Baker McKenzie.

CLINICAL TRIALS HANDBOOK
Asia Pacific

THAILAND

Thailand

Peerapan Tungsuwan | Praween Chantanakomes

Introduction

The Food and Drug Administration (**FDA**) is the regulator of clinical trials in Thailand.

Regulatory framework

Thailand has no specific laws or regulations governing clinical trials. There are, however, regulations pertaining to drugs that are imported for the purpose of conducting clinical trials. Under the Drug Act B.E. 2510 (A.D. 1967), drug importers are required to obtain an import license and undergo product registration. Notification of the Ministry of Public Health (No. 14) B.E. 2532 (1989) ("**Notification**") stipulates, however, that drugs imported for the purpose of clinical trials are exempted from the obligation to undergo product registration. The Notification also authorizes the FDA to issue notifications to outline additional conditions or requirements related to drugs that are imported for the purpose of conducting clinical trials.

In light of the above, the FDA recently issued a new notification ("**Clinical Trial Notification**") stipulating that imported clinical trial drugs can only be used for such clinical trial in accordance with the Clinical Trial Protocol (**CTP**) that has been approved by the FDA. The Clinical Trial Notification stipulates that the clinical trial process may only start once approval has been obtained from the Ethics Committees (**ECs**) that have been approved by the FDA, and the FDA has approved the importation of such clinical trial drugs.

The Clinical Trial Notification further stipulates that drugs that are imported for use in conducting clinical trials must have been manufactured in accordance with Good Manufacturing Practice. Additionally, the clinical trial must be conducted in accordance with Good Clinical Practice (**GCP**) and the Principles of Good Laboratory Practice (**GLP**).

Given the above, it should also be noted that the FDA has issued a separate notification regarding the criteria and conditions for approving the ECs ("**EC Notification**"). Under the EC Notification, ECs wishing to be able to oversee clinical trials in Thailand must obtain approval from the FDA. Moreover, the EC Notification stipulates that the ECs are responsible for ensuring that the clinical trials conducted under their supervision follow the guidelines of the International Conference on Harmonization – Good Clinical Practice (**ICH–GCP**).

As for clinical trials using drugs that have been manufactured in Thailand, such clinical trials are also required to be conducted under the supervision of the EC belonging to the institution that conducts the trials, as required by the Medical Council of Thailand.

To summarize, while there are no regulations governing clinical trials, researchers who wish to import drugs into Thailand for the purpose of conducting clinical trials must submit their CTP to the EC of the institution conducting the trials. Once they have obtained approval from the EC, they may then submit the relevant documents to obtain approval from the FDA to import such drugs. The clinical trials must be conducted in accordance with the guidelines of the ICH–GCP (including the GCP and the GLP), under the supervision of the approving EC. Clinical trials using drugs manufactured in Thailand must also be conducted under the supervision of the EC of the institution conducting the trials.

The above does not change for trials involving molecule-based Investigative Medical Products (**IMPs**) or study drugs and biologically based IMPs.

Clinical trial agreements (CTAs)

There are no requirements governing CTAs under Thai law.

However, CTAs should comply with the ICH GCP (including the GCP and the GLP) guidelines.

Any CTA will, therefore, depend on the agreement of the relevant parties. Most CTAs are tri-party agreements involving the sponsor, the investigator and the institution where the research is to be conducted, as most investigators in Thailand do not have their own facilities or equipment. These agreements generally indicate that the institution where the research is to be conducted permits the investigators to use the facilities and equipment for the purpose of conducting the clinical trial.

The insurance clauses under CTAs are normally 'all-risk' insurance, borne by the sponsor. The sponsor is usually requested to indemnify the investigator and its staff from damages arising from the clinical trial, except for damages arising from malpractice or acts of gross negligence by the investigator or its staff.

There are no additional requirements placed upon different trial phases.

Sponsor and contract research organizations (CROs)

There are no specific legal requirements governing sponsors of clinical trials in Thailand, except where the sponsor is the importer of the clinical trial drugs itself. The sponsors should, therefore, follow the principles of the ICH–GCP (including the GCP and the GLP) guidelines with regard to their responsibilities. This includes the responsibility to inform the investigator, the EC and the FDA of any information that may adversely affect the safety of the volunteers or affect the research, as well as report any adverse effects of the drugs.

In the event that the sponsor is the importer of the clinical trial drugs and has obtained approval from the FDA to do so, the Clinical Trial Notification also stipulates that the importer shall follow the procedures for reporting adverse events that may arise from the clinical trial drugs. Furthermore, it shall prepare and submit to the FDA a progress report annually, as well as a final report upon the completion of the clinical trial process within 60 days from the date of completion at the last trial location in Thailand.

The sponsors of clinical trials in Thailand are not required to be located in the Kingdom or the region, and may be represented by a local representative. The representative's responsibilities are determined by the authority given to it by the sponsor.

The responsibilities of the sponsor may even be partly or wholly delegated to a CRO. However, the ultimate responsibility for the quality and credibility of the information obtained from the research will always fall on the sponsor. There are no specific legal requirements to govern the choice or appointment of CROs. The ICH–GCP (including the GCP and the GLP) guidelines, however, should be considered.

As noted above, the FDA also now has the authority to review the clinical trial process and obtain reports according to the authority granted to it under the Clinical Trial Notification.

Investigator

There are no specific legal requirements governing investigators of clinical trials in Thailand. The investigators should follow the principles of the ICH–GCP (including the GCP and the GLP) guidelines with regard to their responsibilities. The important aspects of these responsibilities are liaising with the EC and compiling and maintaining research reports.

Study drugs

There are no specific legal requirements governing study drugs in Thailand.

Intellectual property (IP) and data

The intellectual property rights of the data obtained from the clinical trial belong to the sponsor, unless the parties involved agree otherwise.

Baker McKenzie helps clients overcome the challenges of competing in the global economy.

We solve complex legal problems across borders and practice areas. Our unique culture, developed over 65 years, enables our 13,000 people to understand local markets and navigate multiple jurisdictions, working together as trusted colleagues and friends to instill confidence in our clients.

www.bakermckenzie.com