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ACCESS AND RATIONAL USE OF STRATEGIC¹ AND HIGH-COST MEDICINES AND OTHER HEALTH TECHNOLOGIES

Introduction

1. Equitable access to medicines and other health technologies is a requisite for universal access to health and universal health coverage, and it is a global priority which should be considered within the context of the principle that recognizes the enjoyment of the highest attainable standard of health for all.² The availability, accessibility, acceptability, and affordability of these medical products and their rational use can be facilitated through the adoption of comprehensive policies, legal and regulatory frameworks, and interventions. The escalating costs of providing access to high-cost medical products, however, poses a particular challenge for the sustainability of health systems.

¹ A “strategic public health supply” is a product that satisfies the following criteria: it is listed, recognized, and recommended by a WHO Expert Committee or Working Group (e.g., essential medicines, WHOPES-recommended compounds, HIV diagnostics); it is included in WHO-recommended protocols or diagnostic algorithms and is considered highly effective in disease treatment or prevention; when continuously available, it significantly contributes to improvements in mortality rates and patient quality of life and/or minimizes possibilities of drug resistance in treatment; it is subject to particular challenges in areas of product sourcing, pricing, forecasting, and purchasing; and economies of scale are achievable as volumes purchased increase.

http://www.paho.org/hq/index.php?option=com_content&view=article&id=12167%3Afaqs-strategic-fund&catid=8775%3Aabout&Itemid=42006&lang=en#9

² The Constitution of the World Health Organization establishes as a principle that the enjoyment of the highest attainable standard of health is one of the fundamental human rights of every human being. The Constitution was adopted by the International Health Conference in New York, signed on 22 July 1946 by 61 Member States, and subsequently ratified by 194 Member States. See also, for example, Pan American Sanitary Conference Document [CSP28/11](#), “Health Technology Assessment and Incorporation into Health Systems,” page 2.

2. This document provides a comprehensive overview of the multidimensional problem of access to high-cost medicines and other health technologies.³ It also identifies policy options that can safeguard the sustainability of health systems, expand access to high-cost strategic products to improve health outcomes, and work to achieve public health objectives.

Background

3. In 2014, the Region adopted Resolution CD53.R14, *Strategy for Universal Access to Health and Universal Health Coverage*. This strategy aims at ensuring that all people and communities have access, without any kind of discrimination, to comprehensive, appropriate, and timely quality health services determined at the national level according to needs, as well as access to safe, affordable, effective, quality medicines in order to avoid financial difficulties, impoverishment, and exposure to catastrophic expenditures, especially for groups in conditions of vulnerability. In 2015, the United Nations General Assembly adopted 17 Sustainable Development Goals. Goal 3, Ensure healthy lives and promote well-being for all at all ages, includes targets on equitable access to medicines and other health technologies.

4. For Member States, improving access to safe, efficacious, and quality medicines and other health technologies has remained a high priority. In 2004, countries adopted Resolution CD45.R7, Access to Medicines, highlighting the need to improve quality, financing, procurement, cost-containment, intellectual property management, and supply management of medicines. *The Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property* (Resolution WHA61.21 [2008]) (1) and the corresponding PAHO plan of action (Resolution CD48.R15 [2008]) encourage the adoption of comprehensive frameworks to promote access to medicines and other health technologies. Resolution CD50.R9, adopted in 2010, called for the strengthening of regulatory capacity to ensure safe, efficacious, and quality medicines (2). The value of health technology assessment (HTA) and other evidence-based approaches that weigh ethical considerations to guide and inform prioritization and selection of products is reflected in Resolution CSP28.R9 (3) and Resolution WHA67.23 (4). A number of resolutions to address critical communicable and noncommunicable diseases (NCDs) highlight the need to improve access to medicines and other health technologies. Notably, the *Plan of Action for the Prevention and Control of Noncommunicable Diseases* (Resolution CD52.R9 [2013]) emphasizes the need to improve access to medicines and health technologies for NCDs. Regarding access to medicines and other technology-related laws and regulations, the Directing Council of PAHO has urged Member States, as appropriate, to promote the formulation, implementation, or review of their legal and regulatory frameworks to facilitate the strengthening of the stewardship and governance role of the health authority to move toward achieving universal access to quality, safe, effective, and affordable medicines and other health technologies (5).

³ For the purpose of this document, medicines and other health technologies include medical products such as pharmaceuticals, biologicals, medical devices, and diagnostics.

5. Essential medicines are those that satisfy the priority health care needs of the population and should be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality, and at a price the individual and the community can afford. The WHO Model List of Essential Medicines (EML) is a model reference list containing products that are affordable and cost-effective for the majority of health systems and that can significantly contribute to positive health outcomes (6, 7). In addition, increasing numbers of other strategic health technologies such as medical devices have become critical for preventive, curative, rehabilitative, and palliative care. Offering a broader number of medicines, beyond those listed in the WHO EML, may reflect the specific context and/or the capacity of some countries to provide access to other priority products, including new and costly ones. Moreover, the adoption of integrated strategies for rational use, such as that adopted by the Meeting of the Ministers of Health of the Andean Region in 2015, which includes clinical practice guidelines (CPGs), incentives, prescription support, and educational strategies, among others, has been shown to improve health outcomes (8-11).

6. A number of new products can meaningfully contribute to improving health. The 19th WHO EML (April 2015) includes several new high-cost medicines for both communicable and noncommunicable diseases. However, not all new molecules provide substantial value; new high-cost medicines may offer only marginal health gains over older lower-cost medicines. It is noteworthy that the concept of high cost is not well defined. Although a distinction must be made between price and affordability,⁴ some countries have chosen to define high cost by the monetary value of treatment (threshold), while for others it is a relative term based on costs that are disproportionate to expected treatment costs to the health system and their financial impact on health budgets and the sustainability of the system. Nonetheless, product prices are not the sole determinant of costs to health systems, since variables such as the frequency and length of treatment impact the overall cost of medical products, and prices are not uniform across countries due to: manufacturers' pricing strategies; variable distribution; the efficiency of the management of the supply chain and procurement mechanism and intermediary and retail markups; and national taxes and duties and price negotiations on medical products (12). Still, many of the products included in the high-cost category are new pharmaceuticals, biologicals (including vaccines), devices, and other health technologies produced and commercialized by a single manufacturer (i.e., sole-source products), and, due to patent protection and data protection, where applicable, such manufacturers retain market exclusivity, do not face competition, and tend to engage in monopolistic pricing behaviors (13).

7. Providing access to high-cost medicines is a cause of concern for countries in the Americas (14). To advance toward universal access to health and universal health coverage, it is critical to expand access to health services for all, particularly for groups in conditions of vulnerability, prioritizing interventions that serve unmet needs. Countries

⁴ This refers to "the cost of treatment in relation to people's income."

face critical choices when prioritizing the expansion of services to ensure that population groups in situations of vulnerability are not left behind (15). Access to high-cost medicines can be lifesaving; at the same time, the cost of these products can dramatically increase the risk of people incurring financial difficulties, impoverishment, and exposure to catastrophic expenditures, and it can constitute a challenge to the sustainability of health systems.

Situation Analysis

8. Difficulties in accessing medicines have been a problem for countries around the world. In 2004, WHO reported that 2 billion people lacked access to essential medicines (16). That same year, the developing nations allocated 30% or more of their health expenditures to pharmaceuticals. Notwithstanding, 30% of the world's population lacked regular access to essential medicines (17, 18). In 2010, Latin America and the Caribbean countries spent an average 7.65% of Gross Domestic Product (GDP) in health, 1.7% of which went to medicines expenditures. Of total expenditures in medicines, 70% came from sources other than public spending (19).

9. Often, medicines and other health technologies represent the highest percentage of the cost of treatment and care. In Latin America and the Caribbean, antiretroviral medicines (ARVs) represent 75% of the cost of care for patients living with HIV/AIDS, reaching more than 90% in some instances. In general, a small number of high-cost medicines represent a large portion of the expenditures. In 2012, of all patients receiving ARVs, 71% used first-line ARVs while 27% and 2.5% used second- and third-line ARVs, respectively. Yet, the cost for second- and third-line ARVs amounted to 52% of total ARV expenditures (20).

10. National regulatory authorities oversee the safety, quality, and effectiveness of medicines and other health technologies and are critical in determining the rate of introduction of new products. Upon patent expiration, especially through the Bolar exemption, national regulatory authorities play a pivotal role in promoting competition by supporting efficient entry of quality generics and/or similar biotherapeutic products (21). Strategies that promote prompt entry of competitor products within health systems result in considerable efficiencies without compromising the quality of care, since competition tends to significantly reduce prices. In the United States, where generics account for 88% of sales, the Hatch-Waxman Act and Bolar exemption adopted in 1984 are considered critical for promoting quality generic entry (21, 22). Since then, the regulatory framework for the introduction of generic medicines has evolved to promote their timely market entry. In Latin America and the Caribbean, generic medicine sales amounted to only 7.8% in 2008 (23). Due to lack of competition, off-patent generic medicines are sometimes marketed at elevated prices, however. Some countries have experienced shortages of essential generic medicines (23) due to a wide range of factors, including manufacturers leaving the market and/or manufacturing licenses that limit the commercialization of generic versions in certain markets (24), resulting in countries opting for costly therapeutic alternatives.

11. The high prices of new medicines are often justified due to the costs of research and development borne by the manufacturer. Yet, the precise research and development costs borne by the private sector are hard to establish and subject to controversy (13) since public spending on scientific research can be a major determinant for new discoveries (25). Some recent initiatives address the lack of transparency in research and development costs. In the United States, a number of states are debating the introduction of legislation to improve research and development cost-information (26). In addition, WHO Executive Board report EB138/41 (23) states that “a better understanding of research and development costs would enable a constructive dialogue on how to establish a fair and affordable price for medicines for children.” Proposals to change the prevailing research and development funding model involving de-linkage of research and development costs and prices were documented by the WHO Consultative Expert Working Group report on Research and Development (27).

12. Taking into account a public health perspective, the implementation of intellectual property policies that promote high-quality patents,⁵ including policies providing for patent opposition, can promote the development of innovative medicines, prevent the inappropriate extension of market exclusivity⁶, and support timely entry of multisource generic products. Intellectual property rights can create incentives for the research, development, and diffusion of new and improved medicines and health technologies. Although some incremental innovations may add value for health systems, these innovations should not be used to delay the timely entry or appropriate use of generic versions of the medicines after the expiration of any relevant market exclusivity term. Health technology assessments can also be used to encourage the use of cost-effective, quality, safe, and efficacious generics and to counter inappropriate marketing strategies to prevent their use. Flexibilities under the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) including those recognized by the Doha Declaration on the TRIPS Agreement and Public Health (Doha Declaration)⁷ such as the use of the subject matter of a patent without authorization of the right holder (compulsory licensing) (Art. 31), and exceptions to rights conferred (Art. 30), can also be used. To date, compulsory licenses have been used in the Region in the following instances: Canada issued an export-only compulsory license authorizing a generic manufacturer to export an HIV/AIDS therapy to Rwanda over the course of two shipments in 2008 and 2009⁸ (28);

⁵ As stated by the World Intellectual Property Organization, “Quality is an essential aspect of the patent system to ensure that it serves its purpose of promoting innovation, contributing to dissemination and transfer of technology and fostering technological, social and economic development of the country concerned.” Available at:

http://www.wipo.int/patents/en/topics/quality_patents.html

⁶ Practices that aim to inappropriately extend market exclusivity are often referred to as “evergreening,” although there is no generally accepted definition of this term, which is often used in different ways. However, for discussion purposes, evergreening may occur when patent holders use various strategies to inappropriately extend the length of their exclusivity.

⁷ Doha Declaration on the TRIPS Agreement and Public Health (Doha Declaration) (20 November 2001 [WT/MIN(01)DEC/2]).

⁸ See World Trade Organization, Minutes of Meeting, IP/C/M/64 (17 February 2011), paragraphs 74-82.

in 2007, Brazil issued a compulsory license for Efavirenz; and between 2010 and 2014, Ecuador issued compulsory licenses for Ritonavir, Abacavir+Lamivudine, Etoricoxib, Mycophenolate, Sunitinib, and Certolizumab (29).

13. Rapid diffusion, adoption, and inappropriate use of new products are major determinants of increasing health care costs. Since 2011, the Regional Network of Health Technology Assessments for the Americas (RedETSA)⁹ has promoted the use of HTA and other evidence-based analysis to inform decisions related to the adoption of new medical products within health systems. In 2015, 12 out of 28 countries that answered the survey had established HTA structures and 7 had adopted legislation requiring use of HTA in decision-making processes. Moreover, 92.9% of countries have national commissions for selection and drug and therapeutics committees and have developed lists of essential medicines at the national level.

14. In large part, the demand for medicines is subject to decisions taken at the time of prescribing. It has been estimated that more than half of medicines worldwide are prescribed, dispensed, or sold improperly (30) and that the rational and responsible use of medicines would save US\$ 500 billion¹⁰ globally (31). More importantly, the inadequate prescribing, dispensing, and use of medicines and other health technologies is critical for deficient treatment outcomes. In 2015, only 42.9% of countries had adopted standards and procedures for developing CPGs.

15. A number of Member States are ensuring access to a number of high-cost medicines and other health technologies using public funding with or without dedicated financing mechanisms. The *Fondo Nacional de Recursos* (Uruguay) (32), the *Componente Especializado da Assistência Farmacêutica* (Brazil), the *Programa de Medicamentos de Alto Costo* (Dominican Republic), and the recently adopted *Ricarte Soto law* (Chile) are notable examples.

16. National authorities can have an impact on the prices of medicines and other health technologies. National reimbursement and pricing policies may impact the affordability, availability, and price of medicines. However, the lack of access to reliable pricing information poses a challenge when opting and assessing these policies and their outcomes. Additionally, the mechanism by which medicines and other health technologies are procured may have a substantial impact on price. Procurement practices that favor competition and concentrate public purchasing power tend to be effective in lowering prices. By consolidating demand across the public sector, national pooled procurement mechanisms are improving their negotiation and bargaining power and subsequent pricing outcomes. Such is the case of the *Comisión Coordinadora para la Negociación de Precios de Medicamentos y otros Insumos para la Salud* in Mexico (33).

⁹ RedETSA is composed of representatives from the ministries of health, regulatory agencies, HTA agencies, PAHO/WHO collaborating centers, and nonprofit educational and research institutions dedicated to promote HTA to inform decision making.

¹⁰ Unless otherwise indicated, all monetary figures in this report are expressed in United States dollars.

Another example is the experience of Ecuador's reverse auction for medicines in the comprehensive public health network (*Subasta Inversa Corporativa de Medicamentos de la Red Pública Integral de Salud*), which has allowed the joint procurement of essential medicines for the entire public sector at the national level, with estimated savings of more than \$300 million in its most recent process (34).

17. Similar results have been observed when the demand is pooled internationally. The most prominent examples are the PAHO Revolving Fund for Vaccine Procurement and the Regional Revolving Fund for Strategic Public Health Supplies, also known as the Strategic Fund. Since 2000, the Strategic Fund has been providing technical cooperation to Member States to ensure access to quality, safe, and effective medicines, diagnostics, and insecticides. The selection of medical products¹¹ for inclusion in the Strategic Fund is evidence based, supports the concept of essential medicines, and aims to improve access to products that are of limited availability, that are difficult to procure at the national level, or that involve a high cost, such as medicines to treat communicable diseases. By achieving economies of scale and promoting competition, the Strategic Fund contributes to the availability, quality, and affordability of strategic public health supplies (35). As of March 2016, 27 Member States had signed participation agreements with the Strategic Fund.

18. Another strategy used by Member States on a number of occasions is joint price negotiations. For example, in 2015, MERCOSUR and associated countries jointly negotiated agreements directly with manufacturers for ARV and hepatitis C medicines. PAHO supported the mechanism with technical advice and enabling procurement through the Strategic Fund (36). With the support of the Central American Integration System and PAHO, Central American countries have also executed multicountry negotiations resulting in significant efficiencies for participating countries (37). Some of the Member States participate at the national and multinational levels in the development of databases of drug prices and other information relevant to access that can support these initiatives.¹²

19. Several PAHO Member States have strengthened their health systems from the perspective of the right to health where nationally recognized and promoting the right to the enjoyment of the highest attainable standard of health (7).¹³ Adequate strong legal and regulatory frameworks promote and protect access to health (5). Demand for medical

¹¹ The list of strategic health supplies in the Strategic Fund includes products for HIV/AIDS, tuberculosis, malaria, and neglected infectious diseases as well as diagnostics and vector control commodities and medicines for noncommunicable diseases (cancer, cardiovascular and respiratory diseases, and diabetes). The Strategic Fund can be accessed at <http://www.paho.org/strategicfund>.

¹² Such as the observatory of high-economic impact medications financed by the Inter-American Development Bank, the UNASUR medicine price bank, and the Drug Price Observatory of the Andean Health Organization (ORAS-CONHU).

¹³ The right to health is enshrined in 20 of the 35 constitutions of PAHO Member States. Other countries, such as Costa Rica, recognize the right to health through the constitutional principle of inviolability of human life.

products is increasing, and ensuring access to medicines and other health technologies constitutes a challenge for health systems.

20. Despite the efforts and investments made by the Member States to improve access to medicines, lawsuits have been filed in several countries by patients or groups of patients to compel their governments to provide access to these products (a process sometimes referred to as “the judicialization of health”). In some cases, legal action may effectively provide access to medical products or procedures. However, the use of some of these products or procedures is often not based on the best available scientific evidence or decisions on efficacy or cost-effectiveness. Thus, these products are sometimes not included in the standard health system financing plans. Such practices have a significant impact on quality of care and on increased expenditures on medicines, as well as on the sustainability of health systems. A study published in 2012 addressed the issue of health-related litigation in Latin America and quantified litigation-related medical expenditures in Brazil at \$550 million in 2010. That same year in Colombia, 95,000 lawsuits were filed with a direct cost to its Contributory Regime of \$300 million (38). In Brazil, an estimated 35% of the budget for medicines and 4.3% of the total health budget correspond to medical expenditures related to lawsuits (39), and in Colombia in 2012, legal decisions had an impact on the health sector’s finances equivalent to 1% of GDP (40). Legal action creates difficulties in terms of prioritization and equitable distribution of available resources for medicines and other health technologies (41).

Proposal

21. Improving access to and rational use of quality, safe, and cost-effective medicines and other health technologies, including those of high cost, is necessary for universal health (42). Member States may provide access to high-cost medicines and other health technologies through mechanisms consistent with the context and capacity of the health systems. To ensure the most efficient and equitable outcomes, Member States can leverage the following policy options:

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

22. Comprehensive national policies and/or strategies, together with legal and regulatory frameworks that contemplate health system needs and the entire product life-cycle—from research and development to quality assurance, use, and supply chain management, including prescribing and dispensing—are critical to improve access to safe, quality, effective, and cost-effective medicines and other strategic health technologies. These policies and strategies should balance public health needs with economic and social development objectives, promoting collaboration with the science and technology and industrial sectors and stimulating research and development models that address pressing health needs and incentivize, when possible, the de-linkage of research and development costs and the price of health products and disincentivize

demands for costly medicines and other health technologies that do not offer sufficient health benefits over lower-cost alternatives (43).

23. The relevant authorities of Member States should strengthen health information systems to monitor the quality and comprehensiveness of the supply chain; the provision of, access to, and use of medical products within health systems; and the results achieved. These systems can also support decision making for the introduction of new and priority medicines and health technologies based on the needs and sustainability of health systems, through participatory and transparent mechanisms, and promote good governance (44).

24. Sustainable health system financing and adequate financial protection to progress toward the elimination of direct payments that constitute a barrier to access at the point of services can avoid financial difficulties, impoverishment, and exposure to catastrophic expenditures and support the progressive expansion of health services according to Resolution CD53.R14 while improving the sustainability of the health system. Improved transparency and accountability in the allocation of resources and the use of resources for medicines and other health technologies can result in more effective and efficient health systems.

25. The adoption by countries of an explicit list¹⁴ of medicines and other health technologies that is based on the criteria established by WHO for the adoption of essential medicines lists, that addresses critical priorities, and that is progressively evaluated, revised, or expanded when appropriate, considering the criteria of efficacy, safety, and cost-effectiveness, can promote efficiency and equity. An appropriate legal and regulatory framework informed by the best available evidence and by collaboration, as appropriate, with the legislative and judicial sectors¹⁵ can reduce judicial actions taken

¹⁴ For the purposes of this document, an explicit list is one that mentions medicines that have been evaluated and selected in accordance with evidence of safety, efficacy, and cost-effectiveness and whose availability is guaranteed in the health services. Another condition is that these medicines must be the same ones that, for various diagnostic conditions and pathologies, are included in the country's clinical practice guidelines; in cases of differences or a lack of guidelines, these medicines prevail in decisions on coverage. The list may indicate whether presentations and doses are specifically addressed, in which case those not mentioned are not covered, or whether some or all presentations and doses are addressed, covering all options. In any case, this list will be considered the mandatory reference for all benefits related to the use of medicines. In contrast, negative lists are those that propose therapeutic options that are specifically excluded, either as a group (e.g., rosiglitazone and gliptins) or for treatment of a given condition or pathology (e.g., medicines used in non-reconstructive aesthetic plastic surgery), in the context of implicit coverage of all options.

¹⁵ The PAHO Directing Council has urged Member States, as appropriate, taking into account their national context, priorities, and financial and budgetary capacities, to strengthen the technical capability of the health authority to facilitate coordination and collaboration with the legislative branch and other actors, including the identification and review of legal gaps and conflicts. See the PAHO Strategy on Health-Related Law (2015), available at: http://www.paho.org/hq/index.php?option=com_docman&task=doc_download&gid=31293&Itemid=270&lang=en

to obtain access to costly health technologies of little or no public health value; in addition, strengthening regulatory capacities should prevent the introduction of ineffective medicines (45).

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

26. The evaluation, selection, adoption, and use of medicines and other health technologies should be based on health priorities and undergo rigorous assessment according to the best available scientific evidence, taking into account the social, intercultural, equity, gender, and ethical implications and the context and sustainability of health systems. Policies in this area could include horizon scanning systems to identify new technologies for medicines and other health technologies to address health priorities in a cost-effective way. The use of HTA can greatly contribute to the managed introduction of new health technologies, expanding their use and/or making disinvestment decisions (46-48). The value of these methods, however, is only as strong as the quality of the effectiveness data and the cost estimations that are input in the assessments. Thoroughly assessing the cost-effectiveness of a new health technology requires a comparative analysis of nationally available and new treatments, considering all incurred and averted costs and the health benefits. Thus, countries should strengthen capacities to estimate health care costs and produce quality scientific evidence. Moreover, they should monitor the quality, safety, and effectiveness of health products, given the limited strength of the evidence that often exists when these products are introduced into health systems.

27. Policies that promote joint efforts with the pharmaceutical sector to improve transparency and access to timely, comprehensive information on the total cost of production and research and development and on trends, as well as price disclosure and a better understanding of costs and price structure, including distribution, taxes, retail costs, and profit margins, will support product selection, pricing strategies, and regulations. Similarly, countries may establish and promote mechanisms that improve the sharing of information on prices and, when possible, procurement volumes among countries and different actors in each country. National and multicountry price databases are useful for decision making and can be considered mechanisms for cooperation and information exchange. Moreover, supply chain transparency and good procurement practices contribute to the efficiency of the system.

Policy Option C: Strategies that improve pricing outcomes and efficiency

28. Improving the affordability of medical products will facilitate timely and equitable access to them. Promoting an environment that generates competition is strategic to this end since access to multisource generic products or low-cost therapeutic alternatives improves efficiency without compromising quality of care. Taking into account a public health perspective, policies to promote competition may include intellectual property and other policies that promote the establishment of incentives and

regulations that permit the timely entry and uptake of quality multisource generic medicines and/or therapeutic equivalents, the reduction of tariffs, and the adoption of procurement and joint procurement mechanisms that limit fragmentation by pooling demand.

29. The strengthening of capacities to implement intellectual property policies taking into account the public health perspective should support quality patent reviews and prevent inappropriate extension of market exclusivity. In cases of a national emergency or other circumstances of extreme urgency, as determined by each Member State, health systems are encouraged to use, in a timely and appropriate manner, flexibilities of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), affirmed by the Doha Declaration on the TRIPS Agreement and Public Health and further considered in WHO's Global Strategy and Plan of Action on Public Health, Innovation, and Intellectual Property (49). Additionally, it is important to weigh the potential impact that international trade agreements may have on access to health products. In order to promote policy coherence, Member States should seek to promote the active participation of both health experts and trade experts in negotiations and policy discussions relevant to trade issues related to health.

30. While there is no one-size-fits-all policy, the strategy that countries choose to influence medicine prices needs to reflect the context of the health system. The WHO Guideline on Country Pharmaceutical Pricing Policies illustrates some of the options available (50). The choice of procurement mechanism also influences prices. Open international tenders promote competition and secure lower prices when compared with other procurement methods. For sole-source and/or limited-source products, national and international initiatives that limit fragmentation by pooling demand across different subsystems and/or across countries, coupled with transparent, open negotiations, are viable options to improve pricing outcomes. Availing of regional pooled procurement mechanisms such as the Strategic Fund, through regional commitments and cooperation among countries, can reduce market fragmentation, improve the ability of countries to negotiate more affordable and equitable prices, and increase market transparency. Such procurement practices should be conducted in a fair and transparent manner and in full compliance with best international procurement practices (50).

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

31. To improve health care effectiveness and efficiency, countries should adopt integrated comprehensive strategies for the assessment, selection, adoption, and use of medicines and other health technologies. Evidence-informed and culturally acceptable principles remain critical for the rational use of medicines and other health technologies.

32. Unbiased information free of conflicts of interest is necessary for the sound selection, incorporation, prescription, and use of medicines and health technologies. The use of the Declaration of Conflict of Interest should be a common practice for selection

bodies. Dissemination of biased information that can wrongly influence prescription and/or use patterns should be prevented through the regulation of pharmaceutical marketing and promotion, facilitating access to evidence-based information for stakeholders.

33. Health systems need to encourage the use of the most cost-effective treatments and prevent the replacement of effective lower-cost medicines and other health technologies with new, more costly products of little or no added value. Ensuring the availability of lower-price products and preventing excessive and wasteful use of high-cost ones is critical. Demand for medical products is mostly in the hands of prescribers. Hence, the adoption of comprehensive strategies directed at prescribers, as well as promotion of the rational use of medicines, may help improve prescription quality and prevent excessive and/or unnecessary use of costly options.

Action by the Directing Council

34. The Directing Council is requested to review the information provided in this document and to consider adopting the resolution presented in Annex A.

Annexes

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55th DIRECTING COUNCIL

68th SESSION OF THE REGIONAL COMMITTEE OF WHO FOR THE AMERICAS

Washington, D.C., USA, 26-30 September 2016

CD55/10, Rev. 1

Annex A

Original: English

PROPOSED RESOLUTION

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

THE 55th DIRECTING COUNCIL,

(PP1) Having reviewed the policy document *Access and Rational Use of Strategic and High-cost Medicines and Other Health Technologies* (Document CD55/10);

(PP2) Considering that the Constitution of the World Health Organization (WHO) establishes as one of its basic principles that “the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, and political belief, economic or social condition”; and observing that countries of the Region affirmed in Resolution CD53.R14 “the right to health where nationally recognized and promoting the right to the enjoyment of the highest attainable standard of health”;

(PP3) Recalling Resolution CD53.R14 (2014) on Universal Access to Health and Universal Health Coverage, and United Nations Resolution A/RES/70/1 adopting the Agenda 2030 for Sustainable Development, including Goal number 3, “Ensure healthy lives and promote well-being for all at all ages”;

(PP4) Recalling Resolution WHA61.21 (2008) which adopts the *Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property*, Resolution CD48.R15 (2008) *Public Health, Innovation, and Intellectual Property: A Regional Perspective*, and the *Report of the Consultative Expert Working Group on Research and Development*;

(PP5) Recognizing that improving equitable access to and the rational use of medicines and other health technologies contributes to achieving universal access to

health and universal health coverage and the achievement of the Sustainable Development Goals;

(PP6) Taking into consideration that the adoption and implementation of comprehensive policies, laws, regulations, and strategies contribute to improving access to medicines and other health technologies, including those considered strategic and of high cost, and the quality of health services and health outcomes, while ensuring the sustainability of health systems;

(PP7) Taking into account that a number of high-cost medicines and other health technologies are now considered essential and can significantly improve quality of life and health outcomes when used in accordance with evidence-based clinical practice guidelines;

(PP8) Recognizing that the adoption of some new and high-cost medicines and other health technologies incorporated into health systems does not provide significant added value as they displace effective lower-cost treatments;

(PP9) Recognizing the need to improve access through comprehensive approaches that focus on improving availability, affordability, and rational use within health systems, as well as the selection processes described in World Health Assembly Resolution WHA67.22;

(PP10) Recognizing the challenges currently faced by Member States in ensuring access and rational use of high-cost medicines and other health technologies,

RESOLVES:

(OP)1. To urge Member States, taking into account their context and national priorities, to:

- a) adopt comprehensive national policies and/or strategies, together with legal and regulatory frameworks, to improve access to clinically effective and cost-effective medicines and other health technologies, which consider the needs of health systems and take into account the overall life-cycle of the medical products from research and development to quality assurance and use, including prescribing and dispensing, and which disincentivize inappropriate demands for medicines and health technologies that are costly and ineffective, or that do not offer sufficient benefits over lower cost alternatives;
- b) in order to improve the efficacy and efficiency of health systems, *i*) strengthen health institutions, mechanisms, and regulatory capacities to promote good governance and evidence-based decision making on the quality, safety, efficacy and the optimal use of medicines and other health technologies, and *ii*) promote transparency and accountability in the allocation of resources for medicines and other health technologies;

- c) regularly evaluate, review, and update formularies and lists of essential medicines through transparent and rigorous selection processes and mechanisms based on evidence and informed by health technologies assessment methodologies to meet health needs;
- d) promote adequate financing and financial protection mechanisms to foster the sustainability of the health system, to improve access and to advance toward the elimination of direct payments that constitute a barrier to access at the point of service, in order to avoid financial difficulties, impoverishment, and exposure to catastrophic expenditures;
- e) work together with the pharmaceutical sector to improve transparency and access to timely and comprehensive information, including in relation to comprehensive research and development costs and trends, as well as pricing policies and price structures, supply chain management, and procurement practices in order to improve decision-making, avoid waste, and improve affordability of medicines and other health technologies;
- f) strengthen institutional capacities to produce quality health technology assessments of new medicines and other health technologies before their introduction into health systems, with special attention to those considered of high cost;
- g) promote competition through comprehensive strategies, which may include intellectual property policies that take into account the public health perspective considering the maximization of health-related innovation, the establishment of incentives and regulations that permit the prompt entry and uptake of quality multisource generic medicines¹ and/or therapeutic equivalents, the reduction of tariffs, and the adoption of joint procurement mechanisms that limit fragmentation by pooling the demand;
- h) adopt effective strategies to improve access to single source or limited source products such as, but not limited to, transparent national and international price negotiations, reimbursement, and pricing policies and strategies, and when appropriate, the use of flexibilities affirmed by the Doha Ministerial Declaration on the TRIPS Agreement and Public Health;
- i) adopt measures to promote access to information on medical products that is impartial and free of conflicts of interest, for health authorities, health professionals, and the general population, in order to promote the rational use of medicines and other health technologies and to improve the prescription and

¹ WHO uses the term “multisource pharmaceutical products”, defined as “pharmaceutically equivalent or pharmaceutically alternative products that may or may not be therapeutically equivalent. Multisource pharmaceutical products that are therapeutically equivalent are interchangeable” (WHO Expert Committee on Specifications for Pharmaceutical Preparations, WHO Technical Report Series 937, 2006, available at <http://apps.who.int/medicinedocs/documents/s14091e/s14091e.pdf>).

- dispensing; and monitor the safe and effective use of these products through solid pharmacovigilance and technovigilance systems;
- j) recognize the role of prescribers in decisions relating to treatment options and provide support to improve practices so that prescriptions are appropriate, ethical, and based on rational use, employing tools such as clinical practice guidelines, educational strategies, and regulations to address conflicts of interest between prescribers and manufacturers of medical products;
 - k) develop frameworks, including through consultations with all relevant stakeholders, that define ethical principles which, from a public health perspective, guide the development of pharmaceutical advertising and marketing, and codes of conduct that guide the ethical behavior of pharmaceutical representatives;
 - l) promote the adoption of instruments or mechanisms to improve the quality of examination of patent applications for pharmaceuticals and other health technologies, and to facilitate examiners' access to the necessary information for appropriate decision-making;
 - m) promote the work of national health authorities and other competent authorities, according to the national context, on issues related to patents for pharmaceuticals and other health technologies and to patenting practices, to promote health-related innovation and the use of mechanisms and procedures such as the United States Food and Drug Administration (FDA) Orange Book and Canada's Patent Register, which support transparent and clear information including information on medicinal ingredients, their associated patents, the patent expiry dates and other related information, and to foster market competition.

(OP)2. To request the Director to:

- a) support Member States in the development of comprehensive policies and legal frameworks² for medicines and health technologies that promote access to essential and strategic medicines and other health technologies, including those considered high-cost;
- b) support Member States in the development, implementation, and/or review of national legal and regulatory frameworks, policies, and other provisions that permit the prompt entry and uptake of quality multisource generic medicines and/or therapeutic equivalents through comprehensive strategies from a public health perspective;
- c) support Member States in building capacities and adopting strategies to improve the selection and rational use of medicines and other health technologies based on

² In accordance with Resolution CD54.R9.

- health technology assessments and other evidence-based approaches to improve health outcomes and efficiencies;
- d) promote cooperation and the sharing of information, successful experiences, and technical capacity with respect to the cost-effectiveness of medicines and other health technologies, supply chain issues, and best practices in pricing, among other topics, through PAHO's channels and networks, and synthesize and report progress made by Member States in key areas;
 - e) continue to strengthen the PAHO Regional Revolving Fund for Strategic Public Health Supplies and the PAHO Revolving Fund for Vaccine Procurement, which are important initiatives to provide ongoing support to Member States on all aspects related to making quality medicines and health technologies available and more affordable, including providing a platform for supporting participating Member States in the pooling, negotiation, and procurement of high-cost single source and limited source medicines;
 - f) support the Member States in developing and adopting frameworks that define ethical principles which, from a public health perspective, guide the development of pharmaceutical advertising and marketing, guide the relationship between industry and patient associations, and support the development of codes of conduct that guide the behavior of pharmaceutical representatives;
 - g) promote the identification and coordination of initiatives that address access to high-cost medicines and other health technologies in the Region in order to contribute to their efficiency and prevent duplication.

CD55/10, Rev. 1
Annex B

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

<p>1. Agenda item: 4.6 - Access and Rational Use of Strategic and High-cost Medicines and Other Health Technologies</p>
<p>2. Linkage to PAHO Program and Budget 2016-2017:</p> <p>a) Categories: 4 - Health Systems</p> <p>b) Program areas and outcomes: Program Area 4.3 - Access to Medical Products and Strengthening of Regulatory Capacity Outcome 4.3 - Improved access to and rational use of safe, effective, and quality medicines, medical products, and health technologies.</p>
<p>3. Financial implications:</p> <p>a) Total estimated cost for implementation over the lifecycle of the resolution (including staff and activities): While the implementation of this resolution should be ongoing and embedded in the technical cooperation under 4.3 and related areas, the expectation is that an additional US\$ 1,750,000 will be required to scale up the technical cooperation from 2016-2021.</p> <p>b) Estimated cost for the 2016-2017 biennium (including staff and activities): US\$ 700,000</p> <p>c) Of the estimated cost noted in b), what can be subsumed under existing programmed activities? As mentioned before, we are only including additional costs.</p>
<p>4. Administrative implications:</p> <p>a) Indicate the levels of the Organization at which the work will be undertaken: The Unit of Medicines and Health Technologies within the Department of Health Systems and Services, is the responsible for this agenda item. Nonetheless, it is essential to mention that the Department of Procurement's Strategic Fund Unit will play a critical role in its implementation. In addition, other units within the Departments of Health Systems and Services, Communicable Diseases and Health Analysis, Noncommunicable Diseases and Mental Health, and Family, Gender and Life Course, as well as the Office of the Legal Counsel will play essential roles in the deployment.</p>

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

One additional P2-P3 staff to support scale-up and coordination among current personnel providing technical cooperation in this area with expertise in pharmaceutical pricing, rational use/HTA, and/or policies.

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

2016-2021: implementation phase

2021: evaluation phase

2022: report to the Governing Bodies

ANALYTICAL FORM TO LINK AGENDA ITEM WITH ORGANIZATIONAL MANDATES

- 1. Agenda item:** 4.6 - Access and Rational Use of Strategic and High-cost Medicines and Other Health Technologies
- 2. Responsible unit:** Health Systems and Services, Medicines and Health Technologies (HSS/MT)
- 3. Preparing officer:** Dr. Analía Porrás, Chief, Medicines and Health Technologies
- 4. Link between Agenda item and [Health Agenda for the Americas 2008-2017](#):**
Items 38, 45, 46, 47, 48, 50, 70.

To increase access to quality, safe, and effective medicines, medical supplies and health technologies promoting the rational use of medicines, strengthening the subregional procurement mechanisms, reducing tariff barriers applied to medicines and health technologies ensuring financial protection and sustainable financing.
- 5. Link between Agenda item and the [PAHO Strategic Plan 2014-2019](#):**
Program area 4.3, Access to Medical Products and Strengthening of Regulatory Capacity

Furthermore, this agenda item will support the achievement of the objectives related to reducing the burden of communicable diseases such as HIV and chronic noncommunicable diseases.
- 6. List of collaborating centers and national institutions linked to this Agenda item:**

National regulatory authorities, in particular those considered of reference by Resolution CD50.R9 (2010), ministries of health, and PAHO/WHO Collaborating Centers as follows:

University of Ottawa, Bruyère Research Institute, Centre for Global Health: PAHO/WHO Collaborating Center for Knowledge Translation and Health Technology Assessment in Health; Universidade Federal de Santa Catarina (UFSC): PAHO/WHO Collaborating Center for Management Technology in Health; Centro Nacional de Excelencia Tecnológica en Salud (CENETEC): PAHO / WHO Collaborating Center on Health Technology; Instituto de Efectividad Clínica y Sanitaria (IECS): Collaborating Centers Unit of Medicines and Health Technologies; Núcleo de Assistência Farmacêutica Fundação Oswaldo Cruz: WHO Collaborating Center for Pharmaceutical Policies; National University of La Plata: WHO Collaborating Center on the Rational Use of Medicines.

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

There are several initiatives in the Region to improve access and rational use of high-cost medicines. The Ricardo Soto Law (CHL), Fondo Nacional de Recursos (URY), Componente Especializado da Assistência Farmacêutica (BRA), Programa de Medicamentos de Alto Costo (DOM), Comisión Coordinadora para la Negociación de Precios de Medicamentos y otros Insumos para la Salud (MEX), and the joint negotiation in MERCOSUR, among others.

8. Financial implications of this Agenda item:

Implementation of this agenda item will be embedded within the 4.3 program of work and thus will require additional funding to scale up the technical cooperation, in particular, for improving rational use of medicines and health technologies. Thus, the additional cost for 2016-2021 is expected to be in the order of US\$ 1,750,000.

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