

## 55th DIRECTING COUNCIL

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

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CD55.R12  
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### *RESOLUTION*

#### *CD55.R12*

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

##### ***THE 55th DIRECTING COUNCIL,***

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

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”;

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”;

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*;

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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;

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;

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;

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;

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;

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

***RESOLVES:***

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 medicines<sup>1</sup> 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

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<sup>1</sup> 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>).

- medicines and other health technologies and to improve the prescription and 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.
2. To request the Director to:
- a) support Member States in the development of comprehensive policies and legal frameworks<sup>2</sup> 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;

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<sup>2</sup> In accordance with Resolution CD54.R9.

- 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 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.

*(Eighth meeting, 29 September 2016)*