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Minister of Health,
Hanoi, Vietnam

10 November 2011

Dear Madam. Nguyen Thi Kim Tien - Minister of Health,

We are writing to you as the group of organisations representing Vietnamese people living with HIV and other civil society organisations dedicated to improving access to medicines in Vietnam.

According to the World Health Organisation (WHO), "available and affordable second-line ARV regimens are a key component of universal access to high-quality HIV treatment[1]". The WHO says, "if patients develop drug resistance to their first-line regimen, they stop responding to it effectively. In order to stay healthy, they need to receive a second-line regimen[2]." Second-line ARVs can help to diminish the accumulation of drug resistant mutations in patients. Delaying access to second-line treatment can lead to cross-resistance and the need for the infected population to be treated by third-line ARVs.

Over the last several years, the Vietnamese government has taken significant strides towards making ARV treatment available to PLHIV, expanding the number of people receiving ARV treatment over 14 fold from 2005 to 2009.[3] However, going forward, Vietnam is likely to confront several issues which will strain the budget for HIV treatment.

- The number of people in need of ARV treatment is continuing to rise (estimated to have increased from 47,516 adults in need of treatment in 2007 to 67,047 in 2009[4]).
- National treatment guidelines are being brought into alignment with WHO guidelines, increasing the number of PLHIV eligible for ARV treatment.
- Despite strong efforts from global health advocates, donor funding may plateau or diminish. Only 1% of treatment resources came from the Vietnamese government in 2007.[5]

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[1] Prioritizing Second-Line Antiretroviral Drugs for Adults and Adolescents: a Public Health Approach, Report of a WHO Working Group Meeting, WORLD HEALTH ORGANIZATION, HIV Department, Geneva, Switzerland 21-22 May 2007, http://www.unaidsrstesa.org/sites/default/files/carenadtreatment/second_line_art_report_2008.pdf at p. 8.
[2] HIV Drug Resistance Fact Sheet, WORLD HEALTH ORGANIZATION, Apr. 2011, http://www.who.int/hiv/facts/WHD2011-HIVdr-fs-final.pdf.
[3] UNAIDS Vietnam 2010 Progress Report. http://www.unaids.org/en/dataanalysis/monitoringcountryprogress/2010progressreportssubmittedbycountries/vietnam_2010_country_progress_report_en.pdf
[4] Ibid.
[5] Ibid.

Considering these developments, Vietnam must explore methods to get the maximum impact from the treatment funding available.
Abbott Laboratories' new tablet formulation of its protease inhibitor, Kaletra (lopinavir + ritonavir or LPV/r), is a vital second-line drug for people living with HIV. Vietnam is a low-income country with a per capita GDP of $1,191, yet the market price of Kaletra/ Aluvia is arround $1092 to $2767 per person per year, and twice the per capita GDP. We are very concerned about the high market price of Kaletra/ Aluvia. This price is prohibitively high for Vietnamese patients living with HIV and imposes a heavy burden on bilateral and other donor financing.

Nonetheless, generics, including WHO-prequalified products, are available on the global market at a fraction of this price. A government use license for Abbott's patents would authorise Vietnam to import these generics, or produce generic LPV/r locally, and make them available to the public through government and donor treatment programs. This would enable Vietnam to provide second-line treatment at low cost to the government and increase the efficacy of donor funding.

We therefore call on the Ministry of Health to request a licence for the government use of ritonavir and lopinavir + ritonavir.

The *Law on Intellectual Property* No: 50/2005/QH11 establishes that the Ministry of Health has full capacity and competence to issue decisions for the use of patented inventions on behalf of the State for disease treatment for the people (Articles 133, 145 and 147).

The Ministry of Health assumes the prime responsibility for, and coordinates with the Ministry of Science and Technology in, guiding and organizing the implementation of procedures for compulsory licensing of inventions and use of inventions on behalf of the State to satisfy the needs of health care and nutrition for the people (Article 23/2 Decree No. 103/2006/ND-CP of September 22, 2006, *Guiding the Implementation of a number of provisions of the law on intellectual property regarding industrial property*).

In this context, we kindly request:

- After consulting the opinion of the Science and Technology Ministry, the Ministry of Health should issue a decision licencing the inventions that are necessary to produce ritonavir and lopinavir + ritonavir (LPV/r) under Point a, Clause 1, article of 145 of *Law on Intellectual Property* No: 50/2005/QH11 (Article 147/1).
- This Decision should set out appropriate use, scope and conditions in compliance with the provisions of Article 146 of *Law on Intellectual Property* No: 50/2005/ QH11.
- The Ministry of Health should promptly notify Abbott Laboratories of its decision to use inventions on behalf the State.

We sincerely appreciate your attention, and look forward to receiving your prompt and favourable response.

Yours sincerely,

Do Dang Dong
Coordinator of Vietnam National Network of People Living with HIV/AIDS (VNP+)