

**Announcement of the Department of Disease Control, Ministry of Public Health,
Thailand on the Public use of patent for Pharmaceutical Products****Translation**

By the virtue of provisions of Article 51 of the Thai Patent Act, B.E. 2522 (as amended by the Patent Act no.2, B.E. 2535 and Patent Act no.3, B.E. 2542), Ministries, bureaus and departments are allowed to use the patent rights of a product for public interests without prior permission from the patent owners. The public use of patent rights clearly aimed for non-commercial purposes and for public interests. In other word, the government has a right to use any patent right for public health services.

It is generally known that HIV/AIDS is an important public health problem. More than 1 million Thais have been infected with HIV, among these, more than 500,000 people are still alive. These infected individuals will eventually need long-term uses of antiretroviral drugs to maintain their productive lives.. However, budget for health services in the national health security system allocated for HIV /AIDS patients in the fiscal year 2006 (B.E. 2549) is only 2,796.2 million baht for the target group of 82,000 patients.

There are several effective anti-retrovirals that can extend the life of HIV infected individuals currently available in the Thai market. The Thai Government has launched a policy of universal access to anti-retrovirals since 1st October 2003, and has a budget specifically allocated for them. However, it is still difficult to get accessed to some effective and safer anti-retrovirals. The high price of these patented anti-retrovirals have hindered their accessibility under the universal access policy.

Efavirenz is a highly effective and safe anti-retroviral. It is also placed in the Thailand's National List of Anti-retrovirals. However, the price of the patented Efavirenz is twice of those generics produced by WHO certified GMP factories in India. With this higher price, the budget allocated from the Thai Government can only cover some patients with Efavirenz, whereas the rest has to use other non-patented more toxic anti-retrovirals.

According to the Doha Declaration on the TRIPS Agreement and Public Health, member countries have a right to issue a safeguard measure to protect public health, especially for universal access to essential medicines using compulsory licensing on the patent of pharmaceutical products. Based on the Declaration, the compulsory licensing measure can be used for the purposes of emergency cases and public uses. These flexibilities applied to drugs used for treatment of HIV/AIDS, tuberculosis, malaria, and other outbreaks. Under the Thai Patent Act, Ministries, bureau, and departments are allowed to use the patent rights of any products for non-commercial public uses.

By the virtue of provisions of Article 51 of the Thai Patent Act B.E. 2522 (as amended by the Thai Patent Act no.2 B.E. 2535 and no.3 B.E. 2542), the Department of Disease Control, Ministry of Public Health, thus use the patent right of a medicine called Stocrin® (or efavirenz as a generic name) and endorse the Government Pharmaceutical Organization of Thailand to exercise the rights contain within Para 1 of Article 36 of the Thai Patent Act B.E. 2522 (as amended by the Thai Patent Act no.2 B.E. 2535 and no.3 B.E. 2542) under these conditions:-

- (1) The use of the above patent rights are effective from today to the 31st December 2011.
- (2) The use of the above patent rights will be limited to the provision of Efavirenz to not more than 200,000 patients per year, for those covered under the National Health Security System Act B.E. 2545, Social Security Act B.E. 2533, and the Civil Servants and government employee's medical benefits scheme.
- (3) A royalty fee of 0.5 percent of the Government Pharmaceutical Organization's total sale value of the imported or locally produced Efavirenz will be paid to the patent holder.

The Department of Disease Control, Ministry of Public Health will notify the patent owner and the Department of Intellectual Property, Ministry of Commerce immediately.

Announced on 29th November 2006

Singed by Mr. Thawatch Soontarajarn

Director General

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