



## **An Appeal to the Chinese State to Rapidly Introduce Second-line Anti-HIV Drugs**

### **Open letter**

November 5, 2007

To: The State Council General Committee to Fight AIDS  
The Ministry of Health  
State Food and Drug Administration:

With promotion by all levels of the government, the central leadership, and the activities of domestic and foreign NGOs, the "Four Free and One Care" policy and AIDS prevention regulations have been promulgated, and China AIDS prevention and control work has continuously deepened and is gradually being integrated into the legal system.

From the view of people living with HIV/AIDS, free antiretroviral treatment has also saved the lives of countless patients. As people living with HIV, we sincerely thank the Chinese government, domestic and foreign NGOs, the Ministry of Health, and the State Disease Prevention and Control Center for all their ceaseless efforts. However, because China's AIDS treatment got off to a late start, because of a lack of available drugs, and because of the lack of education by some people with HIV/AIDS, our collective lack of experience with AIDS treatments did not enable the optimal combination of drugs. As a result, some clinical patients' treatment wasn't successful; a considerable number of patients who had just begun to gain confidence in their lives and futures now face major setbacks; and there is still no second-line antiretroviral treatment program which is urgently needed by many people with HIV.

We are aware that China CDC has confirmed that Gilead Sciences will produce TDF, an essential component of second-line anti-HIV drug treatment for adults. Caledon Michigan (KALETRA) is also already in place. However, because of the import ban on TDF, China is still facing serious delays in the availability of second-line treatment, while a large number of patients are in critical condition.

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According to a report from China CDC about drug resistance in patients who received the experimental treatment (young adults with HIV/AIDS in Henan Province) the fully standardized drug combination has led to a complex pattern of drug resistance. After the repeated appraisals of domestic and foreign experts, TDF not only has become the second-line treatment of children, but also one of the few effective choices.

The current situation is one with a special sense of urgency. If there is no timely access to second-line drugs, experts are expecting that, not only will adult patients continue to die shortly after being diagnosed, but first-line treatment given to children will also fail.

Faced with this urgent treatment situation, Gilead has submitted their complete registration reports about TDF and relevant documents to the State Food and Drug Administration (SFDA) at the end of July 2007, but up until now there has been no clear response. The company has repeatedly discussed with the relevant departments the progress of registration, but whether Chinese patients can get TDF in the short-term can not be guaranteed. In view of the fact that the registration procedures could not be completed recently, all of the state's sale, donation, and usage of clinics related to this drug have been put on hold.

We strongly appeal to relevant state departments to help us in urging the SFDA for such internationally-recognized drugs such that would simplify procedures and expedite the processing; cause the Ministry of Health to pay more attention to this situation, effectively push the necessary paperwork and promote the clinical usage of second-line anti-viral drug as soon as possible, so that we can save countless patients' lives from untold miseries.

Due to the urgent and grim situation, we appeal to all levels of society, to all kind-hearted people who support, care and love the people living with HIV/AIDS to join our group in the treatment of drug advocacy. Your support will play an invaluable role in saving countless patients' lives.

In this letter, we represent all the people living with HIV/AIDS and patients who are suffering from AIDS in expressing our sincere thanks and deep blessings to all of people who care and support us.

It won't take much time out of your life to help – you only need to state your support of accelerating the processing of the much-needed TDF, the HIV second-line key treatment drug, at the bottom of the letter. You can use e-mail, fax or express mail to leave the name of your organization or your individual name before November 15, 2007.

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