

Thailand Continues the Battle for Cheaper Drugs

The Thai government may allow generic production of more than a dozen patented medicines unless companies substantially lower the price of their brandname products. Three compulsory licenses for domestic production and import have already been issued.

Thailand's Ministry of Public Health has set up a panel to review whether compulsory licenses should be granted for at least ten patented drugs in addition to the three issued in November 2006 and January 2007 (see below). According to reports in Thai press, these could include medicines to treat diabetes, cancer, cholesterol-related diseases and possibly some antibiotics, but health officials have not confirmed the exact number or the names of the drugs under consideration. Public Health Minister Mongkol na Songkla told the Thai News Agency on 13 February that no compulsory licenses would be issued in the near future, and that the ministry hoped that brandname pharmaceutical manufacturers would engage in a dialogue with the government over a long-term strategy for public access to quality medical treatment. If companies brought prices down, Thailand would not "have to enforce compulsory licensing because we honestly don't want to," he said.

Kaletra, Plavix Targeted

On 29 January, the Thai government granted compulsory licenses for the AIDS drug Kaletra (lopinvir/ritonavir) manufactured by Abbot Laboratories and Plavix (clopidogrel bisulfate), a blood thinner used to treat heart disease, jointly marketed by the US-based Bristol Myers Squibb and France's Sanofi-Aventis. Generic copies of these would at least initially be imported from India.

The decision to produce generic Plavix without the rightholder's consent was somewhat unusual as most compulsory licenses are granted for medicines that treat epidemics rather than non-communicable diseases. Thai health officials say that only 20 percent of the 200,000 patients that need Plavix – the world's second best-selling drug in 2005 – currently receive it. Generic production would cut the price per tablet more than ten-fold from about US\$2.06 to 18 cents. Bristol Myers Squibb has not publicly commented on the case.

Abbott, however, said in a statement that it did not view the decision to issue a compulsory license for Kaletra 'as legal or in the best interest of patients'. Nevertheless, the company swiftly entered into negotiations with the Thai Ministry of Public Health and was reported by Thai press to have offered on 8 February to lower the price of Kaletra from US\$347 a month per patient to US\$167. This is still considerably higher than the US\$120 Indian generic manufacturers charge for a month's lopinavir/ritonavir treatment, and discussions reportedly continue between Abbott and Thai authorities on a further price reduction. In 2005, Abbott agreed to cut its Kaletra price for Brazil rather than face a compulsory licence.

Merck to Lower Price

In November 2006, Thailand issued a compulsory license for the AIDS drug efavirenz, under which it intends to first import a generic version of the medicine from India and later manufacture it locally (Bridges Year 10 No.8 page 16). Patented efavirenz is marketed by Merck & Co as Stocrin, and a month's treatment cost around US\$40 when the Thai compulsory license was issued. A one-month course of the Indian-made generic was about half the price. On 14 February, however, Merck announced that it was making Stocrin available at US\$0.65 per day for the poorest countries and middle-income countries with an adult HIV prevalence of one percent or more. As a result, the cost of a monthly course of Stocrin treatment would drop to US\$19.6 in Thailand. Merck cited 'efficiencies resulting from improved manufacturing processes' as the reason for the new offer and did not mention Thailand in its press release.

No TRIPS Violations Alleged

While health activists have applauded the efforts to widen access to affordable medicines, the government's compulsory licensing strategy has raised an uproar from original drug producers, including Thailand's Pharmaceutical Research and Manufacturers' Association. The asso-

ciation's president Teera Chakajarnodon told Reuters that the government's action was "completely unprecedented anywhere in world" and could result in companies deciding against marketing their latest drugs in Thailand. Although some of the companies concerned have expressed doubts about the legality of licenses granted without prior consultation, none have alleged a violation of the WTO's TRIPS Agreement.

The 2001 Doha Declaration on TRIPS and Public Health explicitly confirms that governments have the "right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted." According to Professor Frederick Abbott of Florida State University, the notion that there is a 'scope of diseases' limitation on the medicines for which compulsory licenses could be issued is spurious. "The idea that compulsory licensing of patents is limited to treatments for HIV/AIDS or ebola, as opposed to treatments for coronary disease and diabetes, is flat wrong," he said.

WHO Director-General Margaret Chan was seriously criticised for suggesting on 1 February that the Thai government should negotiate with drug companies before taking action. A week later, she wrote to Minister Mongkol to express regrets for any embarrassment her remarks might have caused and confirmed that Thailand's decision to issue compulsory licenses was "entirely the prerogative of the government, and fully in line with the TRIPS Agreement." She also said that there was "no requirement for countries to negotiate with patent holders before issuing a compulsory licence" and that the WHO unequivocally supported developing countries' use of the flexibilities within the TRIPS Agreement, including compulsory licensing. In related news, the UNAIDS Executive Director Peter Piot on 8 February wrote to the Thai Ministry of Public Health to commend the government for taking steps to ensure universal access to affordable HIV/AIDS treatment.