# WEEKLY NEWS - SEPTEMBER 24, 2007 More drugs under threat in Thailand

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***Thailand's National Health Security Office (NHSO) is to ask the Ministry of Public Health to launch negotiations with pharmaceutical companies to lower prices of four drugs***

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The move comes after the Thai government **caused controversy** by issuing three compulsory licences for pharmaceuticals in late 2006 and early 2007.

If these latest negotiations fail then more compulsory licences could be issued.

The drugs now being targeted by the government treat different forms of cancer. Two, Glivec (imatinib) and Femara (letrozole) are made by Novartis.

The other two are Tarceva (erlotinib) and Taxotere (docetaxel), which are produced by Genentech and Sanofi-Aventis respectively.

In July, EU trade commissioner Peter Mandelson wrote to Thailand's Minister of Commerce, Krirk-krai Jirapaet, saying that he was "concerned by recent indications that the Thai government may be taking a new approach to access to medicines".

In particular, he warned that "neither the TRIPs Agreement nor the Doha Declaration appear to justify a systematic policy of applying compulsory licences wherever medicines exceed certain prices".

A source close to the negotiations has told *MIP Week* that the Thai government has now introduced a three-step system for considering compulsory licences. First, an NHSO committee, chaired by Sang-guan Nittayaramphong, chooses drugs that have "problems with access" and sends them to a committee for price negotiations chaired by Siriwat Tiptaradol at the Food and Drug Administration.

If price negotiations fail, the issue is handed to a third committee chaired by Wichai Chokevivatana.

Sang-guan Nittayaramphong told English language newspaper *The Nation* that if the government issued compulsory licences for the four anti-cancer drugs it would enable doctors to use generic versions that are 40 times cheaper than the original.

In his letter to Krirk-krai Jirapaet, Mandelson said he was concerned that the Thai government had stated that if drug companies wish to do business in Thailand, they should offer their drugs for no more than 5% over the generic cost". Mandelson said that such a policy "would be detrimental to the patent system and so to innovation and the development of new medicines".

Mandelson also encouraged the Thai government to engage in direct negotiations with rights holders.

Médecines Sans Frontières and Oxfam International say that Mandelson's request that officials negotiate with drug companies "blatantly ignores public health safeguards incorporated into the WTO TRIPs agreement and reaffirmed in the Doha Declaration".

Some members of the European Parliament also criticized Mandelson's letter as being counter productive.

Both Krirkrai Jirapaet and Thailand's minister of public health, **Mongkol Na Songkhla**, replied to Mandelson. The Health Minister **explained** that the 5% system only applies to medicines already purchased under compulsory licences and is only to apply to patents on drugs under national health insurance schemes.

On September 10 Mandelson replied to the minsters, stating:

"The use of compulsory licensing is an exception to the rights conferred by a patent. It should be used in the spirit of the Doha Declaration and in the respect of the conditions of the TRIPs Agreement."

Ed Kelly, partner of Tilleke & Gibbins, which represents pharmaceutical company Merck, told *MIP Week*:

"His [Peter Mandelson's] position is, in view of the pharmaceutical research-based industries, helpful and consistent with the desire of the companies to forego conflict and bickering about legality and focus on the broader issue of access to medicines without recourse to compulsory licensing."

Last year the Thai government angered originator pharmaceutical companies when it issued a compulsory licence for Merck's antiretroviral drug efavirenz. The product is marketed by Bristol-Myers Squibb in the US and some European countries under the brand name Sustiva and in other countries – including Thailand – by Merck under the name Stocrin.

In January it issued two more compulsory licences for Kaletra, another AIDS drug produced by Abbott, and for Plavix, a blood-thinning medicine developed by Sanofi-Aventis and Bristol-Meyers Squibb to treat heart disease. Plavix was the world's second biggest-selling drug in 2005, with world-wide sales of $5.9 billion.

Merck is still negotiating with the Thai government over the price it charges for efavirenz, but a generic version is now being imported from India. No generic versions of Abbott's Kaletra have been imported so far.

In March, Sanofi-Aventis offered the government a "special access programme" to provide cheaper versions of Plavix. Negotiations are believed to be continuing, but the Government Pharmaceutical Organization has awarded a contract for two million pills of a generic version of Plavix to Indian drug company Emcure, despite a rival bid from Sanofi-Aventis.

On August 25 Sanofi Aventis threatened to sue Emcure for patent infringement if the pills are imported into Thailand.