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Announcement from the Ministry of Public Health.

Regarding the principles, methods, and conditions for conducting drug research to gather information for drug registration.
2023

For the benefit of promoting, supporting, and developing effective drug research, as well as protecting the safety of volunteers, the public, and the environment, due to...
The process or steps involved in drug research, which is a crucial process in gathering evidence.
The process of proving the safety and efficacy for drug registration includes, regardless of...
Drug research studies conducted exclusively in Thailand, or conducted simultaneously with other countries, or utilizing data...
Research studies on drugs from other countries are used as evidence to support drug registration in Thailand.
This information is reliable and comes from drug research that adheres to standard human clinical trials.

Pursuant to the powers under Section 77 Quater, Paragraph One and Section 77 Quint of the Drug Act B.E. 2510 as amended by the Drug Act (No. 6) B.E. 2562, Section 78 of the Drug Act B.E. 2510 and Section 79 Bis (4) of the Drug Act B.E. 2510 as amended by the Drug Act (No. 5) B.E. 2530, the Minister

The Ministry of Public Health, with the approval of the Drug Committee at its 410th meeting -4/2565 on September 12, 2022, hereby issues the following announcement:

Point 1 This announcement shall come into effect three hundred and sixty-five days after the date of its announcement.

From the publication in the Royal Gazette onwards.

Clause 2 of this announcement.

"Drug research" means the study of drugs in humans conducted to obtain data for use.
This serves as supporting evidence for drug registration, including the amendment of information in the drug registration document.
For cases requiring data from human drug

research studies, "drug researcher" means a supporter of drug research or a researcher who conducts the research.
Drug research in Thailand.

“Supporter of pharmaceutical research” means a Thai national, or a legal entity.
Registered in Thailand, government agencies, state enterprises, public organizations, and other government entities responsible for initiating, managing, or financing drug research and development.

“Researcher” means a person responsible for conducting drug research at a research site. If the research is conducted by a team of several people, the researcher in charge, who is the team leader, is called the “principal investigator,” and other members of the research team are called “secondary investigators.”

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"Good Clinical Research Practice Standards" means the international standards for planning…

Format, operation, practice, supervision, inspection, recording, analysis, and

Clinical research reporting ensures that both the data and the results reported are reliable and accurate, and that the rights, safety, well-being, and confidentiality of volunteers are protected. "Research drug" means a pharmaceutical product, either the active ingredient or a placebo,

used in testing or as a control in a research study. This includes pharmaceutical products that have been registered but have been used or altered in their formulation, or are packaged in a different form than that authorized, or used in a way that is not permitted.

For new indications that are not yet permitted, or to gather more information from permitted indications.

"Secretary-General" means the Secretary-General of the Food and Drug Administration.

Clause 3 requires that drug research be conducted exclusively in Thailand, or concurrently with other countries, or conducted abroad only, in order to provide data for registration purposes.

The prescription complies with Good Clinical Practice (GCP) standards for clinical research.

The latest edition of the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH).

Clause 4 requires drug researchers to conduct drug research in research facilities that meet standards.

The latest version of Good Clinical Practice (according to the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH)) and...

Additional standards as prescribed by the Secretary-General and published in the Royal Gazette.

Article 5 stipulates that the person sponsoring the drug research shall submit the application for permission to conduct the drug research to the Secretary-General.

Along with the information, documents, or evidence as specified by the Secretary-General and published in the Royal Gazette.

The Secretary-General shall have the authority to authorize drug research studies as specified in the first paragraph, and the authorization shall be for a period of five years.

From the date of authorization, unless the drug research study is completed before five years, in which case the authorization expires.

Upon completion of the period specified in paragraph two, if the research study is not yet finished, or if necessary, the permit may be extended as appropriate, but not exceeding five years.

Article 6 stipulates that the sponsor of drug research has the duty to procure, manufacture, administer, or order research drugs.

Or, the drugs used in the research are from manufacturers that meet the standards set forth in the Ministry of Public Health's regulations regarding the criteria, methods, and conditions for the production of modern medicines.

Article 7. In cases of urgent necessity for the public interest, the Secretary-General may grant an exemption.

When submitting certain documents, consideration may be given to submitting additional supporting information or documents as necessary to support the approval process.

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Article 8. The Secretary may require drug researchers to perform, refrain from performing, have duties, or accept certain responsibilities to protect the safety of volunteers.

And in order to meet the drug research standards as per point 4.

Article 9. The Food and Drug Administration shall consider monitoring drug research studies or taking appropriate measures during the period before or during drug research studies.

Conducting drug research studies, or following the completion of drug research studies, is essential to protect the safety of volunteers and the drug research data submitted for drug registration, ensuring compliance with good clinical research practices standards.

(Good Clinical Practice of the International Council for Harmonization of Technical

The latest version of the Requirements for Pharmaceuticals for Human Use (ICH).

In the process of evaluating drug registration applications, the Food and Drug Administration (FDA) shall...

Furthermore, consideration may be given to conducting oversight of drug research studies abroad, if necessary, to be used in evaluating drug registration applications in Thailand. The licensed drug manufacturer or the licensed importer or distributor of drugs into the Kingdom will be responsible for the costs.

Point 10. When it is found that the drug researcher has not complied with this announcement, the Secretary has the power to order the drug researcher to improve the drug research study, or temporarily suspend the drug research study, or cancel or stop the drug research study in the following cases:

(1) There is a serious impact on the volunteers or on the reliability of the data as a result of

(2) The drug research study is not conducted in accordance with the request and permission from the Food and Drug Administration (FDA). (3) The data obtained from the drug research study is of poor quality or unreliable. (4) The drug researchers do not comply with the requirements of the Secretary issued under this announcement.

Article 11 requires the sponsor of the drug research to prepare and submit progress reports.

Drug research studies, reporting of adverse drug reactions, and reports on drug research studies in Thailand.

The term ends as determined by the Secretary-General and announced in the Royal Gazette.

Article 12. The Secretary-General shall be responsible for the implementation of this announcement, including having the authority to make decisions in cases of disputes arising from it.

Actions taken in accordance with this announcement.

Announced on January 6, 2023.

Sathit Pitutecha

The Deputy Minister of Public Health is acting on behalf of the Minister.

Minister of Public Health