SÃO PAULO PARLIAMENTARY DECLARATION ON ACCESS TO MEDICINES AND OTHER PHARMACEUTICAL PRODUCTS

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As Parliamentarians from 24 countries representing a range of economic development, from G8 member countries to least developed countries, we are deeply committed to delivering universal access to essential medicines and other pharmaceutical products needed in our communities. We recall that access to medicines is a fundamental element of the human right to the highest attainable standard of health, is essential for saving lives, and that UN member states have repeatedly recognized this right in particular in the context of HIV/AIDS, tuberculosis and malaria. As well, we underscore the fact that all members of the World Trade Organization agreed in 2001 through the Doha Declaration on the TRIPS Agreement and Public Health that the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) ‘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.’

We recognize that generic competition has played a critical role in securing dramatic and sustained reductions in the costs of AIDS medicines. However, we are gravely concerned by emerging threats to access to medicines and other pharmaceutical products, particularly for newer medicines and pharmaceutical products that are subject to a range of intellectual property rights barriers, such as patent monopolies and data exclusivity.

We note that the global consensus of the Doha Declaration, brokered a decade ago, is under threat, as some governments are negotiating for bilateral and regional trade and investment agreements that create obligations for developing countries that exceed the standard set out by TRIPS, and that undermine the Declaration. Efforts by some governments to take advantage of the agreed-upon flexibilities recognized in TRIPS, including those reaffirmed by the Doha Declaration and the WTO General Council’s Decision of August 30, 2003, have also faced significant challenges, including pressure from other governments and from private industry. We reiterate the commitments undertaken by Parliamentarians meeting under the auspices of the Inter-Parliamentary Union in Manila, Philippines in 2007 at the First Global Parliamentary Meeting on HIV/AIDS, to facilitate access to affordable medicines and other pharmaceutical products.

In the interest of ensuring access to medicines and other pharmaceutical products and promoting public health, we urge all governments to undertake the following steps:

- Actively encourage and support developing countries to utilize all policy options available to them, including the flexibilities contained in the WTO TRIPS agreement, to ensure affordable access for their populations to the medical tools needed to prevent, diagnose and treat HIV, Tuberculosis, Malaria and other public health problems, including by amending as needed national laws and regulations.
• Urgently address obstacles which limit the capacity of developing countries to provide affordable treatment and related technologies, including laws, regulations, policies and practices, as well as trade agreements and initiatives, that impose intellectual property protections stricter than required under the TRIPS agreement; extend the 2016 deadline for least developed countries to implement the TRIPS agreement; revise the WTO General Council’s Decision of August 30, 2003 and find a truly workable, straightforward and expeditious solution for developing countries with no or insufficient pharmaceutical manufacturing capacity to make effective use of compulsory licensing; and encourage the use of new mechanisms such as the UNITAID Medicines Patent Pool to help reduce treatment costs and promote the development of new treatment formulations, including paediatric formulations and fixed-dose combinations.

• More specifically, to oppose, and refrain from pursuing or adopting, provisions in bilateral and regional trade and investment agreements, that would undermine access to medicines and other pharmaceutical products, including provisions that would further limit the use of policy options such as compulsory licensing and parallel importing; data exclusivity restrictions; linkage between patent status and registration of generics; patent term extension; and enforcement measures and investment provisions that include intellectual property rights.

• African governments to honor the commitments undertaken in the 2001 Abuja Declaration to devote at least 15% of their budgets to health, and donor governments to honor their longstanding commitments to allocate at least 0.7% of GNP to ODA, as well as emerging economies undertaking progressively enhanced commitments for ODA.

• Ensure that negotiations of bilateral and multilateral trade and investment agreements are conducted with full transparency and accountability to Parliamentarians and the public to enable them to comprehensively and objectively evaluate the provisions of the proposed agreements and ensure that they do not impede access to medicines and other pharmaceutical products.

• To refrain from interfering with the transit of generic medicines and other pharmaceutical products between exporting and importing countries where those medicines and pharmaceutical products are in conformity with the laws of those countries.

• Explore and promote global norms on medical research and development, including innovative incentive mechanisms that de-link the cost of research and development from the price of products and a global research and development treaty as agreed through the World Health Assembly Resolution 61.21 Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property.
We call on the Global Fund to Fight AIDS, Tuberculosis and Malaria and other multilateral donors to:

- Adopt and implement policies that leverage their buying power to maximize value for money, and encourage and reward the rapid adoption by countries of TRIPS flexibilities.

- Work towards the progressive extension of the Affordable Medicines Facility - Malaria to all countries in which the Global Fund is supporting programs to fight malaria.

We call on all patent-holders, including pharmaceutical companies, governments, universities and research institutions to:

- License their patents with the UNITAID Medicines Patent Pool to facilitate the production of affordable medicines and the development of needed formulations for all developing countries;

- Refrain from misleading policy-makers and the public by inaccurately equating or conflating generic medicines with counterfeit medicines;

- Put rigorous regulatory mechanisms in place to ensure that medicines and other pharmaceutical products, both generic and brand name, meet all required medical standards; and

- Refrain from pressuring governments to avoid using the flexibilities available to them under TRIPS and other agreements in the pursuit of the agreed-upon development and human rights objective of access to medicines and other pharmaceutical products for all.

We, Parliamentarians gathered at this meeting of the Global Fund Partnership Forum in Sao Paulo, Brazil in June, 2011, undertake to actively promote awareness of and support for this Declaration, in collaboration with partners in civil society, in our countries and in regional and international Parliamentary networks.