

## **Conclusions and Proposals:**

### **I Pan American Seminar on the Economic Regulation of Medicines (Brasilia, 17 – 19 March 2009)**

The representatives of Argentina, Australia, Barbados, Bolivia, Brazil, Canada, Chile, Colombia, Costa Rica, Cuba, El Salvador, Ecuador, Guyana, Guatemala, Jamaica, Mexico, Mozambique, Nicaragua, Panama, Paraguay, Peru, Portugal, Saint Lucia (in representation of the OECS countries), South Africa, Surinam, Uruguay and Venezuela;

With the participation of representatives from the World Health Organization (WHO) and Joint United Nations Program on HIV/AIDS (UNAIDS).

Invited jointly by the Brazilian National Health Surveillance Agency (ANVISA) and the Pan American Health Organization (PAHO).

#### Observing:

The approval of the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (WHA61.21) as well as the implementation of the Regional Perspective in the Americas (CD48R15);

#### Noting

The recommendations and conclusions of the First International Meeting on Access to High Cost-Limited Source Medicines held in Brasilia, in November 4-6, 2008.

#### Considering:

The proliferation of new medicines in the region presenting challenges to countries concerning the assessment of therapeutic efficacy and cost-effectiveness. The exponential increase in the expenditure in medicines in all countries in addition to the scarcity of available treatments for those diseases that disproportionately affect the region.

The need to set out regional strategies to reduce the prices of medicines, increase transparency, promote the exchange of information and implement measures aimed at facilitating trade in medicines amongst countries in the region.

The need to take into account the economic component related to medicines assessment and adopt mechanisms to support decision-making processes, relative to medicines prices and the incorporation of new medicines into public health systems.

The different characteristics of health systems within the Region, posing particular challenges in the systematic compilation of information related to economic regulation of medicines

The dimensions of economic regulation of medicines being: 1) Price regulation; 2) Generic medicine promotion; 3) Financing and Procurement; 4) Assessment and incorporation of new medicines and technologies; 5) Intellectual Property Rights

The need to strengthen a set of interventions related to the economic regulation of medicines in the Region as a means of improving access to medicines, within the framework of the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property as well as the implementation of the Regional Perspective in the Americas.

The need to address asymmetries in information regarding the price of medicines as well as the need to appropriately address these asymmetries. In this sense, the establishment of a price database that allows price comparison amongst countries is of great importance.

It is critical to set up mechanisms for collecting and disseminating relevant information and to optimize financial resources, through information and communication management tools and technologies

That some countries have advanced in the development of regulatory framework for price regulation based on international price references, cost-effectiveness analysis for new medicines and/or application of *cost-plus* systems for medicines

Imperfections in pharmaceutical markets within the region, as well as disparities in medicines prices and other health care expenditures in countries (sub-systems), amongst countries and sub-regions, the need to have easy, transparent and rapid access to available and updated information on the behavior of medicine prices.

The experience of economic integration blocks (MERCOSUR, SISCA...) as well as the experience of some countries in the Region in setting up operational price databases for priority medicines as a support mechanism for the public procurement of medicines.

The importance of the economic evaluation of medicines and health technologies to measure the comparative cost effectiveness and evidence based inclusion in Public Health systems, as a complementary method to price regulation.

The need to strengthen the human resource capacity within the health sector in the use and management of information, instruments and tools needed for the development and application of mechanisms in a systematic manner for the economic evaluation of medicines and health technologies.

The need to examine diverse alternatives to improve access to medicines including the concept of equity pricing.

The opportunity for countries to share experiences and information within a cooperation framework that allows the consolidation of a common work program and joint collaboration.

### Recommending:

The characterization of the regulatory framework for medicines through the collection and systematization of information in the area of the economic regulation of medicines in countries, adapting and applying the questionnaire prepared by PAHO and ANVISA.

Disseminate information at the regional level and between countries on strategies and interventions in the regulation of medicines including regulatory and legislative frameworks to support the development and implementation of activities in the countries.

Document experiences in price regulation for dissemination in countries within the region: strengthen cooperation between interested countries through the establishment of a data base of medicines prices, regulations and legislations, as well as a forum to facilitate the exchange and development of these activities.

Identify and exchange country experiences in the area of Observatories or national / regional data bases of medicines price.

Develop a public and free data base of medicines prices as a public good and other relevant information (patents, formulations, specifications...) relating to medicines as a mechanism to support the decision making process (pricing, incorporation of medicines in health systems, public procurement...) in the Region. Initially develop a pilot project using a list of selected medicines based on criteria previously agreed (impact, condition, patent status...)

Task PAHO with the technical secretariat and management / maintenance of the data base, and jointly with countries and other actors, the mobilization of resources for cooperation (bilateral cooperation agencies, international organizations..). The countries commit to supporting and providing the necessary information on a regular basis to support operations of the data base etc.).

Establish a working group with the participation of the countries within the region (and designated experts), coordinated and supported by PAHO, with the objective of elaborating a proposal for the development of the project including a methodology, a timetable, a detailed implementation plan and a mechanism to promote participation in the data base.

Promote the identification of reference institutions as well as existing collaborating networks and price and economic evaluation data bases. Support the dissemination of related publications and studies.

Support the development of human resources within the health sector for the economic regulation, the critical evaluation of available evidence, and the adaptation of studies taking into consideration of the realities of the countries, through actions focused in the area of capacity building, training programs and the inter-country exchanges.

Use virtual tools for the development of forums or platforms as a means of disseminating, exchanging and transferring knowledge, experiences and case studies (cost – effectiveness, comparative effectiveness, cost minimization....) in order to contribute to the decision making process within national health institutions. Such tools may facilitate the incorporation of data relating to the economic regulation of medicines, risks, advantages (access to medicines for patients, rational use of medicines..).

Establish collaborative links in the area of the regulation and economic regulation of medicines between regulatory authorities in the region as well as with other regions. Include technical visits and joint studies.

Effectively implement strategies to promote WHO good procurement practices for medicines, especially for priority medicines for countries within the region. Explore the possibility of preparing a publication based on the regional context and centered on mechanisms for the cost containment of pharmaceutical expenditure.

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