# LEGAL PROBLEMS ON DRUG QUALITY CONTROL IN THE DRUG LOGISTICS IN THAILAND*

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## ABSTRACT

Assuring the quality of drugs throughout the drug supply chain, from the point of manufacture to the point of delivery to the patients is of extreme importance. There are many factors affecting the stability of drugs, ranging from the manufacturing process, the environmental conditions, such as,, temperature, light, and humidity encountered during transportation to distribution, storage and other activities in the logistics process.

In Thailand, the problems of drug degradation, drug contamination and other drug quality problems are continuously raised by the hospitals, drugstores and patients because some drugs were not properly transported, distributed and stored in accordance with the conditions required on the label of each drug during the logistics process ,despite the fact that the drugs are sensitive products and required special conditions, e.g. control over temperature, humidity, light, cleanness, sanitation, prevention of contamination and other factors encountered during transportation, distribution and storage.

This thesis, thus, aims to study the problems of Thai law on drug quality control, comparing them with foreign legislations, such as those of the United Kingdom and Singapore, as well as the guidelines of the World Health Organization and the European Union on the various stages of activities in the drug logistic chain, in order to propose an appropriate legislative solution in the Thai context.

**Keywords:** Drug Logistics, Drug Quality Control

**บทคัดย่อ**

ในกระบวนการโลจิสติกส์ยา การประกันคุณภาพของยามีความสำคัญเป็นอย่างยิ่ง เพื่อให้มั่นใจได้ว่าคุณภาพของยาจะได้รับการรักษาไว้ตลอดโซ่อุปทานยาซึ่งเริ่มต้นตั้งแต่โรงงานผลิตยาจนยาถูกส่งถึงผู้ป่วย มีปัจจัยหลายประการที่มีผลกระทบต่อความคงสภาพของยา อาทิ กระบวนการผลิต สภาวะแวดล้อม ได้แก่ อุณหภูมิ แสง และความชื้น ที่ต้องเผชิญในระหว่างการขนส่ง การจัดจำหน่าย การเก็บรักษา และการดำเนินการอื่นๆ ในกระบวนการโลจิสติกส์ยา

ในประเทศไทย ปัญหาเกี่ยวกับการเสื่อมสภาพของยา การปนเปื้อนของยา และปัญหาคุณภาพยาอื่น ๆ นั้นได้มีการร้องเรียนจากโรงพยาบาล

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ร้านขายยา และผู้ป่วยอย่างต่อเนื่องตลอดมา เนื่องจากยาบางตัวถูกขนส่ง จัดจำหน่าย และจัดเก็บอย่างไม่เหมาะสม ไม่ถูกต้องตามเงื่อนไขที่กำหนดไว้ในฉลากยาแต่ละตัวถึงแม้ว่าในความเป็นจริงแล้ว ยาเป็นผลิตภัณฑ์ที่ไวต่อสภาวะที่สัมผัสซึ่งต้องปฏิบัติตามสภาวะที่กำหนด ตัวอย่างเช่น ต้องมีการควบคุมอุณหภูมิ ความชื้น แสง ความสะอาด สุขอนามัย ป้องกันการปนเปื้อน และปัจจัยอื่น ๆ ที่อาจต้องเผชิญในระหว่างการขนส่ง การจัดจำหน่าย และการจัดเก็บ

ดังนั้น วิทยานิพนธ์ฉบับนี้ จึงมุ่งศึกษาถึงปัญหาของกฎหมายไทยในการควบคุมคุณภาพของยา และศึกษาเปรียบเทียบกับหลักของกฎหมายต่างประเทศ อาทิ อังกฤษ สิงคโปร์ และหลักเกณฑ์ขององค์การอนามัยโลก และสหภาพยุโรป ในกิจกรรมต่าง ๆ ของผู้ที่เกี่ยวข้องกับกระบวนการโลจิสติกส์ยา เพื่อทำการวิเคราะห์และเสนอแนวทางแก้ปัญหากฎหมายไทย

## Introduction

There is a growing concern regarding the drug quality in Thailand. The problems of drug quality such as drug degradation, drug contamination and drug instability might have been caused by any party involved in the drug supply chain , from the point of manufacturing through the marketing channels.. Therefore, all parties involved in the drug logistics have the responsibility to guarantee the quality and integrity of the drugs. There are many factors affecting the stability of drugs, e.g. the manufacturing process, the environmental conditions such as temperature, light, and humidity encountered during transportation, distribution and storage of drugs and other activities in the logistics process. To ensure the drug stability and efficacious use, the drugs must be transported, distributed and stored in proper conditions in accordance with the conditions required on the label of each drug.

However, many problems affecting the quality of drugs have been reported to the Bureau of Drug and Narcotic, Department of Medical Sciences, Ministry of Public Health in Thailand, by hospitals, clinics and individuals. Between 2009 and 2011, there were 2,424 reports of drug quality problems filed with the drug quality problems reporting center. 28% of the total reports concerned drug degradation, 18% caused by loss of package integrity, 17% was attributable to problems of standards of manufacture and transportation, and 8% involved drug contamination.[1] In 2012, there were 559 reports of drug quality problems filed with the center. Among the incidents reported, 30% were drug degradation, 19% loss of package integrity, 19% concerned standards of manufacture and transportation, and 10% involved drug contamination.[2] In 2013, a total of 814 complaints were filed with the center and the most common problem among them was drug degradation which attributed to 26%.

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[1] สำนักยาและวัตถุเสพติด , **การเฝ้าระวังปัญหาทางกายภาพของผลิตภัณฑ์ยาที่มีใช้ในสถานบริการสาธารณสุขปี พ.ศ. 2552-2554**, (Bureau of Drug and Narcotic, **Monitoring Physical Problems of Drugs Used in Health Centers in the Year 2009 – 2013**), at 19, *available at* http://dmsc2.dmsc.moph.go.th/webroot/drug/qa30/problem/หนังสือปัญหาคุณภาพยา52-54.pdf (last visited Jan. 18, 2015).

[2] สำนักยาและวัตถุเสพติด, *ปัญหาคุณภาพยาที่ได้รับรายงานปี พ.ศ. 2555*, **จดหมายข่าวศูนย์รวบรวมข้อมูลปัญหาคุณภาพยา**, มกราคม – เมษายน 2556, (Bureau of Drug and Narcotic, *Drug Quality Problems Reported in the Year 2012*, **Drug Quality Problems Reporting Center Newsletter**, January – April 2013), at 3-4, *available at* http://dmsc2.dmsc.moph.go.th/webroot/drug/surveillance/newsletter/Newsletter16-1-2556.pdf (last visited Jan. 18, 2015).

Apart from that, 23% of the complaints concerned loss of package integrity, 14% wasattributable to standards of manufacture and transportation, and 7% concerned drug contamination.[3] These complaints showed that the drug quality problems have been increasing steadily and there is no solution in sight. These drug quality problems such as drug contamination, drug degradation and drug instability may cause not only ineffective treatment, but also pose as a potential harm to the patient's life.

In this regard, World Health Organization (WHO) recommends that "To maintain the original quality of pharmaceutical products, every party active in the distribution chain has to comply with the applicable legislation and regulations. Every activity in the distribution of pharmaceutical products should be carried out according to the principles of good manufacturing practices (GMP), good storage practice (GSP) and good distribution practice (GDP) as applicable."[4]. WHO also recommends that the principles of GDP should be included in national legislation and guidelines in a country as applicable as a means of establishing minimum standards[5] and GSP should be applicable in all circumstances where pharmaceutical products are stored and throughout the distribution process[6]. The Ministry of Public Health of Thailand has adopted GMP based on the principles of WHO good manufacturing practices for pharmaceutical products (GMP).[7]

In Thailand, the Drug Act, B.E. 2510 (1967) regulates that any manufacturers, importers and distributors of pharmaceutical products must obtain a license. All licensees must comply with the rules, measures and conditions prescribed in the Ministerial Regulations issued in accordance with the provisions of the Drug Act, B.E. 2510 (1967)[8]. The Drug Act, B.E. 2510 (1967) regulates the standard of manufacturing that the manufacturers must comply with the notifications of the Ministry of Public Health regarding GMP which are the notification of the Ministry of Public Health on good manufacturing practices for modern drugs according to the law on drugs B.E. 2554 (2011) and the notification of the Ministry of Public Health on good manufacturing practices for traditional drugs according to the law on drugs B.E. 2557 (2014). However, the Drug Act, B.E. 2510 (1967) does not regulate or provide guideline on how to properly transport, distribute and store the drugs so that it will not affect the quality and integrity of drugs or contaminate the drugs.

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[3] สำนักยาและวัตถุเสพติด, *ปัญหาคุณภาพยาที่ได้รับรายงานปี พ.ศ. 2556*, **จดหมายข่าวศูนย์รวบรวมข้อมูลปัญหาคุณภาพยา**, มกราคม – เมษายน 2557, (Bureau of Drug and Narcotic, *Drug Quality Problems Reported in the Year 2013*, **Drug Quality Problems Reporting Center Newsletter**, January – April 2014), at 1-4, *available at* http://dmsc2.dmsc.moph.go.th/webroot/drug/surveillance/newsletter/newsletter17-1-2557.pdf (last visited Jun. 2, 2015).

[4] World Health Organization, **WHO Good Distribution Practices for Pharmaceutical Products** 237, *available at* http://www.who.int/medicines/areas/quality_safety/quality_assurance/GoodDistributionPracticesTRS957Annex5.pdf (last visited Jun. 2, 2015).

[5] *Id.* at 243.

[6] *Id.* at 248.

[7] Government Pharmaceutical Organization, **Good Manufacturing Practice:GMP**, *available at* https://www.gpo.or.th/Default.aspx?PageContentMode=1&tabid=107 (last visited Jun. 2, 2015).

[8] The Drug Act, B.E. 2510 (1967) Section 12.

**Drug and Drug Stability**

A drug is defined as a chemical substance intended for use in the diagnosis, treatment, or prevention of disease in human or other animals.[9] Drugs are widely used to treat the illness, both physically and mental. According to the Drug Act, B.E. 2510 (1967), drugs are classified into two major groups namely modern drugs and traditional drugs.[10] Modern drugs mean "drugs intended for use in the practice of medical profession, the practice of modern science of healing or the treatment of animal diseases" and traditional drugs mean "drugs intended for use in the practice of the traditional science of healing or the treatment of animal diseases included in the pharmacopoeias of traditional drugs notified by the Minister, or drugs notified by the Minister to be traditional drugs, or drugs having been permitted for drug formula registration as traditional drugs" as defined in Section 4 of the Drug Act, B.E. 2510 (1967) as amended by the Drug Act (No. 3), B.E. 2522 (1979).

Each particular drug is a formulation unique into itself. To ensure the stability of drug in a formulation and the continued effectiveness of the drug throughout its usual shelf life, the formulation must be preserved against decomposition due to chemical degradation and protected from microbial contamination and the destructive influences of excessive heat, light and moisture. In addition, the drug product must be effectively packaged and clearly and completely labeled according to legal regulations. Once the drug product is prepared, it must be properly administered in order to ensure the stability of drug for the patient's maximum benefit.[11]

Labelling is the process of identifying a product including the following information: name of the product, active ingredients (type and amount), batch number, expiry date, special storage conditions or handling precautions, directions for use, warnings and precautions, names and addresses of the manufacturer and/or the supplier.[12] If the drug product is not handling in accordance with the instructions or not stored under recommended conditions shown on the label, then, the drug product may be expected to degrade more rapidly and may not be fitness for use because its stability may be affected. There are many factors affecting the stability of a drug product, namely the active ingredients stability; the potential interaction between active and inactive ingredients; the manufacturing process; the dosage form; the container/closure system; the environmental conditions encountered during shipment, storage, and handling; and the length of time between manufacture and usage.[13] In addition,

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[9] The American Heritage, **Medical Dictionary**, *available at* http://medical-dictionary.thefree dictionary.com/drug (last visited Jun. 2, 2015).
[10] The Drug Act, B.E. 2510 (1967) Section 4.
[11] Loyd V. Allen, Jr. & Howard C. Ansel, **Ansel's Pharmaceutical Dosage Forms and Drug Delivery Systems** 97 (Sirkka Howes ed., Wolters Kluwer 10th ed. 2014).
[12] World Health Organization, *supra* note 4 at 235.
[13] Brahmaiah Kommanaboyina & C.T. Rhodes, **Trends in Stability Testing, with Emphasis on Stability During Distribution and Storage** (Drug Development and Industrial Pharmacy, Marcel Dekker) 859, 858 (1999), *available at* http://www.informahealthcare.com (last visited Dec. 17, 2014).

other factors such as the cleanness, sanitation and prevention of contamination should also be considered while the drugs are distributed and stored before delivering to the patients.

Storage conditions to maintain the drug stability can be divided into 3 factors, i.e. temperature, humidity and light based on environmental factors affecting drug stability.[14] If the drugs lost its stability, then effects are loss of active, increase in concentration of active ingredients, alteration in bioavailability, loss of content uniformity, loss of pharmaceutical elegance and patient acceptability, formation of toxic degradation products, loss of package integrity, and reduction of label quality.[15]

**Drug Supply Chain and Drug Logistics**

The drug supply chain process is the process which all involving parties working together to source, manufacture and distribute the drug products to the entity responsible for dispensing or providing the drug products to the patients.[16] A basic drug supply chain comprises sourcing of raw materials to manufacture the finished drug products or importing of finished drug products and distributing to the market channels to the patients.

Logistics is the process of planning, implementing, and controlling procedures for the efficient and effective transportation and storage of goods including services, and related information from the point of origin to the point of consumption for the purpose of conforming to customer requirement. Logistics management is that part of supply chain management that plans, implements, and controls the efficient, effective forward and reverses flow and storage of goods, services, and related information between the point of origin and the point of consumption in order to meet customers' requirements.[17] In general, logistics is involved in order-processing, purchases, inbound transport, production plans and schedules, inventory management, distribution and delivery transport, warehouse management, and several information systems such as customer response management, materials requirements planning and distribution requirements planning.[18] There is a risk that the inventory management, the distribution and delivery transport, and the warehouse management will impact on the quality of drugs, apart from the manufacturing process.

The fact that the drugs are sensitive products and must be handled in accordance with instructions and storage conditions in order to maintain the drug quality and avoid the drug

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[14] สมชัยยา สุริฉันท์, **การเก็บรักษากับความคงตัวของยาและเภสัชภัณฑ์** (Somchaiya Surichan, **Storage and stability of a drug product**), *available at* http://www.gpo.or.th/rdi/html/stability.html (last visited Jun. 2, 2015).

[15] *Id.*

[16] Healthcare Supply Chain Excellence Centre (LogHealth) Mahidol University, **Healthcare Logistics & Supply Chain – Status in Thailand**, *available at* http://www.nrct.go.th/th/Portals/0/data/ภค/2556/06/3รศ_ดร_ดวงพรรณ_คุณโสภณ.pdf (last visited Jun. 2, 2015).

[17] Kate Vitasek, **Supply Chain Management Terms and Glossary** 117 (2013), *available at* http://cscmp.org/sites/default/files/user_uploads/resources/downloads/glossary-2013.pdf (last visited Jun. 2, 2015).

[18] Ian Sadler, **Logistics and Supply Chain Integration** (Sage Publications) (2007).

contamination and drug degradation, the parties active in the drug logistics have to strictly comply with the drug legislation and guidelines for manufacturing, transportation, distribution and storage of drugs.

## Overview of International Standards of Practices

### 1. World Health Organization (WHO)

According to WHO, the quality assurance can be divided into four major areas: quality control, production, distribution, and inspections.[19] For pharmaceutical products, WHO has developed and laid down guidelines for Good Manufacturing Practices (GMP), Good Distribution Practices (GDP) and Good Storage Practices (GSP) to provide globally accepted standards.

GMP is that part of quality management which ensures that pharmaceutical products are consistently produced and controlled according to the quality standards appropriate to their intended use and as required by the marketing authorization, clinical trial authorization or product specification. It is aimed primarily at managing and minimizing the risks inherent in pharmaceutical manufacture to ensure the quality, safety and efficacy of products.[20]

GDP is that part of quality assurance that ensures that the quality of a pharmaceutical product is maintained by means of adequate control of the numerous activities which occur during the distribution process as well as providing a tool to secure the distribution system from counterfeits, unapproved, illegally imported, stolen, counterfeit, substandard, adulterated, and/or misbranded pharmaceutical products.[21] GSP is that part of quality assurance that ensures that the quality of pharmaceutical products is maintained by means of adequate control throughout the storage thereof.[22]

### 2. The Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S)

PIC/S consists of the Pharmaceutical Inspection Convention (PIC) and the Pharmaceutical Inspection Co-operation Scheme (PIC Scheme), which operate together in parallel in the field of GMP. PIC/S mission is "to lead the international development, implementation and maintenance of harmonized GMP standards and quality systems of

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[19] World Health Organization, **About Quality Assurance**, *available at* http://www.who.int/medicines/areas/quality_safety/quality_assurance/about/en/ (last visited Jan. 18, 2015).

[20] World Health Organization, **WHO Good Manufacturing Practices for Pharmaceutical Products**, *available at* http://www.who.int/medicines/areas/quality_safety/quality_assurance/TRS986annex2.pdf (last visited Jun. 14, 2015).

[21] World Health Organization, *supra* note 4 at 240.

[22] *Id*.

inspectorates in the field of medicinal products".[23] PIC/S provides PIC/S Guide to GMP for Medicinal Products and PIC/S Guide to GDP for Medicinal Products.

Although Food and Drug Administration of Thailand (Thai FDA) is not a member of PIC/S, Thai FDA applied the PIC/S Guide to GMP for Medicinal Products to Thai GMP. Because Thailand has to comply with the ASEAN Sectorial Mutual Recognition Arrangement for Good Manufacturing Practice (GMP) Inspection of Manufacturers of Medicinal Products which was signed on April 10, 2009 by 10 Member States of the Association of Southeast Asian Nations (ASEAN).[24] As a result, Thailand has to standardize GMP to be in line with those Member States of ASEAN and has to comply with the PIC/S Guide to GMP for Medicinal Products.

PIC/S Guide to GMP for Medicinal Products is that part of quality management which ensures that the holder of a manufacturing authorization must manufacture medicinal products so as to ensure that the medicinal products are fit for their intended use, comply with the requirements of the Marketing Authorization and do not place patients at risk due to inadequate safety, quality or efficacy.[25] PIC/S Guide to GDP for Medicinal Products lay down appropriate tools to assist wholesale distributors in conducting their activities and to prevent falsified medicines from entering the legal supply chain. Compliance with these guidelines will ensure control of the distribution chain and consequently maintain the quality and the integrity of medicinal products. Manufacturers performing any distribution activities with their own products must comply with GDP. In addition, relevant sections of these guidelines should also be adhered to by other actors involved in the distribution of medicinal products.[26]

### 3. European Union (EU)

European Commission provides Guidelines on GMP and GDP of medicinal products for human use. EU Guidelines for GMP for Medicinal Products for Human and Veterinary Use provides that the holder of a Manufacturing Authorization must manufacture medicinal products so as to ensure that medicinal products are fit for their intended use, comply with the requirements of the Marketing Authorization or Clinical Trial Authorization, as appropriate

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[23] Pharmaceutical Inspection Co-operation Scheme, *available at* http://www.picscheme.org/ (last visited Jun. 14, 2015).

[24] ASEAN Secretariat, **The ASEAN Sectorial Mutual Recognition Arrangement for Good Manufacturing Practice (GMP) Inspection of Manufacturers of Medicinal Products**, *available at* http://www.asean.org/archive/documents/Agreement%20on%20MRA%20for%20GMP%20Pharmaceutical.pdf (last visited May 29, 2015).

[25] Pharmaceutical Inspection Co-operation Scheme, **PIC/S Guide to Good Manufacturing Practice for Medicinal Products Part I** 1, *available at* http://www.picscheme.org/publication.php (last visited Jun. 2, 2015).

[26] *Id.*

and do not place patients at risk due to inadequate safety, quality or efficacy.[27] EU Guidelines on GDP of medicinal products for human use stated that the wholesale distribution of medicinal products is an important activity in integrated supply chain management. These Guidelines lay down appropriate tools to assist wholesale distributors in conducting their activities and to prevent falsified medicines from entering the legal supply chain. Manufacturers performing any distribution activities with their own products must comply with GDP. Compliance with these Guidelines will ensure control of the distribution chain and consequently maintain the quality and integrity of medicinal products.[28]

**Foreign Laws and Legislations of Standards of Practices**

**1. Singapore**

Singapore is a member of ASEAN, WHO and PIC/S. Singapore is also one of the 10 ASEAN Member States signing the ASEAN Sectorial Mutual Recognition Arrangement for Good Manufacturing Practice (GMP) Inspection of Manufacturers of Medicinal Products.

Currently, the Singapore law regulating the medicinal products is the Medicines Act. Under the Medicines Act, the law empowers the minister to issue the regulations prescribe the requirements as the minister may consider necessary to the sanitation, cleanliness, temperature, humidity or other factors relating to the risks of drugs deterioration or drug contamination in connection with the manufacture, storage, transportation, sale or supply of medicinal products and violation of the regulation shall be convicted under the penalty prescribed in the Medicines Act.[29]

For manufacturing of drugs, the Medicines Act controls licensing of manufacturers and wholesale dealer that no person shall manufacture or sell any medicinal product except in accordance with the license granted by this law. The law required that all manufacturers and assemblers of medicinal products for both Western medicines and Chinese Proprietary Medicine must comply with GMP. For the storage, transportation and distribution of drugs, the Medicines Act controls licensing of importers and wholesale dealer of both Western medicines and Chinese Proprietary Medicine. According to Singapore Health Sciences Authority (HSA), before the granting of the license, importers and wholesale dealers must comply with GDP standard and prove to the authority.[30]

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[27] European Commission, **EU Guidelines for Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use** 2, *available at* http://ec.europa.eu/health/files/eudralex/vol-4/vol4-chap1_2013-01_en.pdf (last visited Jun. 2, 2015).

[28] European Commission, **EU Guidelines of 5 November 2013 on Good Distribution Practice of Medicinal Products for Human Use**, *available at* http://eur-lex.europa.eu/Lex UriServ/LexUriServ.do?uri=OJ:C:2013:343:0001:0014:EN:PDF (last visited Jun. 2, 2015).

[29] Health Sciences Authority of Singapore, **Medicines Act (Chapter 176)**, *available at* http://www.hsa.gov.sg/content/dam/HSA/HPRG/Useful_Information_for_Applicants/Legislation/MEDICINES%20ACT.pdf (last visited Jun. 2, 2015).

[30] Health Sciences Authority of Singapore, **Guidance Notes on Good Distribution Practice (2010)**, *available at* http://www.hsa.gov.sg/content/dam/HSA/HPRG/Manufacturing_Importation_Distribution/

### 2. United Kingdom (UK)

The regulation of medicines on the UK market is under taken by the Medicines and Healthcare Products Regulatory Agency (MHRA). According to MHRA, before a medicine for human use can be sold in the UK, the medicine product must have a license called a 'marketing authorisation' and the companies involved in all stages of the manufacture and distribution of the product must have the relevant license for the activity in question i.e. Manufacturer's license (MIA) and/or Wholesale Dealer's license (WDA(H)) as required by the Human Medicines Regulations 2012.[31]

The holder of MIA must comply with the provisions set out in the Regulations including EU GMP and is required to comply with EU GDP if the holder of MIA distributes the medicinal product too. If there is a violation of legislation, there is a legal sanction that the licensing authority is authorized to take regulatory action in form of adverse licensing action and/or the instigation of criminal proceedings. The holder of WDA(H) must comply with the provisions set out in the Regulations including EU GDP. If there is a violation of legislation, there is a legal sanction that the licensing authority is authorized to take regulatory action in form of adverse licensing action and/or the instigation of criminal proceedings. In compliance with EU GDP, if any activity covered by the GDP is outsourced to the third party such as a transportation provider, it is required that a written contract must be made by and between the contract giver and the contract acceptor with the terms clearly establishes the duties of each party. As stated in EU GDP, the contract giver is responsible for the activities contracted out and for ensuring that the principles and guidelines of GDP are followed.[32]

## Conclusion and Recommendation

The problems of drug degradation, drug contamination, and other drug quality problems incurred in the drug logistics happened for several years and until now those problems have not been resolved. The existing drug law in Thailand is the Drug Act, B.E. 2510 (1967) applied the principles of GMP based on the principles of WHO good manufacturing practices for pharmaceutical products and the PIC/S Guide to GMP for Medicinal Products. The existing law is controlling the manufacturing process, but not covering the drug quality assurance during the transportation, distribution and storage of drugs in the drug logistics. Therefore, it is necessary to have adequate legal control measures or drug legislation to ensure that the quality of drugs will be maintained in the logistics activities of transportation, distribution and storage throughout the drug supply chain from the point of origin to the point of consumption. The handling of drugs shall meet the requirement on the label of each drug at all times throughout the logistics of drugs. All

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Guidelines-on-Good-Manufacturing-Practice-Standard-and-Good-Distribution-Practice-Standard/GUIDE-MQA-013-009.pdf (last visited Jun. 2, 2015).

[31] Medicines and Healthcare Products Regulatory Agency, *available at* http://www.mhra.gov.uk/Howweregulate/Medicines/Licensingofmedicines/ (last visited Jun. 2, 2015).

[32] European Commission, *supra* note 28.

parties involved in the activities in the drug supply chain have to comply with the principles of GMP, GDP and GSP. However, the Drug Act, B.E. 2510 (1967) applied only the principles of GMP by issuance of the Notifications of the Ministry of Public Health for both modern drugs and traditional drugs.

The Drug Act, B.E. 2510 (1967) shall be amended by regulating that the licensees under the Drug Act have to comply with the principles of GDP and GSP to be issued by the drug committees when carrying out the activities of transportation, distribution and storage of drugs. Any violation shall be subject to the legal sanction under the Drug Act. The licensees shall be suspended for the license to operate and penalized with the penalty as prescribed by law. If the drugs are degraded or instability to the extent that it harms the patient who consumed such drugs, the licensees under the Drug Act shall be jointly liable to the injured party for damages incurred from the drug usage.

The principles of GDP and GSP shall be issued by the drug committees of the MOPH for both modern drugs and traditional drugs as the notification of drug committee. The issuance of the principles of GDP and GSP require technical knowledge, skill and special expertise. Besides the principles of GDP and GSP need to be revised and updated regularly to ensure that those principles are appropriate and up-to-date. So it will be more flexible to empower the drug committee to draft, revise and update the principles of GDP and GSP instead of incorporating all principles of GDP and GSP as law in the Drug Act.

The principles of GDP and GSP shall cover the outsourcing activities in case the licensees outsource any activity to a third party. It shall be required that a written contract must be made by the licensee who is the contract giver and the third party who is the contract acceptor with the terms clearly established the duties of each party and stated that the contract acceptor have to follow GDP and GSP in carrying out his duty under the contract. However, the licensees are responsible for the activities contracted out and for ensuring that the GDP and GSP are followed. The licensees have to liable for violation of GDP and GSP even though they hire the third party to handle that. This will make the licensees to be more careful.

Accordingly, it is recommended that the principles of GDP and GSP should be applied in addition to the principles of GMP in the legislation and binding all persons to comply with when carrying out the drug logistics activities in order to solve the drug quality problems arising from the transportation, distribution and storage of drugs in the drug logistics in the drug supply chain.

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