

# EXPEDITING PRODUCT REGISTRATION AT THE THAI FDA

A wide variety of products need to be registered at the Thai Food and Drug Administration (FDA) before they can be marketed in Thailand. These products range from food, food supplements, beverages and medical devices to animal health products, cosmetics, hazardous substances and all types of pharmaceuticals. Due to the large number of product applications that are filed at the Thai FDA and the stringency of registration requirements, registration timelines — particularly for pharmaceutical products — can be very long.

Whereas cosmetic products can usually be registered at the Thai FDA in one day, general medical devices in one week, and food supplements in three to four months, the registration timelines for pharmaceutical products may require much more time. Registration timelines for generic drug products can range from six months to one year. New generics require about one year. New drugs may take one to one-and-a-half years, and biological drug products sometimes require as long as two or more years to achieve registration.

Of course, these extended timelines often raise significant concerns among companies that have filed applications, as these companies cannot market their products in Thailand until Thai FDA registration licences have been received. What services can be provided at the Thai FDA to expedite receipt of registration licences? Three key elements that will contribute to an expedited registration process are document review, regular follow-up, and the guidance of experienced counsel. This article will examine each of these elements in order to give companies a head start on securing the timely registration of their products.

**Document review:** Experience has indicated that a substantial amount of the delay in the registration process is due to the filing at the Thai FDA of incomplete registration applications. This problem is particularly acute for pharmaceutical products because of the complexity of the supporting documents that are required by the Thai FDA. Frequently, the registration dossiers that are filed do not include all of the documents required for the specific class of product. As a result, when Thai FDA officers review the application, they ask questions relating to the missing documents. The review of the application is usually suspended until a reply is received. It is important to ensure that the application filed with the Thai FDA includes all of the documents required



by the product classification.

The principal service that can be provided at the Thai FDA to reduce or eliminate questions that delay the registration process is to make certain before the registration application is filed that all required documents are included. A thorough document review by lawyers and pharmacists or other technical experts who are familiar with Thai FDA requirements prior to filing the registration application can reduce months from the registration timeline.

**Regular follow-up:** The second service that must be provided in order to expedite the receipt from the Thai FDA of registration licences is to follow up the applications at the Thai FDA on a regular basis until registration licences have been obtained. Because the Thai FDA is inundated with work, making the effort to follow up in person reminds them to prioritise the application. If an application is filed at the Thai FDA with no follow-ups, it is likely that the registration process will be delayed due to the large volume of other applications. Therefore, it is important to conduct regular progress report checks to ensure that Thai FDA officers are fully aware of the need to expedite the review of the application.

**Experienced counsel:** Finally, companies that plan to file registration applications at the Thai FDA should look for a product registration counsel that has a proven track record of success and has been in business long enough to develop a tried and tested relationship with the Thai FDA. Counsel should also have a client base that has enabled it to develop in-depth regulatory and required industry knowledge. In addition, it should have a multidisciplinary staff of lawyers and pharmacists or scientists with the technical knowledge required to register pharmaceutical products and large enough to prepare, file and follow up all product applications. Thai FDA registration licences will then be obtained in the shortest possible time, which is key to serving the commercial interests of the applicant.

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