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Thailand Food and Drug Administration Unveils New Official Fees

Higher life expectancy, a growing middle-income population, and the government's policy of promoting access to medicine are key drivers boosting demand for healthcare-related businesses in Thailand. In 2015, healthcare expenditures accounted for 4.6 percent of Thailand's GDP, and there is an increasing trend in government budgetary spending in healthcare. Due to these factors, the healthcare market is experiencing strong growth, bringing opportunities in cosmetics, health supplements, medical devices, and pharmaceuticals.

Nonetheless, a major obstacle for these industries is the slow-moving registration process of the Thai Food and Drug Administration (FDA). This registration process is a mandatory prerequisite for introducing new healthcare products to the Thai market.

There are currently thousands of drug registration dossiers under evaluation by the FDA that have been stalled under successive governments. A similar backlog has been found in the process to obtain licenses for moderate- to high-risk medical devices, novel foods, food supplements, and innovative herbal products.

The backlog of pending product approvals hinders industries from competing effectively in the market, and it impacts companies eager to launch their new products in a timely manner. More importantly, from a consumer standpoint, the slow approval process prevents Thais from being able to buy products at lower competitive prices and restricts access to the latest innovative drugs.

Delays in the approval process stem from the fact that the FDA lacks sufficient qualified officers to examine technical dossiers to assess the quality, efficacy, and safety of products. The FDA has difficulty in hiring qualified experts, and there are not enough specialists to handle the ever-increasing number of application dossiers.

Reforming the FDA Approval Process

In order to solve this backlog issue, the prime minister has exercised his power as head of the National Council for Peace and Order (NCPO) by using section 44 of the 2014 interim constitution to issue NCPO Order No. 77/2559 Re: Increasing the Efficiency of the Health Products Approval Process, which was published in the *Government Gazette* on December 28, 2016. The order directs that the FDA approval process for healthcare products must be reformed. The main implications of the order include the following:

- The FDA's product approval timeline must not exceed the time specified in its public manuals, which are handbooks that inform the public about the application procedures, relevant legislation, timelines, and list of documents needed for product registration at the FDA.
- The FDA will consider the official fee schedule in its approval process. Official fees earned by the FDA will be used as honorariums for reviewers/experts to assess technical dossiers, as well as to improve the approval procedure, as per regulations of the Ministry of Finance. Unlike in the past, official fees earned by the FDA will not be refunded to the Ministry of Finance as government revenue.
- The FDA will outsource some work, such as onsite inspections and evaluations of technical documents, to external experts of local or overseas agencies, who have been approved by and registered with the FDA.

New FDA Official Fees

The FDA engaged in over 10 meetings with major pharmaceutical companies to discuss the overhaul of its approval process and official fee schedule. Subsequently, the Ministry of Public Health (MoPH) issued MoPH Notification Re: Actual Official Fees in the Approval Process to Be Paid by the Applicant on August 4, 2017. The notification prescribes the highest rates of official fees and actual fees to be paid by applicants, with the highest rates to remain effective for 10 years, and revisions by the FDA allowed in five years.

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In the past, the FDA approval process charged only one fee for obtaining a license. The new official fee schedule introduced by the MoPH notification itemizes fees to be incurred for each step of the application process, from filing the application, to dossier evaluation, to obtaining a license.

As of August 4, 2017, an applicant now pays THB 2,500 for filing an application, THB 182,500 for dossier evaluation, and THB 2,000 for obtaining the Marketing Authorization (MA) Drug Product License for a new chemical drug. The MoPH notification also prescribes fees covering the lifecycle of a drug product, including fees for an importation/manufacturing license, a sales license, an advertisement approval license, variations of these licenses, etc. More interestingly, the FDA now charges an hourly consultation fee of THB 500–2,000, depending on the consultation matter.

Healthcare business operators should closely monitor the registration and approval process reforms of the Thai FDA. Although the FDA's official fees have increased substantially, product owners hoping to bring their new products to the Thai market are likely to benefit greatly from the invigorated registration process that promises drug product approval in a more timely and systematic manner.