

## SAFETY MEASURES FOR MEDICINAL PRODUCTS\*

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### **Abstract**

This article explores the problems on safety measures for medicinal products in Thailand, which is a major problem in Thailand because there are plenty of defective medicinal products causing injuries to consumers in Thailand. The existing safety measures for medicinal products, in practice, are ineffective to protect the consumer from unsafe products and lead to the continuously raising of defective medicinal products on the market.

This article applies a comparative study to examine how other countries i.e. the European Union, the United States, and Singapore solve the problem. Therefore, this article explores the provisions regarding safety measures for medicinal products of the EU Directive 2001/83/EC, the US Code of Federal Regulations (CFR), and the Singapore Health Products (Therapeutic Products) Regulations 2016 in order to find a recommendation for Thailand.

From the comparative study, this article proposes that the provisions concerning safety measures for medicinal products under Thai Drug Act of B.E.2510 (1967) (as amended in 2019), the validity of drug registration, re-evaluation measure before distribution, monitoring, and safety alert on dangerous medicinal products should be amended.

**Keywords:** Medicinal Products, Safety Measures, Product Safety Law

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## 1. Introduction

Medicinal products are substances intended for use in the diagnosis, cure, or prevention of human or animal disease.<sup>1</sup> However, this article only focuses on medicinal products designed for use in humans, not include animals. Unlike other general products, medicinal products are considered as unavoidably unsafe products because they have particular characteristics and even appropriately administered, their side effects may be harmful to the consumer, so it is important to prevent the occurrence of adverse effects and guarantee safety of medicinal products.

There is legislation governing safety measures for medicinal products that are applied in the European Union,<sup>2</sup> the United States,<sup>3</sup> and Singapore<sup>4</sup> where there are distinctive legal approaches in resolving medicinal product problems. These safety measures for medicinal products cover in all parts of the medicinal product's lifecycle, initiate from the manufacturing, clinical trial, marketing authorization, distribution, to pharmacovigilance. The main goal is to support medicinal products to meet three criteria of quality, safety, and efficacy.<sup>5</sup>

Thailand has legal protection both general and specific for product safety. Consumer Protection Act of B.E. 2522 is the general product safety law that protects the fundamental rights of consumers in general and only applies to the general consuming products.<sup>6</sup> Meanwhile, the drug is the special product governed by other laws, namely Drug Act of B.E. 2510 (1967)

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<sup>1</sup> Drug Act of B.E.2510 (1967) (as amended in 2019) s 4.

<sup>2</sup> Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use.

<sup>3</sup> Code of Federal Regulations (CFR).

<sup>4</sup> Health Products (Therapeutic Products) Regulations 2016.

<sup>5</sup> Nuala Calnan, 'Overview of the recent FDA Process Validation Guidance for Medicinal Product Development and Manufacture' (PDA Ireland Symposium: Embracing the Challenges of Lifecycle Based Validation, 7 June 2013).

<sup>6</sup> Susom Supanit, *Commentary on Consumer Protection Laws* (8th edn, Chulalongkorn University 2014).

(as amended in 2019) – Thai Drug Act, which shall apply the Consumer Protection Act as long as it does not contrary to such provision. Although the Thai Drug Act imposes safety measures for drug in several aspects of registration, labelling, advertising, monitoring, and enforcement, the problems relevant to the drug are continuously raised because current safety measures are not comprehensive and effective as preventive measures to protect the consumer and prevent the injuries from a defective drug.

## **2. Development of safety measures for medicinal products**

In Thailand, the private law imposes product liability as a remedial measure, but it does not prevent dangerous products from being placed on the market, so defective medicinal products are continuously rising. Besides, the development of establishing safety measures for medicinal products has the characteristic to enacts the public law to dominate the private law and cannot set up preventive measures. Therefore, there is a need for establishing preventive measures to protect consumer. To understand the necessity and importance of preventive measures for medicinal products, this part explores the development of safety measures for medicinal products by explaining and comparing product liability on medicinal products with medicinal products safety.

### **2.1 Product liability on medicinal products**

It is essential that when a product causes damage to consumers, preventive measures are proceeded to prevent or avoid such products be available in the market. However, the private law enforced at that time mainly focuses only on correcting harm and injuries that occurred and providing compensation. Private law only addresses the problem and compensates after the injury occurred. Besides, private law does not directly prevent harmful products to market circulation and to prevent damage from occurring.

Meanwhile, the safety of the products is the essential goal of product safety measures to protect the consumer. Hence, product safety systems are designed as a preventive measure to protect unsafe products from accessing the market or the consumer. It is insufficient for preventing injury even though producers design, manufacture and sell products by intended to be safe. The method of use may also affect the safety of the product.

Therefore, there is a need for preventive measures relevant to certain controls to protect the consumer, which prevents dangerous products from reaching the market, along with providing post-marketing measures such as monitoring and surveillance.

## **2.2 Medicinal products safety**

Product safety laws are preventive measures taking unsafe products away from the markets. In the case of medicinal products which fall within specific guidelines to qualify as an “unavoidably unsafe products” because although a product is cautiously designed, produced, and marketed, it is still hazardous. Moreover, the use of medicinal products associated with some injuries because they are hazardous products and have a pharmacological effect.<sup>7</sup> The higher risk, the more serious action should be taken, particularly medicinal products are more complex and must have the appropriate and effective measures to guarantee the safety of the medicinal products.

Consequently, medicinal product safety was considered to separate from the general product safety and have an explicit requirement that is covered by specific legislation, namely medicinal product safety provisions. Furthermore, the safety evaluation of the products is taken at pre-marketing stage is merely provisional and must be continuously reassessed throughout

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<sup>7</sup> Natthaphon Chaichatchawan, ‘Kotmai Waduay Khwamplotphai Khong Sinkha [Product Safety Law]’ (Masters of Laws Thesis, Thammasat University 2013) (ณัฐพร ชัยชัชวาล, ‘กฎหมายว่าด้วยความปลอดภัยของสินค้า’ (วิทยานิพนธ์ปริญญาโทนิติศาสตร์, มหาวิทยาลัยธรรมศาสตร์ 2556)).

the lifetime of marketing the product. For the entire duration of medicinal products' lifetime, continued safety surveillance is required to discover adverse reactions, to constantly reassess the safety profile through a re-assessment of benefit-risk ratio of the product, and to attempt to quantify the risk to the patient.

### **3. Analysis of safety measures for medicinal products**

This part analyzes the problems on safety measures for medicinal products in Thailand. The analysis is based on the comparative study of the law of the European Union, the United States, and Singapore to explore effective safety measures for medicinal products in Thailand. From the study of Thai Drug Act concerning safety measures for medicinal products, there are problems on product safety measures for medicinal products as follow:

#### **3.1 The inappropriateness of safety measures relevant to the renewal of the marketing authorization**

##### **3.1.1 The flaw of the validity of drug registration**

The Thai Drug Act regulates that “The drug registration certificate will be valid for seven years from the date of issue.”<sup>8</sup> This demonstrates that the period of the validity of drug registration is too long. As a result, the assessment of medicinal products at the time of application for renewal of drug registration will be delayed. Besides, there is no evaluation of medicinal products to identify defects, reassess the safety, and recheck whether a product placed on the market is safe. Therefore, a long period of validity of drug registration shall increase the risk of defective products in the market circulation and the consumer may be harmed before the assessment is performed.

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<sup>8</sup> Drug Act of B.E.2510 (as amended in 2019) s 86/2 para 1.

Meanwhile, the EU regulates the validity of a marketing authorization for five years, which is an appropriate period to reassess products after launching to the market because if the period is too short, it will increase the burden to authority or responsible person to assess products frequently. By taking the EU as a model law, Thai Drug Act should be revised by amending the period of validity of drug registration from seven years to five years from the date of issue.<sup>9</sup>

Therefore, the author recommends that Section 86/2 paragraph 1 should be amended as “The drug registration certificate will be valid for five years from the date of issue. In the event where there is a reason to suspect the danger of medicinal products, competent authorities have the power to prescribe a period of the validity of drug registration shorter than five years from the date of issue.”

### **3.1.2 The absence of the review of drug formula upon the renewal application**

In the process of application for renewal of the marketing authorization, Thai Drug Act regulates that “The renewal of drug registration certificate shall conform to the Ministerial Regulation and such Ministerial Regulation may be prescribing the review of drug formulas.”<sup>10</sup> This demonstrates that Ministerial Regulation may prescribe the application for the renewal of the marketing authorization without the review of drug formulas, so there is no certainty to review drug formulas because the review of drug formulas depends on whether the Ministerial Regulation prescribes to perform. As a result, information relevant to medicinal products shall not be updated as it should be, and it will increase the risk of injuries from unsafe medicinal products on the market.

However, the drug formulas should be monitored and revised periodically to ensure maintaining the quality of medicinal products.

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<sup>9</sup> Christopher Hodge, *European Regulation of Consumer Product Safety* (OUP 2005).

<sup>10</sup> Drug Act of B.E.2510 (as amended in 2019) s 86/2 para 5.

Likewise, the EU and the U.S. both require the revision of the drug formulas periodically to update the information relevant to medicinal products and ensure the quality of medicinal products. Therefore, the author recommends that Section 86/2 paragraph 5 should be amended by adding “The renewal of drug registration certificate shall be compliance with the rule, conditions, and procedures prescribed in the Ministerial Regulation. Before the renewal of marketing authorization, the drug formula must be reviewed.”

### **3.2 An absence of safety measures before distribution**

After the authorization process, whether the manufacturing of medicinal products complies with the authorized specification is unknown. Medicinal products change hands many times between the manufacturer and consumer; so there is a risk of medicinal products to become dangerous in every transaction. Moreover, the danger of medicinal products may not occur at the time of authorization but may present inherent risks after the first testing or clinical trials. Thus, the way risks will be minimized once medicinal products are reassessed before distribution. The purpose of the re-evaluation of medicinal products is to confirm and discover the side-effects of the tested medicinal products in order to prove their safety or efficacy in human use.

Thai Drug Act does not regulate the provision regarding the repeated testing of medicinal products before distribution. Meanwhile, the U.S. establishes the release testing to test medicinal products before distribution and ensure the compliance of medicinal products with their granted specification.<sup>11</sup> Therefore, by taking the U.S. as a model law, Thai Drug Act should be amended by adding the provision regarding the re-evaluation measure for approved medicinal products. Furthermore, the licensee should

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<sup>11</sup> U.S. Food and Drug Administration, ‘The FDA’s Drug Review Process: Ensuring Drugs Are Safe and Effective’ (FDA, 24 November 2017) <<https://www.fda.gov/drugs/drug-information-consumers/fdas-drug-review-process-ensuring-drugs-are-safe-and-effective>> accessed 10 July 2019.

be responsible for submitting a benefit-risk evaluation report to the Food and Drug Administration – FDA, before releasing medicinal products to the market.

Therefore, the author recommends that Thai Drug Act should be amended by adding Section 26/1 “Before distribution of medicinal products, licensee to sell must submit a benefit-risk evaluation report to the Food and Drug Administration.”

### **3.3 An absence of monitoring measures by the licensee**

Although Thai Drug Act prescribes the rules for monitoring obligations to supervise medicinal products, the Act only empowers the competent authorities to monitor drug and enter the premises for the production, sale, importation or storage of drug, take reasonable quantities of drug as samples for testing or analysis, size or attach drug and equipment concerned with offense.<sup>12</sup> Meanwhile, the licensees and all persons involved such products are liable to provide reasonable facilities when the competent authorities perform their duties.<sup>13</sup>

Furthermore, in the case that the competent officials know that any drug may be dangerous to the consumers, the competent authorities are authorized to recall dangerous products and to order licensee to produce, sell, or import to recall their products from the market<sup>14</sup> and sent to the FDA within 15 days if the product has been found to cause serious health problems or within 30 days if the product is suspected of causing severe

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<sup>12</sup> Drug Act of B.E.2510 (as amended in 2019) s 91(1)-(4).

<sup>13</sup> *ibid*, s 91 para 2.

<sup>14</sup> *ibid*, s 91(5).

health problems.<sup>15</sup> Besides, the competent authorities are empowered to destroy such products.<sup>16</sup>

These provisions under Thai Drug Act as mentioned above demonstrate that there is an absence of monitoring measures by the licensee because the Thai Drug Act does not require the licensee to recall suspected dangerous products from the market. Besides, the existing rules do not provide adequate protection against defective medicinal products. Meanwhile, the EU and Singapore require the licensee to provide information relevant to their products, collect the sample of the product for conducting quality testing, and periodical report an assessment of the risk-benefit balance in order to reduce the risk of dangerous product and assure the quality of products placed on the market.<sup>17</sup> Therefore, by taking the EU and Singapore as a model law, Thai Drug Act should be amended by adding the provision regarding monitoring obligation for the licensee to monitor their medicinal products placed on the market by sampling and reporting the result of sampling to the competent authorities every year. The reporting must contain the sampling of medicinal products with the minimum information covering the name of the product, dosage form, indications, an adverse effect, place, and date of practice, and the result of sampling. In the case of danger, the licensee shall voluntarily recall defective medicinal products or ordered by competent authorities to

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<sup>15</sup> Kod Krasuang Chabub Tee 20 (Por Sor 2525) Ork Tarm Kwam Nai Pra Ratchabunyat Ya Por Sor 2510 [Ministerial Regulation No. 20 B.E. 2525 (1982) Issued under the Provisions of Drug Act B.E.2510 (1967)] (กฎกระทรวง ฉบับที่ 20 (พ.ศ. 2525) ออกตามความในพระราชบัญญัติยา พ.ศ. 2510).

<sup>16</sup> Sutthinee Borisuttham, 'Mattrakan Riekkheun Sinkha Pheua Kan Khumkhong Phuboriphok [The Consumer Protection : Product Recall]' (Master of Laws Thesis, Thammasat University 2011) (สุทธิณี บริสุทธิ์ธรรม, 'มาตรการเรียกคืนสินค้าเพื่อการคุ้มครองผู้บริโภค' (วิทยานิพนธ์มหาบัณฑิต, คณะนิติศาสตร์ มหาวิทยาลัยธรรมศาสตร์ 2554)).

<sup>17</sup> Directive 2001/83/EC, art 104, 211.110(a) and Health Products (Therapeutic Products) Regulations 2016, regulation 34.

remove a defective product from the market, and the FDA withdraw such products from the market.

Therefore, the author recommends that Thai Drug Act should be amended by adding Section 26/2 “Licensee to sell shall monitor medicinal products placed on the market by yearly sampling and reporting the result of sampling to the competent authorities. The reporting shall consist of the sampling of medicinal products covering the name of the product, dosage form, indications, an adverse effect, place, and date of practice, and the result of sampling. In the case of danger, the licensee shall voluntarily recall defective medicinal products or ordered by competent authorities to remove a defective product from the market, and the Food and Drug Administration shall withdraw such products from the market.”

### **3.4 The ineffectiveness of safety alert measures on dangerous medicinal products**

Thailand established a pharmacovigilance center, the Health Product Vigilance Center (HPVC), to monitor and collect the Adverse Drug Reactions - ADRs reporting of health products, detect signals and assess ADRs in order to identify the product safety problem, and then collaborate the ADRs data with the local and international levels. The scope of health products covers medicinal products, narcotics and psychotropic substances, foods, cosmetics, medical devices, and hazardous substances.<sup>18</sup> The FDA has issued The Announcement regarding the guidance for Market Authorization Holders -MAHs on post-marketing safety reporting to provide a guide for MAHs to submit health products safety reports to HPVC.<sup>19</sup> The MAHs are required to

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<sup>18</sup> Health Product Vigilance Center, ‘The Statistics of the HPVC Reporting of All Suspected Adverse Events of the Health Products in 1984-2019 (September)’ (*Thai FDA*, 10 November 2019) <[http://thaihpvc.fda.moph.go.th/thaihvc/Public/News/uploads/hpvc\\_5\\_13\\_0\\_100805.pdf](http://thaihpvc.fda.moph.go.th/thaihvc/Public/News/uploads/hpvc_5_13_0_100805.pdf)> accessed on 11 October 2019.

<sup>19</sup> The Announcement of Food and Drug Administration: The guidance for marketing authorization holders on post-marketing safety reporting for human drugs, narcotics, and medicinal neurophychotropic substances, dated 18 December 2015.

submit health product safety reports to Thai Vigibase, developed by the HPVC, which is a national database that collects reports of health products. Although the responsible person to report is the MAHs of health products, the majority of reports submitted to HPVC are voluntarily reported by governmental hospitals, drug stores, and healthcare professionals.<sup>20</sup>

There are problems on the ineffectiveness of safety alert measures on dangerous medicinal products. The reporting of ADRs is a vital system for the detection of defective medicinal products, but the ADRs reporting is not regulated under the Thai Drug Act, which is specific legislation governing medicinal products in Thailand. The FDA only issued “The Announcement entitled the guidance for MAHs on post-marketing safety reporting”. The legal status of the guidance on post-marketing safety reporting lack of effective enforcement and lead to ineffectiveness of the reporting in practice. As a result, the HPVC received reports of adverse events of health products that occurred in Thailand less than was actually received. Therefore, to regulate the reporting measure to be enforceable in practice, the ADRs reporting should be imposed under Thai Drug Act.

The scope of health products required for submitting ADRs reports to the HPVC covers the wide range of health products. The identification of the product safety problem from the various product reports leads to confusion and wasting time to categorize the type of products before the assessment and cause the delay of the evaluation to decide to take further regulatory action. Moreover, medicinal products are unavoidably unsafe products, so they should be taken appropriate action abruptly when an adverse event occurs. Therefore, a pharmacovigilance center for medicinal products should be separated from other health products to emphasize more on the problem regarding medicinal products in order to effectively assess the ADRs reports, take directly and appropriate actions to resolve

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<sup>20</sup> Wimon Suwankesawong, ‘Pharmacovigilance in Thailand’ (HPVC) <[https://www.genome.gov/Multimedia/Slides/SJS\\_TEN2015/12\\_Sewankesawong.pdf](https://www.genome.gov/Multimedia/Slides/SJS_TEN2015/12_Sewankesawong.pdf)> accessed 11 October 2019.

with the safety problem of medicinal products, and communicate ADRs reports to relevant parties and foreign countries readily.

Moreover, the guidance imposed The MAHs as the responsible person; in fact, they submitted a few ADRs reports. Meanwhile, healthcare professionals, hospitals, and consumers should be required to submit the ADR reports because they are an essential part of the treatment team, especially when an ADRs occurs, and can contribute more safety data related to medicinal products. Moreover, the majority of ADR reports submitted by healthcare professionals, hospitals, and consumers are voluntary. As a result, many reports do not contain enough details about the event to evaluate the occurrence of adverse events appropriately. Thereby, healthcare professionals, hospitals, and consumers should be included as the responsible person to report ADR on medicinal products.

To effectively detect adverse events on medicinal products and ensure the safety of medicinal products placed on the market, the EU, the U.S., and Singapore establish a pharmacovigilance system for medicinal products and require the licensees, healthcare professionals, hospitals, patients and others to monitor, record, and submit the report of suspected adverse reactions regarding medicinal products to the competent authorities as soon as possible. In the case of danger, authority shall take regulatory actions such as changing label, issuing warnings, withdrawal or requesting the licensee to recall their product from the market.<sup>21</sup> Therefore, by taking the EU, the U.S., and Singapore as a model law, Thai Drug Act should be amended by adding the provision relevant to the pharmacovigilance system.

Therefore, the author recommends that Thai Drug Act should be amended by adding CHAPTER 13/1 Pharmacovigilance which should contain main issues as follows

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<sup>21</sup> U.S. Food and Drug Administration, 'Postmarketing Safety Surveillance and Oversight: MedWatch, FAERS, and the Sentinel System' (FDA, 3 August 2018) <<https://www.fda.gov/drugs/drug-safety-and-availability/drug-safety-priorities-2016-initiatives-and-innovation#post>> accessed 10 July 2019.

The pharmacovigilance system shall be operated for the fulfillment of pharmacovigilance tasks and used to collect information on the risks of medicinal products as regards public health. That information shall refer to adverse reactions arising from the use of the medicinal product within the terms of the marketing authorization as well as from use outside the terms of the marketing authorization.

To strengthen the pharmacovigilance regarding medicinal products, The Medicinal Products Vigilance Center (MPVC), as a pharmacovigilance center, should be established with the purpose to collect adverse reactions and related problems on medicinal products, detect signals, assess adverse reactions, and report safety information to the public and related institutes in order to identify the product safety problem, manage the risk, and communicate the ADR reports with the local and international level.

The pharmacovigilance committee is responsible for assessing all aspects of risk management of medicinal products for human use, including the detection, assessment, minimization, and communication of the risk of adverse reactions. The pharmacovigilance committee consists of representatives from the Thai FDA, the independent experts in medical or pharmacological or pharmaco-epidemiological fields, and representatives from the public sector.

Licensees, healthcare professionals, hospitals, and consumers shall be the responsible person to monitor, record, and report all suspected adverse reactions on medicinal products in Thailand or third countries to the competent authorities and the Medicinal Products Vigilance Center (MPVC) as soon as possible and within 15 days from becoming aware of these reactions. These reports will send to Thai Vigibase, developed by the MPVC administered by Thai FDA, which is a national database to collect reports from medicinal product surveillance systems with the purpose to assist safety inspection of the safe and effective use of medicinal products in Thailand.

In the case of danger, the licensee shall voluntarily recall defective medicinal products or ordered by competent authorities to remove a

defective product from the market, and the Thai Food and Drug Administration shall withdraw such products from the market.

The Medicinal Products Vigilance Center (MPVC) shall communicate safety information through the bulletin, annual reports, safety alerts, and Thai FDA website. Moreover, the Medicinal Products Vigilance Center (MPVC) also sharing adverse event reports to the World Health Organization (WHO) International Drug Monitoring Programme for the international surveillance of adverse drug events and ASEAN Post Marketing Alert System (PMAS).

#### **4. Conclusion**

Thailand prescribes Drug Act of B.E.2510 (1967) (as amended in 2019) as the specific product safety law directly related to medicinal products. However, in practice, the existing safety measures for medicinal products are insufficient to protect the consumer from unsafe products and have some flaws to detect adverse events. The consequences of the ineffective of safety measures for medicinal products in Thailand can be summarized as four legal problems: 1) a long period of validity of drug registration and an absence of the review of drug formula; 2) an absence of re-evaluation of medicinal products before distribution; 3) an absence of monitoring measures by the licensee, and 4) the ineffectiveness of safety alert measure on dangerous medicinal products.

Therefore, this article has studied on the safety measures for medicinal products from three countries, namely the European Union, the United States, and Singapore in comparison which has been aware of unsafe products for many years, so these countries not only have product liability law, but also have product safety law to protect consumers and ensure that the products are safe. Thus, these three countries are good models for further development and implementation of safety measures for medicinal products in Thailand.

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