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The Honorable Dilma Rousseff
Secretary of State
Federative Republic of Brazil

Sent by facsimile: + 55.61.33211461 and e-mail: casacivil@planalto.gov.br

Dear Ms Rousseff,

I am writing to you on behalf of Health GAP (Global Access Project), a U.S. organization working for equitable access to HIV treatment around the world. Health GAP, like many other organizations, has long advocated that Brazil exercise its rights to use the public health flexibilities established by the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and reaffirmed by the Doha Declaration on TRIPS Public Health, and issue a compulsory license for production of generic lopinavir/ritonavir (Kaletra) as well as other medicines whose high prices are threatening the sustainability of the Brazilian National AIDS Program.

On July 8, in response to negotiations with the government of Brazil, Abbott presented Brazil with a cost containment proposal that would result in a gradual price reduction as more Brazilians living with HIV require Kaletra therapy. Additionally, Abbott pledged to transfer technology that would permit Brazil to produce Kaletra after patent expiration in 2015.

Health GAP believes that Abbott's proposed cost containment agreement does not truly benefit Brazil. The proposed agreement is bad for Brazilian people with HIV, consumers elsewhere in the region and indeed around the world. The agreement also limits Brazil's local manufacturing capacity, perpetuating exclusive marketing rights for Kaletra and guaranteeing a monopoly until the patent expires. If the Brazilian government accepts Abbott's proposal, it would be accepting a short-term compromise that is a distraction from the overriding and urgent need to secure multiple sources of production of important medicines such as lopinavir/ritonavir and other second-line antiretroviral medicines in order to ensure the maximum price reductions needed to increase access and save lives. Briefly, the main defects in the proposed agreement are as follows:

1. **Over-estimation of cost savings.** Although Kaletra will be available for all patients in Brazil under the proposed agreement, the price will drop only gradually and the projected price reductions may be exaggerated because of over-prediction of the number of patients switching to Kaletra. Presently, only two thousand new patients are starting the use of Kaletra per year. In order to reach 60,000 patients by 2010, it would be necessary to prescribe Kaletra to three times as many patients, nearly 6,000 per year. Since the expected price benefits are based on what may well be an over-estimate of expected need, this proposed agreement will keep Abbott's sales volume constant while producing little per-pill cost savings for the Brazilian government.

Moreover, these speculative price advantages must be compared to the known price advantage of producing Kaletra domestically at \$.71/pill starting in 2006. In 2006, Brazil would have to pay Abbott US\$ 0.99 per capsule, a value much higher than the price considered fair by the World Health Organization and well above the price set by Far-Manguinhos, the official laboratory of the Ministry of Health and potential local manufacturer of the generic medicine. Far-Manguinhos's cost advantages are certain and immediate, and in fact they will increase over time as the price of active pharmaceutical ingredients decreases and as economies-of-scale are realized.

2. **International impact.** By keeping prices high in Brazil, Abbott will also be able to sustain high prices in smaller market, middle-income countries. The fact that Brazil, the largest market amongst the middle-income countries, will not achieve a dramatic cut in price until 2010 at the earliest will dramatically restrict maneuvering room for other developing countries seeking price concessions from Abbott.

By creating an expanded market for active pharmaceutical ingredients, Brazil can help promote lower-cost production by other generic suppliers such as those in India. The World Health Organization has previously estimated that it was Brazil's creation of a market for Active Pharmaceutical Ingredients (APIs) that resulted in the 70%-98% price reductions offered by generic companies in India.

Finally, despite its initial reluctance to do so, Brazil should consider becoming a regional supplier of generic lopinavir/ritonavir for other Latin American countries, particularly those that cannot manufacture the medicine efficiently for domestic consumption. Achieving sustainable and growing price reductions for Brazilian citizens is important, but people living with AIDS in other countries also need reliable access to more affordable versions of second-line AIDS medicines.

3. **Illusory Technology Transfer.** As Abbott's proposal only promises the transfer of technology starting sometime after 2009 and would preclude production until the Kaletra patent in Brazil expires in 2015, there is little real technology transfer in this agreement. Since Far-Manguinhos has the appropriate technical capacity to start the production in 2006, the promise of technology transfer far in the future is largely illusory.

For these reasons, it remains clear that issuing a compulsory license and for manufacture of lopinavir/ritonavir by Far-Manguinhos is a far superior solution for assuring a sustainable and low-cost supply of this important medicine. Moreover, this solution leads to more low-cost sourcing alternatives for other developing countries thereby ensuring that second-line treatments for all patients in need. The same logic applies to other drugs where Brazil has technical capacities for local manufacture.

Accordingly, compulsory licenses are also appropriate for Gilead's tenofovir and Merck's efavirenz and the government should follow through with its rights to issue those licenses expeditiously.

Brazil worked hard with other developing countries to clarify rights and to create flexibilities for prioritizing access to medicines via compulsory licenses. By issuing the compulsory license of these drugs, Brazil exercises its sovereign right to gain control over the entire manufacturing process from synthesis of raw materials to the formulation of the final product. In doing so, it can help the sustainability of its own comprehensive HIV/AIDS program at the same time that it expresses leadership towards and pragmatic solidarity with other developing countries.

Finally, we call on the government of Brazil to move forward in its negotiations with the utmost respect for basic principles of transparency and accountability. Issues of such national and international importance should not be determined in secret.

Sincerely,

Brook K. Baker, Professor of Law, Northeastern University
and Health GAP Policy Analyst

cc: Sarayva Felipe, Minister of Health
Pedro Chequer, Director, National HIV/AIDS Program
Roberto Abdenur, Brazilian Ambassador to the United States
Renata Reis, Associação Brasileira Interdisciplinar de AIDS

