

Sao Paulo, March, 27<sup>th</sup>, 2009.

Mr. Michel Sidibé  
Executive Director of UNAIDS

The Working Group on Intellectual Property of the Brazilian Network for the Integration of Peoples (GTPI/REBRIP) is comprised of several Brazilian civil society organizations that work to assure the right to health, including organizations working with people living with HIV/AIDS, human rights and consumers rights. GTPI, created in 2001, conducts studies and advocacy actions to overcome the negative effects of patents protection and other monopoly mechanisms on access to essential medicines and the implementation of health policies in Brazil.

In this context, **we express major concern with public health implications of the recent events related to the seizure of generic medicine cargos in transit in European ports.** The importance of generic drugs to public health in developing and least developed countries is enormous and measures of this nature clearly impact national public health policies and are against the principle of universal access to medicines.

The retention by Dutch authorities of generic medicine Losartan in transit at the Netherlands for alleged violations of domestic patents and trademarks on the basis of Council Regulation (EC) No. 1383/2003, was the first case that affected directly Brazilian patients. The generic medicine retained was produced by the Indian manufacturer Dr. Reddy's Laboratories Ltd and sold to the Brazilian private company EMS, and would be sold in the Brazilian market for hypertension control. In Brazil, hypertension is one of the main causes of death, and most patients rely on generic medicine to be able to have access to treatment.

The generic medicine was produced in India in accordance to the legal international provisions about intellectual property rights, especially the TRIPS Agreement, since losartan potassium is not protect by a patent in that country. In Brazil it is also not protected by a patent. This means that, although this drug is under patent in the Netherlands, India can produce and Brazil can import the product without any restriction by intellectual property laws and regulations. By restricting legitimate trade of generic products (assured by article 40, TRIPS), Netherlands is trying to enforce its intellectual property rights beyond its territory, which cannot be accepted.

We believe this is a distorted use of the international system of intellectual property and absolutely contrary to the "Doha declaration on TRIPS Agreement and Public Health" and to the TRIPS Agreement itself. The Doha Declaration on TRIPS and Public Health – signed by the members of the European Union - is clear on the fact that the protection of intellectual property rights should not avoid the adoption of measures to protect public

health. The Declaration also affirms the countries' right to fully use the TRIPS Agreement flexibilities to guarantee universal access to medicines. This measure is also against the *Global Strategy on Public Health, Innovation and Intellectual Property*, approved by all members of World Health Organization – WHO at the last World Health Assembly held in May 2008, and violates the resolution 2002/31 of the United Nation's Commission on Human Rights on the right to enjoy the highest standards of physical and mental health.

While we recognize that the seizure of counterfeit drugs is justified, we do not accept that Regulation 1383/2003 can be used to justify the seizure of legitimate goods in transit, especially in the case of medicines. **Generic medicines are not counterfeited medicines** and by treating them as such the Dutch authorities are obstructing the legitimate trade of generic medicines, with quality and competitive prices. We recall that a generic medicine is sold at much more affordable prices than branded medicine, contributing to improve the access to medicines, especially in developing and least developed countries. As such, the trade in legitimate medicines between countries is fundamental to improve the right to health for millions of people in the developing world. Equitable access to safe and affordable medicines is vital to the attainment of the highest possible standard of health by all. **The concept of generic must not be mistaken with fake, counterfeited or pirated and generic medicines are not substandard or illegal.**

We draw attention to the fact that it is imperative to take a further look into the responsibility not only of the Dutch authorities, but also of the brand-name companies that led Dutch authorities to intervene in the shipments, who are illegally frustrating lawful generic competition in countries where their intellectual property rights have no effect, and violating the right to health of thousands of people.

This is the first case that is directly affecting Brazilian patients, but it is important to notice that this measure is not only against the interest of the affected population, but can be a dangerous precedent against access to treatment of any disease in which production of generic medicine is available such as HIV/AIDS. We consider that the seizure by the Dutch customs authorities is in contradiction with the TRIPS Agreement and with the Doha Declaration and is a violation of the human right to health.

Therefore, we ask UNAIDS to include this discussion in its international agenda on universal access to treatment and enhance dialogue with European governments and partner agencies in order to prevent further damage to public health policies in developing countries.

Sincerely,

GTPI/Rebrip

Associação Brasileira Interdisciplinar de AIDS (ABIA); Conectas Direitos Humanos;  
Federação Nacional dos Farmacêuticos (Fenafar); Fórum de ONGs/AIDS do Maranhão,  
Gestos Soropositividade, Comunicação e Gênero; Grupo de Incentivo a Vida (GIV); Grupo



de Apoio e Prevenção a AIDS de São Paulo (GAPA/SP); Grupo de Apoio e Prevenção a AIDS do Rio Grande do Sul (GAPA/RS); Grupo de Incentivo a Vida (GIV); Grupo de Resistência Asa Branca (GRAB); Grupo Pela Vidua/SP; Instituto de Defesa do Consumidor (IDEC); Médicos sem Fronteiras; Oxfam.