THAILAND PHARMACEUTICAL UPDATE

Alan Adcock and Siraprapha K. Rungpry analyse the issues raised in Thailand by the imposition of recent compulsory licences on patented drugs

Thailand has quickly become the country to watch in the pharmaceutical field since the Thai Ministry of Public Health (MoPH) stepped in and issued compulsory licences on various key patented drugs. The attempts of the MoPH to intervene in the pharmaceutical market have attracted considerable attention from governments, stakeholders, and various interest groups and experts around the world. While the pharmaceutical regulatory system in Thailand operates independently of the IP system, interactions between the two systems are crucial to the existence of the pharmaceutical industry and directly affect the development of the healthcare system in Thailand.

The Thai pharmaceutical regulatory system is based on the Drug Act B.E. 2510 (1967) together with its four amendments, ministerial regulations and ministerial notifications. The fundamental basis of Thai drug regulation is that all activities in relation to the trading of pharmaceutical products must be licensed/approved by the competent authorities.

Conducting clinical trials in Thailand

In the last decade, Thailand started to see a large number of clinical trials of new drugs being carried out at hospitals, medical centres and research institutes nationwide. From a regulatory standpoint, it is surprising that the process of approving clinical trials has not yet been centralised. While drug regulation in centred at the Thai FDA, the FDA does not directly monitor clinical trials of drugs in humans. The FDA's role in this area is at most an

indirect one, through its authority to control the import of drugs into the country for research purposes. Government agencies that play a central role in regard of clinical trials include the Ethical Review Committee for Research in Human Subjects of the MoPH (ERC) and the Department of Medical Services.

Prior to launching a clinical trial in Thailand, a drug developer/sponsor needs to obtain approval from an ethics committee overseeing human research projects undertaken in an implementing institution. Approval must also be obtained from the ERC and from the ethics committee of the research institute or university that will conduct the trial. A protocol for the conduct of the clinical trial must be established and approved at the outset before approval can be obtained. The proposed protocol is sent to the Department of Medical Services within the MoPH for review and consultation.

Once a drug developer/sponsor receives approval from an ethics committee to conduct a study in humans, the developer/sponsor may proceed to request a licence from the FDA to import drugs into Thailand for research purposes.

Marketing approval for new drugs and generics approval

Before launching any drugs in Thailand, companies must obtain a licence to produce, sell or import pharmaceuticals into the country, as well as register their products for actual sales. The Thai FDA is the main agency in charge of drug approval and regulation. Generally, the procedure for seeking marketing approval for drugs will depend on whether the applicant is the drug originator or a generic producer. Drug originators face the most onerous task as each element of drug safety, efficacy and effectiveness must be demonstrated to the satisfaction of the Drug Control Division of the FDA.

Generic producers, on the other hand, receive more lenient treatment before the FDA. Such practice is partially due to the government's healthcare policy, which seeks to improve access to medicines and make affordable drugs available to all patients who need them. This policy seemed to have translated itself into an almost pro-generic policy before the Thai FDA. As in many countries, an abbreviated form of approval is available in Thailand for generic drugs. The generic applicant only needs to submit bioequivalence data as opposed to conducting rigorous trials and tests to prove safety and efficacy of the chemical entity or biological molecule. Currently, the Thai FDA does not require the generic applicant to reproduce clinical trials or preclinical tests.

Other than the leniency shown with regard to approval of generics, the MoPH has also taken various efforts towards making affordable drugs available for all. The most recent and perhaps most controversial attempt was the MoPH's decisions to issue compulsory licences on six key drugs that are still under patent in Thailand.

Compulsory licensing

During December 2006 to January 2007, Thailand's Ministry of Public Health, acting under a post-coup military-appointed administration, decided to issue the first set of compulsory licences on three patented drugs. The Health Minister at the time, Dr. Mongkol na Songkla, took a strong view against expensive patented drugs and believed that compulsory licensing was the solution to improving access to medicines for Thai patients. The three drugs that were subject to compulsory licences were Merck's antiretroviral efavirenz (Stocrin®), Abbott Laboratories' antiretroviral lopinavir/ritonavir (Kaletra®) and sanofi-aventis' heart disease drug clopidogrel (Plavix®). The legitimacy of these compulsory licences was debated extensively both at home and abroad. As a policy matter, it was widely questioned whether the actions of the Health Ministry would benefit Thai patients and help to improve the healthcare system and access to medicines in the long run.

From the legal perspective, the validity of the compulsory licences issued by the MoPH remains questionable. A careful reading of Section 51 of the Thai Patent Act and its reference to the procedures for issuance of compulsory licences under Section 50 would seem to suggest that the MoPH has not taken the appropriate steps required by law in seeking to impose compulsory licences on the patented drugs. This view, however, is not the prevalent view among Thai government authorities at present.

Despite the question as to the legitimacy of the first three compulsory licences issued by the MoPH, and the efforts of the industry to work with the Ministry to improve Thai patients' access to medicines and resolve compulsory licensing issues through collaboration and dialogue, the MoPH has insisted upon implementing the compulsory licences to import generic products into Thailand through the state-owned Government Pharmaceutical Organisation (GPO). In early 2008, Dr. Mongkol na Songkla signed a further announcement of compulsory licences on three cancer drugs right before the end of his term as the Health Minister. The new compulsory licences include the breast cancer drug *letrozole* produced by Novartis, the breast and lung cancer drug *docetaxel* made by sanofi-aventis, and the lung cancer drug *erlotinib* produced by Roche.

In view of the newly elected government, it is yet to be seen whether the compulsory licence policy will be continued or whether the new administration will adopt a less drastic measure to solve the problem of access to medicines.

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