Atthachai Homhuan
Senior Consultant
atthachai.h@tilleke.com

Pharmaceutical Product Recall: New FDA Requirements

Medicine is an integral part of our lives, helping us to recover from illness and allowing us to live a longer and healthier life. However, the great benefits derived from medicine are also accompanied by a great many risks, which may be derived from the properties of the drug substance, the quality of the medicine, or in some cases, the defectiveness of the drug product itself.

A product recall is required when safety issues arise, and the defective products are required to be returned to the manufacturer or distributor. Drug recalls can be extremely costly and can damage consumer confidence in the product or company, so naturally all companies try their utmost to avoid such a scenario.

Recalls can be initiated either voluntarily or at the request of the Thai Food and Drug Administration (FDA). A recall usually results from some combination of a discovery by the manufacturer, customer complaints, or FDA observation.

Discoveries by the Manufacturer

A recall that is initiated by a manufacturer may be based on corporate conscience (or corporate social responsibility), in order to ensure compliance with the essential elements of the law, ethical standards, and business norms. Such recalls may also be designed to limit liability for corporate negligence, which can result in huge amounts of legal penalties, and can also represent an attempt to minimize damage to corporate image.

Recalls are costly to a company, because they often entail replacing the recalled product or paying for damage caused by use of the product, although this is possibly less costly than the costs that might otherwise be caused by damage to the brand name and diminished trust in the manufacturer.

Last year, a multinational company discovered, through its own routine testing program, a microbial contamination in its mouthwash product. Because the microorganism could cause adverse effects in people with weakened immune systems, the company voluntarily removed its product from all market shelves in Thailand.

Customer Complaints

People generally do not ask sufficient questions when they lack knowledge about a subject, including medication. Some people think that new medicines are more effective or safer, but this may not necessarily be true.

As a safeguard measure, the Thai FDA has implemented a Safety Monitoring Program (SMP), in which healthcare providers are requested to collect, evaluate, and study drug safety information in a proactive manner. This process relies on consumers or medical practitioners first identifying an abnormality and reporting it to the FDA and the company, which will in turn evaluate the complaint. This post-marketing surveillance system is gaining increasing importance, as it facilitates the Thai FDA's handling of drug safety information, and enables them to take any necessary measures promptly.

FDA Observation

Drug product recalls can also be necessitated as a result of an observation made by the FDA during an inspection. Samples of marketed products are regularly tested in the analysis laboratory at the Ministry of Public Health. Significant compliance deficiencies that are noted by the FDA can result in a company having to recall some, or all, of its drug lots.

For example, the Thai FDA recently found the adulteration of methyl alcohol—a toxic impurity—in traditional medicine, which led to two batches of these drug products being recalled and an announcement of the violation and the manufacturer's name by the FDA.

The Thai FDA has also demanded the product recall of cold remedies containing pseudoephedrine (PSE), which has been used as a precursor of methamphetamine, referred to locally as *yaa baa*.

On April 3, 2012, the Ministry of Public Health distributed a Notification stating that remedies containing PSE are type 2 psychotropic substances, and thus people cannot possess more than 5 grams of PSE.

To avoid being penalized, pharmacies that sell medicines containing PSE have been given 30 days to return the drug products to the manufacturers or distributors. Violations will incur a fine of between THB 100,000 and THB 400,000 (approximately USD 3,415 to USD 13,650), and a jail term of between 5 and 20 years.

New Requirements of the Thai FDA

Last year, a Ministerial Notification from the Ministry of Public Health announced a new Good Manufacturing Practice (GMP), which emphasizes that manufacturers must have in place a prompt and effective system to facilitate drug product recalls.

The importer or distributor should have a person who is responsible for assessing risks and coordinating product recalls with the FDA.

If there are grounds to justify the health assessment risks, the company must submit the recall submission document, which contains all the details required to enable the FDA to evaluate the product failure, assess how the failure will affect consumer safety, and formulate an adequate course of action.

This plan must include the product details, a description of the problem, distribution information, a health-hazard assessment, and the proposed recall strategy. Maintaining detailed and accurate records is absolutely critical, and indeed this can be the most important aspect in conducting the product recall.

The Thai FDA has outlined the form that the importer or distributor must fill out and submit to the FDA on completion. In addition, the Thai FDA announced on February 16, 2012, that all applicants must submit the "Recall Commitment" document, together with the drug product registration documents. Failure to comply will result in the rejection of the registration dossier, as it will be deemed to be incomplete.

In summary, recent amendments in the Ministerial Notifications have helped to advance voluntary product recalls by business operators, so that such actions are more compulsory. This, in turn, will provide supplementary assistance to government agencies and enable them to pinpoint issues and identify potentially harmful drug products more promptly and effectively, thus offering consumers a greater degree of protection.