHO-listed authorities. In addition, 40% of Member States still have regulatory systems that do not perform all of the WHO-recommended tasks (16).

Strategies that improve transparency and knowledge for decision making

13. Seventeen countries answered that they had some mechanism in place to improve decision-making on the incorporation of health technologies. Among these mechanisms, the most widely adopted strategy is health technology assessment (HTA) (17). Highlights of advances in recent years include: *a)* in Argentina, the creation of the National Commission for Health Technology Assessment (CONETEC) in 2018; *b)* in Brazil, the definition of cost-effectiveness thresholds for the incorporation of health technologies in 2022; *c)* in the Dominican Republic, the implementation of an HTA program within the Superintendency for Health and Occupational Risks, since 2022; *d)* in Ecuador, the establishment of a National Directorate for HTA within the Ministry of Public Health in 2022; *e)* in Peru, the creation in 2020 of a National HTA Network (RENETSA), responsible for the assessments of all high-cost health technologies for cancer and rare and orphan diseases, coordinated since 2023 by the Center for Health Technology Assessment (CETS); and *f)* in Uruguay, the creation of the National Health Technology Assessment Agency (AETSU) in 2021.

³ Those of Argentina, Brazil, Canada, Chile, Colombia, Cuba, Mexico, and the United States of America.

14. The Health Technology Assessment Network of the Americas (RedETSA) was strengthened and now includes 42 institutions from 21 countries (18). More than half of the countries that responded noted that their HTA reports are publicly available online. Likewise, progress was made in sharing HTA reports through the Regional Database of Health Technology Assessment Reports of the Americas (BRISA), which exceeded 3000 reports in 2023 (19). In the Caribbean, the establishment of a subregional HTA group was approved, with a view to developing a roadmap for the subregion.

15. When asked about lists of essential medicines, 17 countries reported having such national formularies. Lists of priority medical devices, however, are much less common: only three countries reported having specific lists for these technologies. In addition, Chile has a list of priority assistive products,⁴ while Ecuador is the only country with a specific list of essential medical devices for in vitro diagnostics; in Paraguay, the list of essential medical supplies includes medical devices.

16. Of the countries that responded to the consultation, 15 reported that their health systems included a benefits plan that had been updated within the last three years. In Argentina, the Mandatory Medical Program is included in national health insurance plans and is also compulsory for private health insurers. Chile implements strategies for universal access to medicines and benefits under the purview of the System of Explicit Health Guarantees, the Ricarte Soto Act, and the High-Cost Medicines Coverage System, while Peru has specific benefit plans for the members of each organization that administers health insurance.

17. Improving access to information and transparency remains a major challenge in the Region, particularly with respect to transparency around costs throughout the technology development process and along supply chains, as well as the impact of these costs on the end-user price of MHTs. There is very little information available on public procurement of MHTs. Another challenge concerns access to information on overall R&D costs, manufacturing costs, and cost structures. Five Member States report sharing information on government procurement prices at the subregional level. PAHO's Regional Revolving Funds⁵ publish an online price list (21, 22). To promote transparency in clinical trials, some Member States have created registries, and these are mandatory in several countries.

18. There are initiatives in the Region to encourage patient and community participation in the process of incorporating health technologies into health systems. These initiatives include public consultations that allow for the active participation of stakeholders, as well as the dissemination of reports providing detailed information on the criteria considered when deciding whether or not to incorporate such technologies.

19. Information regarding access to MHTs is limited, and most countries in the Region have problems with data management, quality, capture, and access. A review of the scientific literature since 2013 found only 42 published studies with data on access to medicines, 76% of them from

⁴ An assistive product is defined as any external product (including devices, equipment, instruments or software) that is specially produced or generally available, and whose primary purpose is to maintain or improve an individual's functioning and independence, and thereby promote their well-being. Assistive products are also used to prevent impairments and secondary health conditions. Examples include wheelchairs, eyeglasses, and hearing aids (20).

⁵ The Regional Revolving Funds are the Revolving Fund for Access to Vaccines (the Revolving Fund, formerly the Revolving Fund for Vaccine Procurement), the Regional Revolving Fund for Strategic Public Health Supplies (the Strategic Fund), and reimbursable procurement on behalf of Member States.

Brazil. Only 7% of the studies were related to high-cost medicines. Data on access to other high-cost technologies is even scarcer.

Strategies that improve pricing outcomes and efficiency

20. In the Region, the most widely used joint procurement mechanisms are the Strategic Fund and the Revolving Fund. Purchases facilitated by the Strategic Fund led to 90% cost savings for hepatitis C treatment between 2015 and 2023. The Revolving Fund has been able to reduce the price of the human papillomavirus vaccine by 92% since 2007 (23). Several noteworthy joint subregional negotiations have also taken place, such as the joint procurement by MERCOSUR countries of tacrolimus, an essential medicine for organ transplants, in 2018 (24).

21. Of the Member States that responded to the consultation, 11 do not use national demand aggregation schemes. Some countries have made advances with national joint procurement strategies in which other subnational levels participate through a variety of mechanisms. These include: *a)* in Argentina, the REMEDIAR program for consolidated procurement of outpatient medicines for all provinces; *b)* in Canada, the federal government cooperates with provinces and territories through the pan-Canadian Pharmaceutical Alliance, which jointly negotiates for lower drug prices; *c)* in Chile, a centralized procurement agency for medicines and other health supplies, CENABAST; *d)* in Mexico, the state-owned company Birmex, in collaboration with the Ministry of Health, issues guidelines for consolidated procurement; and *e)* Guatemala and Panama have implemented centralized electronic procurement systems.

22. Member States promote financial protection mechanisms to improve access and eliminate out-of-pocket payment, thus avoiding impoverishment and exposure to catastrophic expenditures. There is wide variability in funding sources: 80% of Member States have multi-payer systems, which include general revenues, social security, and specific funds, while the remaining 20% have a single-payer system, funded through general revenues. For coverage of strategic or high-cost MHTs, funding mechanisms also differ across countries: some use general revenue, which can fund the treatment of diseases covered by certain laws or specific programs, while others have special funds set aside to cover the care of high-cost diseases.

23. Despite countries' efforts to improve funding, out-of-pocket spending on medicines remains high in the Region. A study published by PAHO found that spending on medicines is the most representative line item among out-of-pocket health expenditures, accounting for 48% to 74% of these expenses (25). According to the WHO, out-of-pocket spending on health is regressive, exclusionary, runs counter to solidarity, and deepens existing inequities (26).

24. Eight countries report using price regulations for medicines; some regulate both publicly funded and privately purchased medicines, while others regulate only those procured with public funds. Among those countries that regulate medicine prices, various methodological approaches are employed, which incorporate internal and external reference pricing. In Brazil, HTA is used to cap the prices of new drugs based on their added therapeutic benefit, and a mandatory minimum discount based on the Human Development Index is applied in all public procurement. In Canada, the Patented Medicine Prices Review Board is responsible for regulating the prices of patented medicines.

25. Member States also mentioned other measures to lower medicine prices, such as reductions in customs and tax duties, value-added tax exemptions for generic products, or tax reductions for certain groups of medicines, such as cancer and HIV treatment and other high-cost medicines.

26. Countries expressed concern about the increase in judicialization. In as little as a decade, the number of health-related lawsuits has increased significantly in several countries⁶ (27, 28). While these lawsuits allow some patients to access some MHTs, in many cases they petition for technologies not approved by regulatory authorities or not recommended by HTA; in the case of approved technologies, more cost-effective alternatives may be available.

Strategies that promote the rational use of medicines and other health technologies

27. Eighteen countries responded that they have regulatory or legal frameworks in place to promote rational prescription and rational use of MHTs. The Bahamas and Barbados have regulations that require approval prior to use of some high-cost options. In Colombia, the MIPRES electronic platform was created in 2016 to facilitate the process of prescribing, dispensing, and supplying MHTs not included in the Health Benefits Plan. The Costa Rican Social Insurance Fund has a Central Committee on Pharmacotherapy, while Mexico has a Committee on Pharmacy and Therapeutics. Guatemala has a specific regulation for prescription of antimicrobials and steroids. Some Member States have made progress in making antimicrobials prescription-only medicines. More than 10 countries in the Region conducted studies on the use of antimicrobials and made progress in the implementation of institutional stewardship strategies (29).

28. Significant progress has been made toward therapeutic interchangeability and substitution by generic and multisource medicines. Overall, 90% of countries reported that they allow therapeutic interchangeability. As for the strengthening of dispensing practices, PASB has designed and agreed on a regional tool to assess the quality of the provision of pharmaceutical services in primary health care (30).

29. Although the concept of rational use is generally associated with medicines, the importance of its application to other health technologies should not be overlooked. Progress has been made in training personnel in the management of biomedical devices in the Caribbean, with activities being developed in five countries of this subregion. It is estimated that up to 75% of assistive products provided are abandoned due to improper use (31). Finally, six countries have a system in place to regulate advertising of inaccurate or unethical information about MHTs.

Lessons Learned

30. Member States have made progress regarding access to MHTs by designing and implementing policies or strategies with different levels of development and scope. However, the legal and public policy frameworks of several countries in the Region remain inadequate for improving access to MHTs, especially high-cost ones. Greater effort is needed to strengthen strategies related to R&D and regional manufacturing and promote competition, public procurement, price regulation, transparency, and mechanisms for the incorporation of evidence-based technologies, among other aspects. Further progress must be made in changing legal frameworks and implementing

⁶ 130% in Brazil, 119% in Colombia, and 144% in Costa Rica. In addition, in Argentina the number quintupled in seven years (28) and in Uruguay it increased sixfold in just three years (27).

comprehensive, multisectoral public access policies that cover all MHTs and that take into account the entire life cycle of these technologies.

31. Joint procurement and price regulation are effective in achieving price reductions for MHTs. Progress is being made in establishing national consolidated procurement strategies and using regional joint procurement mechanisms, such as PAHO's Revolving Fund and Strategic Fund. Challenges include prioritizing those MHTs which provide the greatest therapeutic benefit and cost-effectiveness, achieving lower prices, consolidating demand with greater use of PAHO funds, and promoting transparency and competition.

32. The Region has made progress in the development and implementation of mechanisms aimed at improving decision-making for the incorporation of health technologies into health systems, with HTA being the most widely used strategy to improve transparency in decision-making processes. Collaborative work between HTA bodies has been consolidated through RedETSA. However, despite the progress in making HTA part of institutional frameworks in the Region, few countries have managed to link assessment processes to decision-making around incorporation via legal frameworks and make the necessary integrations with rational use, practice guidelines, and monitoring.

33. Increasing access to novel high-cost technologies represents a growing challenge for countries. Among the highest-cost technologies are gene therapies, such as onasemnogene abeparvovec for the treatment of spinal muscular atrophy, with a significant price disparity ranging from US\$1 million to US\$ 2 million per course of treatment (32).

Action Needed to Improve the Situation

34. In light of the achievements and challenges described herein, the following measures are proposed for consideration by the Member States:

- a) *Develop and implement comprehensive and multisectoral access policies.* It is necessary to develop consistent policies and strategies that cover the entire life cycle of MHTs: R&D, manufacturing, regulation, HTA, funding, decision-making, supply management, coverage, prices and competition, and rational use and monitoring-. It is recommended to strengthen public access policies so they are comprehensive and multisectoral, and to broaden their scope to cover all health technologies.
- b) *Promote competition.* One of the most successful strategies to reduce prices and expand access to MHTs is to promote the use of generic and biosimilar multisource medical products.⁷ Measures to expedite the market entry of biosimilar products include the establishment of priority regulatory routes (fast-tracking); the use of real-world evidence to facilitate regulatory approval; encouragement of appropriate prescribing by doctors and other health professionals; therapeutic interchangeability; the regulation of actors in advertising, pharmaceutical marketing, and other practices involving commercial influence; support for regional innovation and manufacturing processes; technology transfer; and the use of TRIPS flexibilities. It is also recommended that the use of competition laws be promoted as a means of preventing practices such as contractual arrangements that are detrimental to consumers

⁷ It is estimated that 40 biological therapeutics will lose patent protection by 2030 (33).

and public health; predatory prices; abuse of monopoly power and creation of barriers to entry of competitors into the market; and mergers that lead to detrimental market power. Improved coordination between ministries of health, patent offices, and antitrust authorities in countries is necessary.

- c) *Establish strategies and legal frameworks for the evidence-based incorporation of MHTs through transparent deliberative processes.* Member States are advised to strengthen the link between HTA processes and decisions to incorporate MHTs into the health system. Likewise, it is expected that progress in the establishment of these legal frameworks, with deliberative processes, civil society participation, and the promotion of multisectoral strategies that incorporate the judiciary and reduce conflicts of interest, will help curtail the growing judicialization in the Region.
- d) *Joint procurement and price regulation of MHTs.* Increased use of the Revolving Fund and the Strategic Fund is recommended. Whenever possible, tenders should be conducted by therapeutic class and should incorporate strategies that promote competition and regional manufacturing. It is also recommended that price regulation policies be implemented, including criteria to compare the efficacy, effectiveness, and prices of different MHT options.
- e) *Improve transparency, generation of information, and access to information.* It is proposed that the countries and PASB implement policies and strategies to improve transparency in the health sector, including the availability of information on regulatory decisions, investments, R&D subsidies and incentives, production costs, procurement prices, HTA reports, criteria for incorporation of MHTs, patents, terms of procurement agreements, risk-sharing and technology transfers, clinical trial data, and conflicts of interest, among other aspects. While acknowledging the complexity of obtaining information on effective access to health technologies, as well as barriers and associated costs, a joint effort by Member States and PASB is needed to find tools that can bridge this gap and allow for the creation of indicators to quantify problems and monitor progress.
- f) *Foster innovation and regional manufacturing of MHTs, active pharmaceutical ingredients, and pharmaceutical intermediates, as well as incorporate access planning strategies during R&D.* Necessary strategies include implementing coherent regional policies and ecosystems for science and technology manufacturing; increasing public investment in science and technology; ensuring access to knowledge and technology transfer; introducing conditionalities to public financing so as to facilitate access; and promoting innovation models that delink the cost of R&D from the end price of MHTs, among others.

Action by the Directing Council

35. The Directing Council is invited to take note of this report and provide any comments it deems pertinent.

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