

Garuda

Translation

Ministry of Public Health Announcement
Regarding Exploitation of Patents on Drugs and Medical Supplies for Clopidogrel

As part of Section 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 affirms that in order to carry out any service for public consumption, ministry or bureau or department of the government may exercise the rights in any patent without the requirement of prior negotiation with the patentee. Its objective is clearly aimed for non-commercial purposes and public interests, for example, public health service.

Myocardial ischemia and cerebro-vascular accident are the most serious public health burden because of high mortality and disability loss. Its mortality rate is in top three annual ranking. Both diseases cause much DALY loss and are in top ten ranking for Thai male and female. Even though these diseases could be prevented by diet control, mental and physical exercise, but the incidents are high and need medicine for treatment and secondary prevention from thrombosis which leads to morbidity and mortality.

Clopidogrel or the trade name in Thailand namely Plavix® has evidence based effectiveness for prevention of myocardial ischemia, cerebro-vascular accident and coronary stent implantation by inhibition of platelet aggregation. However, the medicine is expensive thus has hindered their accessibility. Owing to its patent exclusive right, there is no competition. Government Pharmaceutical Organization or other manufacturers can not produce or import the medicine for price competition.

Regarding the diseases incidents, only 45 millions members of the Universal Coverage scheme will need for 20.5 million pills per annum. However, since the high price and limited budget, 20 percent of patients covered under Universal Coverage scheme can access to the medicine. As a result of provision of market competition by imported or locally produced generics, price will reduce dramatically and accessibility will increase 6 to 12 times which will conform to the Universal Coverage policy.

Under the Doha Declaration on TRIPS and Public Health stated that WTO members have rights to protect public health and, in particular, to promote access to medicines for all by granting compulsory licenses in a national emergency and public needs. In addition, the Thai Patent Act states that the ministry or bureau or department of the Government may exercise the rights in any patent for public non-commercial consumption.

By the virtue of provisions of Section 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, Ministry of Public Health, thus use the patent right of medicine called Plavix® and medicines contain Clopidogrel in all formulas, including its derivatives patented in Thailand and endorse the Government Pharmaceutical Organization of Thailand to exercise the rights contain within Para 1 of Section 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 is effective from today until the patent expired or no essential need.
- (2) The use of the provision of generic drugs of Clopidogrel is unlimited for patients covered under the National Health Security Act B.E.2545, Social Security Act B.E.2533 and Civil Servants and Government Employees Medical Benefit Scheme but is under doctors' judgment
- (3) A royalty fee of 0.5 percent of the Government Pharmaceutical Organization's total sale value

Ministry of Public Health will notify the patentee and the Department of Intellectual Property in writing without delay.

This announces to the public.

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