Pan American Health Organization

World Health Organization
REGIONAL OFFICE FOR THE Americas

ACTA

REGIONAL MEETING ON HIGH COST AND STRATEGIC MEDICINES

SANTIAGO DE CHILE, CHILE – 2-3/September/2015

In 2014, the Region of the Americas became the first of the six WHO regions to adopt a Strategy for the attainment of Universal Access to Health and Universal Health Coverage. The resolution that was unanimously adopted by the PAHO Member States and had recognized that "***all people and communities should 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, while ensuring that the use of these services does not expose users to financial hardship, especially groups in conditions of vulnerability".***

Ensuring access to safe, quality and cost-effective medicines for all is an essential requisite for Universal Access to Health and Universal Health Coverage. Medicines access, affordability and appropriate use are fundamental for the strengthening of health systems.

Poor access to safe, efficacious and quality medicines and other health technologies is a persistent problem in the Region. In general, a small number of high cost medicines represents a large portion of the health budgets. While a few Member States have put in place dedicated mechanisms devoted to the financing and provision of high-cost products, these medicines pose a particular challenge to the sustainability of all health systems and to achieving Universal Health. Thus, access to high cost and strategic medicines constitutes a high priority within the national and integration mechanisms agenda.

Recognizing the importance of this issue, PAHO organized a Regional meeting in Santiago de Chile, Chile, 2-3 September, 2015, where representatives of 22 Member States came together to analyze the impact of incorporating high-cost medicines into the health system; share experiences and lessons learned among different stakeholders and discuss strategies to improve access and decrease the financial impact of the incorporation of high cost medicines; and, explore the adoption of common strategies that may improve access to high-cost and strategic medicines in countries in Latin America and the Caribbean.

Through a series of expert presentations, exchange of experiences and discussions, the gathering reached the following general conclusions:

- PAHO Member States should consider a Resolution to the Executive Council on this subject to ensure comprehensive technical cooperation and work to facilitate the access to high cost and strategic medicines taking into account National, sub Regional and Regional needs;

- Ensuring equitable access to medicines poses many challenges for Member States and the people in the Americas since, in most countries, medicines represent the highest household out-of-pocket health expense.

- Escalating medicine costs can limit the sustainability of health systems and, today, ensuring access to a small number of new high-cost medicines consumes a disproportionate part of national health budgets.

- The current R&D and innovation model is driven by economic interests of the market and not always based on public health needs. The system fosters the introduction into health services of new, high-cost, single source products that result in monopolies. These products are out of reach for most individuals unless the health system is able to provide adequate coverage. In addition, Intellectual Property and Trade Related issues can have a significant impact on the affordability capacity of countries, specially low and middle income countries by preventing competition from lower cost generic versions. Furthermore, a growing industry trend is the extension of voluntary licenses and agreements between manufacturers that limit the ability of generic manufacturers that are granted licenses to commercialize the generic versions in certain markets. Representative of Member States have expressed urgent need for competence development in intellectual property issues and on the management of the implications of trade agreements and its impacts on health systems.

- To address this problem, countries need to establish comprehensive health and pharmaceutical policies and strategies that provide long-term and sustainable, yet effective, solutions to ensuring access to life-saving medicines. Policies must be predicated on strong information and data for decision making and promote good governance, efficiency and equity. Pharmaceutical policies should contemplate the products overall life cycle -- from R&D through the use, including prescribing and dispensing. Sharing of information and well succeeded experiences shall be considered.

- In the field of regulation, the participants pointed that NRAs have to develop regulation on health technologies for the promotion of the access to medicines, through actions that go beyond the issue of registration. Anyway, strategies such as approval and abbreviated procedures are effective to increase access, especially in countries with limited regulatory structures. Rational use must been considered as part of these processes.

- The regulatory system needs to protect the population from ineffective and of substandard quality medicines while promoting competition and availability of strategic products. Moreover, countries should ensure that they take advantage of competition promoting measures such as *Bolar* exemption and make full use of the flexibilities expressed at the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) while avoiding the incorporation of clauses that can negatively impact public health on Trade Agreements.

- Countries need to improve financing and financial protection for medicines according to their means. Transparency, accountability, effective and efficient allocation of resources and cost saving strategies that do not compromise the quality of care such as generic substitution are central to the sustainability of the system.

- While not all new molecules provide significant added value to the health system and to the welfare of its population, a number of high-cost products can be substantive to public health. Underscoring the relevance these products might have for health systems, the WHO model list of essential medicines now includes several high cost products to treat both communicable and non-communicable diseases. Health Technology Assessment (HTA) and other evidence-based approaches that weight ethical considerations should guide decisions for the selection, incorporation and removal of products within the health system. In addition, rational and appropriate use of medicines within health systems and services will ensure quality and efficiency of care.

- Some country experiences have highlighted the importance of rationalizing the process of selection, incorporation and use of high cost products within national health systems taking into consideration evidence-based prioritization and established norms for financial coverage. Equally, these processes must be monitored and followed by a strict impact evaluation.

- Countries need to ensure affordability of the products to facilitate timely and equitable access. Comprehensive price strategies are essential as well as practices that improve transparency in procurement systems, promote competition, affordability and/or the availability of medicines and discourage monopolies and other market distortions. Currently the international market for pharmaceuticals lacks pricing transparency and in many cases, middle-income countries have been known to pay some of the highest prices in the market. While there is not a one size fit all in price regulation, transparency and competition are considered key determinants in preventing excessive prices. Both providers and purchasers should ensure disclosure of the real cost of the product paid. Regional initiatives such as price banks may facilitate this information to decision makers and may constitute a critical tool for decision making.

- Joint approaches and strategies at the regional level have already proven to be efficient in promoting affordability and availability of quality products and the Region should continue to seek cooperation in this regard. Since its inception in 2000, PAHO's Strategic Fund has been providing technical cooperation and support to countries in the Americas as a means to ensure access to quality, safe and effective products, in particular those considered high-cost, through pooled procurement. Pooled procurement initiatives such as the Strategic Fund represent an effective mechanism for improving access to high-cost medicines in low- and middle-income countries; the procurement of antiretroviral (ARVs) in the Americas is a testament in this regard.

- In middle-income countries, the procurement of new, single source and high-cost products still represents a challenge. Strengthening the Strategic Fund and the ability of countries to negotiate more affordable and equitable prices, as well as other innovative models may help overcome the fragmentation of the pharmaceutical market, improve market transparency and eventually, improve the affordability of strategic products. Regional commitments and cooperation among countries are critical components to the achievement of this objective.