

**First Latin American Conference on Research  
and Innovation for Health**

**Río de Janeiro, Brazil, 15 to 18 April 2008**

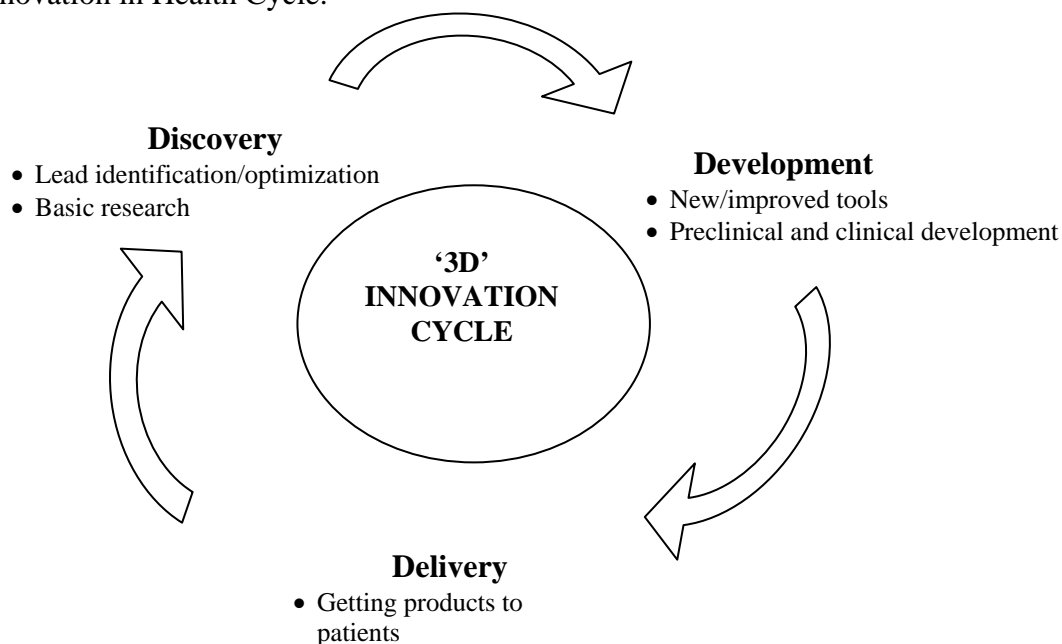
Working Group:

**Innovation, Product Development & Access**

**Background: Global landmarks & frameworks.**

1. Scientific and technology knowledge is crucial to promote social and economic development at local, regional and global levels. The production and application of evidences for the technology development and innovation for health, brings huge challenges for the national health systems.
2. The introduction of new products for diagnosis, prevention and treatment of diseases depends on a long chain of scientific research and development. However, health innovation is not only a matter of science and should be understood as a cycle, consisting of three major phases that feed into each other: Discovery, Development and Delivery (Figure 1).

Figure: Innovation in Health Cycle.



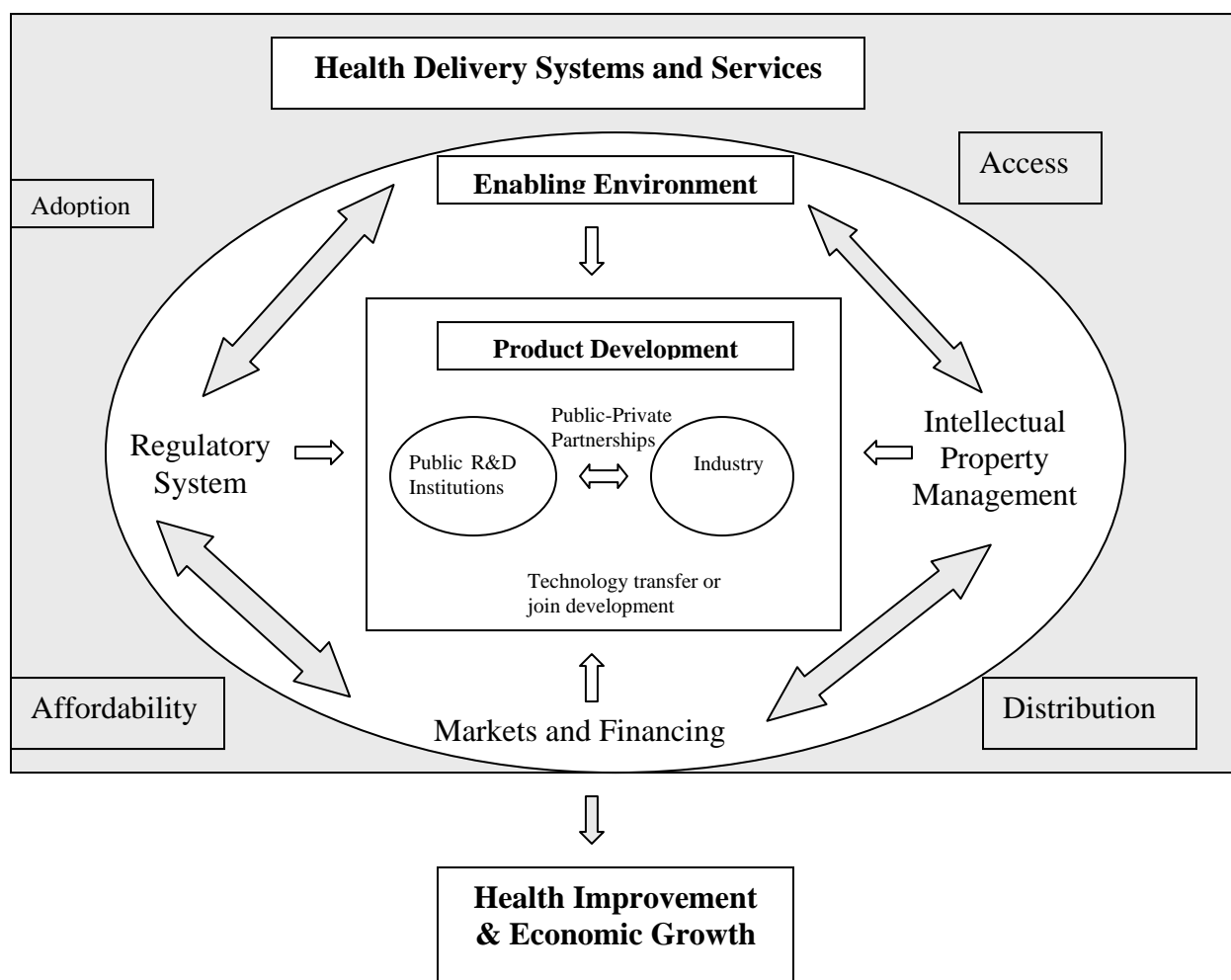
Source: Commission on Intellectual Property Rights and, Innovation and Public Health, 2006.\*

3. Although one of the most challenging aspects of drug discovery is identifying candidate compounds, the most expensive part is the process of taking the candidate through all the required stages of pre-clinical and clinical research and the regulatory process. In developed countries, the rapidly rising costs of health care, including supplies of medicines, are a matter of intense public concern. In developing countries, and even in some developed countries, the cost of medicines, often not available through public health-care systems, can be a matter of life and death (CIPIH, 2006).
4. However, successful efforts should develop new products to address the public health problems of developing countries; they will be worthless if they cannot be available and accessible to those who need them. Adopting this paradigm, the access of product is considered the end of innovation cycle in order to promote innovation for health.
5. The '3D' innovation cycle implementation, therefore, should establish a complex interaction among a wide range of economic, social, and political actors and agendas. Governments play a critical role in providing the innovation policy framework and ensuring it will be guided by health-needs. In this perspective, the governments should lead the development of policies, strategies and actions related to intellectual property rights, funding, tax, partnerships, priority-setting process, R&D&I capacity-building, regulatory process and other incentives, as well as consider that other actors in the public, private, non-profit sectors and international organizations are essential components of this complex system.
6. As a complement of the '3D' cycle, it is suggested adopting the framework proposed by Morel et al (2005) which scheme presents the main elements of the health innovation system and the interdependence among them. This framework considers multiple components, operating in both public and private sectors, addressing different areas, such as: education, research, financing, manufacturing, technology management practices, intellectual property rules, regulatory rules, domestic and export markets, including public procurement. The system refers not only to these components but also to the technical, commercial, legal, social and financial interactions; to the inter-linkages among components; and to the policies and practices that guide them. The function of this mechanism and the dynamic linkages of these elements form a framework that contributes to the health-need driven production and delivery of products and services to people.

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\* Commission on Intellectual Property Rights and, Innovation and Public Health (CIPIH). 2006. Public health, innovation and intellectual property rights: Report of Commission on Intellectual Property Rights and, Innovation and Public Health. Geneva: WHO, 204 p.

Figure 2: Innovation health System Framework.



Source\*: Morel, et al, 2005

- The current innovation paradigm has considered, predominantly, the market interested, instead of health-needs. According to World Health Organization (2003), only 10% of pharmaceutical industry investments focus on infectious diseases, which occur in 90% of the cases in developing countries. Other available data indicates noted that only 13 out of 1400 new products developed by pharmaceutical industry between 1975 and 1999 were for tropical diseases which affect mainly the developing countries. This scenario indicates that insufficient research, technology development and innovation (R&D&I) were focusing on communicable diseases, especially for neglected diseases. Despite of the high burden of communicable disease in developing countries, the epidemiological transition phenomenon has increased the challenges for their national health systems which also should deal with a triple burden of diseases (injuries, communicable and non-communicable diseases), considering them in the priority-setting exercises, strategies and

\* Morel, Carlos, et al. 2005. Health innovation networks to help developing countries address neglected diseases. *Science*, 2005, v. 39, n. 15, p. 401-403.

actions in R&D&I initiatives. The table 1 shows the proportion of Disability-Adjusted Life Years (DALYS) lost by disease group and the differences among regions.

Table 1 – Percentage of DALYs lost by income group, disease group and region

Cause	High Income Countries	Low Income Countries	Low and Middle Income Countries by WHO Region					
			African	Americas	South-East Asia	European	Eastern Mediterranean	Western Pacific
Communicable	5.6	53.5	71.7	21.8	39.3	12.1	43.6	18.7
Non-Communicable	85.7	35.0	19.2	62.4	47.1	71.5	43.3	67.0
Injuries	8.7	11.5	9.1	15.8	13.6	16.4	13.1	14.3

Source\* : Commission on Intellectual Property Rights and, Innovation and Public Health, 2006.

8. In this context, the World Trade Organization (WTO) was created in 1995 as a global body to promote liberalization of trade in goods and services. Of a particular importance for our enquiry, the global application of minimum standards for intellectual property under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) has been the subject of controversy, particularly in regard to its potential impact on public health. As a result of this controversy, governments meeting at Doha in 2001 clarified some aspects of the relationship between the TRIPS agreement and public health in the Declaration on the TRIPS Agreement and Public Health (CIPIH, 2006).
9. The impacts of these economic and political trends on global health are complex and demands to prioritize R&D&I and related issues, such as intellectual property rights and market/product regulation, in the health agendas. Being aware of the complex challenges, the governments addressed this discussion in the 56<sup>th</sup> World Health Assembly\* in 2003, demanding from WHO the establishment of the Commission on Intellectual Property Rights and, Innovation and Public Health. In 2004, the Director-General of WHO created it in order to make a global overview, analyze current situation and propose recommendations for health innovation and related themes. The Commission's report was launched in 2006, outlining, recommendations to health innovation, product development and access which are presented in annex 1.
10. During the 59<sup>th</sup> World Health Assembly\* in 2006, governments endorsed the Commission's recommendations and indicated the need to develop a global strategy and action plan for public health, innovation, essential health research and intellectual

\* Commission on Intellectual Property Rights and, Innovation and Public Health (CIPIH). 2006. Public health, innovation and intellectual property rights: Report of Commission on Intellectual Property Rights and, Innovation and Public Health. Geneva: WHO, 204 p.

\* WHO. 2003. 56 World Health Assembly: Resolution 56.27.

\* WHO. 2006. 59 World Health Assembly: Resolution 59.24

property rights. Additionally, it was established the Intergovernmental Working Group (IGWG) in order to lead this task.

11. The IGWG efforts have involved diverse stakeholders, such as governments, NGOs, international organizations, experts. The draft of the global strategy and action plan for public health, innovation and intellectual property were discussed at global level in two sessions held in December 2006 and November 2007. The international community agreed that the global strategy should be based on eight elements which are crucial to promote innovation for health, such as:
  - Prioritizing research and development needs;
  - Promoting research and development;
  - Building and improving research capacity;
  - Transfer of technology;
  - Application and management of intellectual property to contribute to innovation and promote public health;
  - Improving delivery and access;
  - Promoting sustainable financing mechanisms;
  - Establishing monitoring and reporting systems.
  
12. Particularly in the Latin American and Caribbean region, the global initiatives have strengthened the regional debate. In 2006, during the 58<sup>th</sup> Session of the Regional Committee of the Pan-American Health Organization (PAHO)\*, it was launched a specific resolution to public health, health research, production and access to essential medicines. The regional resolution has endorsed the previous global initiatives, as well as has encouraged the Latin-American and Caribbean countries to participate actively in the IGWG discussion, also outlining a set of regional recommendations which is presented in the annex 2.
  
13. In this context, during the 60<sup>th</sup> World Health Assembly\* held in 2007, WHO Member States have emphasized the need to support regional consultative meetings in order to set regional priorities that would inform the work of the IGWG.
  
14. These global and regional deliberations have stimulated the organization of consultations in Latin-American and Caribbean Regional. Two of them were held in 2007 in La Paz-Bolivia and Rio de Janeiro-Brazil, and one regional meeting was held in 2008 in Paramaribo, Suriname.
  
15. These endeavors have mobilized a set of key-stakeholders in the region, contributing, consequently, to assign a higher priority for R&D&I in sanitary agendas at national, regional and global levels.

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\* PAHO.2006. 47<sup>th</sup> Directing Council- 58<sup>th</sup> Session of the Regional Committee. Resolution CD 47.R7.

\* WHO. 2007. 60 World Health Assembly: Resolution 60.30

16. Even though there are advances, the national health innovation systems in most Latin American and Caribbean countries are still incipient and do not focus on the national health priorities. In the region, it could be underlined the experience developed in Argentina, Brazil, Chile, Cuba and Mexico. These countries have strengthened their innovation ability and promoted the articulation among health, science & technology and production sectors, in order to establish health-needs product and process development and access. Could that become a reality for all Latin American and Caribbean countries? Is it affordable? How could the regional capacity in R&D&I in health better used to improve access?
17. Those questions show the need to deeply debate and establish a regional framework that can articulate a set of stakeholders, catalyze processes, and optimize resources and capacities to improve access in the region.
18. Considering the frameworks and landmarks as references, as well as the regional context of health innovation capacity, the I Latin-American Conference of Research and Innovation for Health aims to strength the regional debate in order to support the development of an action plan for cooperation in innovation, product development and access fields, according to the regional capacity and priorities.

### **Objectives of the innovation working group debate**

Propose a regional framework for innovation and product development in order to strength cooperation and improve the health product access in the Latin American region.

### **Main outcomes of the innovation working group debate**

- Indicate national and regional priorities in R&D&I in health, considering the national and regional capacity and the burden of disease.
- Define strategies and actions for future cooperation (bilateral and multilateral) within and beyond the region in the R&D&I field.
- Produce inputs for the regional consultation of the Latin American Ministers of Health

### **Guide-questions for the discussion**

*April 16 - 16:30-18:00 h*

#### *1) Regional Priority-setting in R&D&I for health:*

- Which are the regional capacities for product development and innovation for health?

- What is currently being done in R&D&I, and where are the gaps?
- Which are the regional competitive advantages in R&D&I in health, considering the population health-needs and market interests?
- What should be the regional priorities for cooperation in R&D&I in health field, considering the regional capacity and regional burden of disease? South-South, North-South, bilateral and multilateral ones?
- Given that innovation can be incorporated to the non-technological field, which of the experiences of innovation in technologies can be transferred to social research? what are the processes which best would facilitate that process?

*April 17- 9:00 - 10:30 h*  
*15:00 - 16:00h*

*2) Policy Framework to promote innovation, health product development and access:*

- Which mechanisms and incentives could improve the technology development in LA region? (Local development? Public-Private Product Development Partnerships? Knowledge about patent process? Patent incentives and regulation?)
- How could the Latin American innovative countries contribute to improve access for health products in the region as a whole?
- Which are the best mechanisms to improve the articulation of national health research systems and the existing LA health innovation systems?
- Which issue can be addressed to improve the regional collaboration in R&D&I, considering the national policy frameworks and countries health-needs?
- How health international organizations could collaborate for the health innovation systems strengthening?
- How can the potential of traditional medicine be tapped? What policies will promote innovation based on traditional medicine, and also ensure a fair share of the benefits from that innovation?
- How can the regulatory mechanism be improved to ensure the quality, security and efficient of drugs/health products, harmonizing international and national regulations?
- How can we use innovation to improve access to products?
- How can we research and institutionalize mechanisms to innovate health systems?
- Can innovative financing mechanisms improve access to products?
- Do social innovations (f. ex. innovative cash transfers) have an impact in health?

*April 17- 16:30 - 18:00hs*

*Strategies and Actions*

- What can be done to increase the contribution of developing countries to addressing their own and regional needs for new diagnostics, and preventive and curative treatments? How can access to products be improved to reach equity in their distribution?
- How could the cooperation among countries be improved?
- Which strategies can facilitate technology transfer, according to the countries health-needs?
- How can we learn from social innovation mechanisms across countries in the region?
- Which strategies and actions could contribute to decrease & regulate the drug costs, facilitate the distribution among LA countries, in order to improve the access?
- LAC is an innovative region. How can experiences from the region be better transferred to other regions?

## References

Commission on Intellectual Property Rights and, Innovation and Public Health (CIPIH). 2006. Public health, innovation and intellectual property rights: Report of Commission on Intellectual Property Rights and, Innovation and Public Health. Geneva: WHO, p.204.

Morel, Carlos, et al. 2005. Health innovation networks to help developing countries address neglected diseases. *Science*, 2005, v. 39, n. 15, p. 401-403.

PAHO.2006. 47<sup>th</sup> Directing Council- 58<sup>th</sup> Session of the Regional Committee. Resolution CED 47.R7.

WHO. 2003. 56<sup>th</sup> World Health Assembly: Resolution 56.27.

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## **Annex 1 - Synthesis of the Commission on Intellectual Property Rights and, Innovation and Public Health (CIPRH) Recommendations**

### *Policies & Frameworks*

- Governments of developed countries should seek to define explicit strategies for R&D and devote a growing proportion of their total health R&D funding to the health needs of developing countries.
- Government and funder attention should be paid to upstream research that enables and supports the acquisition of new knowledge and technologies that will facilitate the development of new products, including drugs, vaccines and diagnostic tests to tackle the health problems of developing countries. Attention should also be paid to the current inadequacy of the research tools available in these fields of research. These include techniques to understand new pathways to discovery, better ways to use bioinformatics, more suitable animal models and other disease-specific technologies.
- Countries should seek through patenting and licensing policies to maximize the availability of innovations, including research tools and platform technologies, for the development of products of relevance to public health, particularly to conditions prevalent in developing countries.
- Public funding bodies should introduce policies for sensible patenting and licensing practices for technologies arising from their funding to promote downstream innovation in healthcare products.
- Patent pools of upstream technologies may be useful in some circumstances to promote innovation relevant to developing countries.
- Developing countries need to consider in their own legislation what form of research exemption might be appropriate in their own circumstances to foster research and innovation for health.
- Countries should provide in their legislation powers to use compulsory licensing, in accordance with the TRIPS agreement, where this power might be useful as one of the means available to promote, inter alia, research that is directly relevant to the specific health problems of developing countries.
- Governments need to prioritize health care in their national agendas and, given the leverage to determine prices that patents confer, should adopt measures to promote competition and ensure that pricing of medicines is consistent with their public health policies.
- In bilateral trade negotiations, it is important that governments ensure that ministries of health be properly represented in the negotiation, and that the provisions in the texts respect the principles of the Doha Declaration. Partners should consider carefully any trade-offs they may make in negotiation.
- Digital libraries of traditional medical knowledge should be incorporated into the minimum search documentation lists of patent offices to ensure that the data contained within them will be considered during the processing of patent applications.

- To enhance public–private partnerships, providing appropriate capacity-building in order to ensure the substantiality of technology transfer process, according the countries priority.
- Developing countries should adopt or effectively implement competition policies and apply the pro-competitive measures.
- WHO, including its regional offices, should consider the recommendations of the Commission report, in consultation with others, and recommend how these should be taken forward in each region and country.
- WHO should bring together academics, small and large companies in pharmaceuticals and biotechnology, governments in the form of aid donors or medical research councils, foundations, public–private partnerships and patient and civil society groups for a standing forum to enable more organized sharing of information and greater coordination between the various players.

### *Product Development*

- Governments and the appropriate national authorities and funders should assign a higher priority to research on the development of new animal models, biomarkers, surrogate end–points and new models for assessing safety and efficacy, which would increase the efficiency of product development. They should also work with their counterparts in developing countries to formulate a mechanism to help identify research priorities in this area for Type II and Type III diseases particularly relevant to developing countries, provide funding for this R&D, and find affordable and technologically appropriate means for their diagnosis, prevention and treatment.
- Developed countries, and pharmaceutical companies (including generic producers), should take measures to promote the transfer of technology and local production of pharmaceuticals in developing countries, wherever this makes economic sense and promotes the availability, accessibility, affordability and security of supply of needed products.
- Countries should strengthen the clinical trials and regulatory infrastructure in developing countries.
- Developing countries need to assign a higher priority to improving the regulation of medical products. Governments also have an important responsibility to put in place mechanisms to regulate the quality, safety and efficacy of medicines and other products, assigning high priority to the international norms and regulations.
- Governments should continue to develop forms of advance purchase schemes which may contribute to moving later stage vaccines, medicines and diagnostics as quickly as possible through development to delivery.

### *Access*

- Governments need to invest appropriately in the health delivery infrastructure, and in financing the purchase of medicines and vaccines through insurance or other means, if existing and new products are to be made available to those in need of them. Political commitment is a prerequisite for bringing about a sustained improvement in the delivery infrastructure and health outcomes.
- Policies must emphasize affordable innovations adapted to the realities of health-care delivery in developing countries, and covering appropriate technologies for the diagnosis, prevention and treatment of both communicable and non-communicable diseases. Mechanisms for promoting such adaptive research in a systematic way must be improved.
- Governments and companies should consider, for non-communicable diseases, how treatments, which are widely available in developed countries, can be made more accessible for patients in developing countries.
- Access to drugs can not depend on the decisions of private companies but is also a government responsibility and regulation.
- Developing countries should provide in their legislation for the use of compulsory licensing provisions, consistent with the TRIPS agreement, as one means to facilitate access to cheaper medicines through import or local production.
- The restriction of parallel imports by developed countries is likely to be beneficial for affordability in developing countries. Developing countries should retain the possibilities to benefit from differential pricing, and the ability to seek and parallel import lower priced medicines.
- Governments and concerned international organizations should promote new purchasing mechanisms to stimulate the supply of affordable new products and to enhance the number of suppliers in order to provide a more competitive environment.
- Countries should provide in national legislation for measures to encourage generic entry on patent expiry.
- Bilateral trade agreements should not seek to incorporate TRIPS-plus protection in ways that may reduce access to medicines in developing countries.
- Governors and donors should invest for developing innovative capacity is investment in the human resources and the knowledge base, especially the development of tertiary education.
- The formation of effective networks, nationally and internationally, between institutions in developing countries and developed countries, both formal and informal, is an important element in building innovative capacity.



PAN AMERICAN HEALTH ORGANIZATION  
WORLD HEALTH ORGANIZATION



**47th DIRECTING COUNCIL**  
**58th SESSION OF THE REGIONAL COMMITTEE**

*Washington, D.C., USA, 25-29 September 2006*

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***RESOLUTION***

***CD47.R7***

**PUBLIC HEALTH, HEALTH RESEARCH, PRODUCTION AND  
ACCESS TO ESSENTIAL MEDICINES**

***THE 47th DIRECTING COUNCIL,***

Having considered the Report of the Commission on Intellectual Property Rights, Innovation and Public Health;

Taking into account Resolution WHA59.24 entitled “Public health, innovation, essential health research and intellectual property rights: towards a global strategy and plan of action;”

Recalling that WHO shall soon convene an Intergovernmental Working Group to draw up a global strategy and plan of action to provide a sustainable reference framework for needs-driven essential health research and development, relevant to diseases that disproportionately affect developing countries;

Conscious of the need for adequate incentive for research and the development of treatment for diseases that disproportionately affect developing countries;

Conscious of the need to develop policies to make health a priority and facilitate production, purchase, distribution and quality control of essential medicines that interest the governments, the population, the scientists, and the industry;

Reaffirming that the Doha Ministerial Declaration on the TRIPS Agreement and Public Health confirms that the Agreement does not and should not prevent Members from taking measures to protect public health;

Observing that the Declaration, reiterating the commitment with the TRIPS Agreement, affirms that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all;

Recalling that there are medicines for the treatment of diseases that do not have the advantage of innovative financing mechanisms; and

Taking into account the necessity to make accessible to all the combined set of essential medicines,

***RESOLVES:***

1. To urge Member States to:
  - (a) actively participate in the Intergovernmental Working Group to draw up a global strategy and plan of action to provide a sustainable reference framework for needs-driven essential health research and development, relevant to diseases that disproportionately affect developing countries;
  - (b) work to guarantee adequate incentive to research and the development of treatment to neglected diseases or very neglected diseases;
  - (c) develop policies to make health a priority and facilitate production, purchase, distribution and quality control of essential medicines;
  - (d) examine the possibility to utilize innovative financing mechanisms, following the model of the Strategic Fund of PAHO, to further the production, purchase, distribution and quality control of essential medicines to recover and promote the health of the most needy population;
  - (e) continue initiatives of joint negotiation and joint purchasing of medicines to consider the needs of public health, thereby strengthening and enlarging the activities of the Strategic Fund of PAHO;
  - (f) to encourage trade agreements to take into account the flexibilities contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights and recognized by the Doha Ministerial Declaration on the TRIPS Agreement and Public Health;

- (g) study the possibility to adapt, as needed, national laws to take full advantage of the flexibilities foreseen in the TRIPS Agreement.

*(Sixth Meeting, 27 September 2006)*