SYSTEM ANALYSIS AND STRATEGIC DEVELOPMENT FOR MEDICINAL PRODUCT IMPORTATION

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พัชรีวรรณ ฝังนิล: การวิเคราะห์และพัฒนายุทธศาสตร์ของระบบการนำเข้ายา (SYSTEM ANALYSIS AND STRATEGIC DEVELOPMENT FOR MEDICINAL PRODUCT IMPORTATION) อ.ที่ปรึกษาวิทยานิพนธ์หลัก: ผศ.ภญ.ดร. รุ่งเพ็ชร สกุลบำรุงศิลป์, อ. ที่ปรึกษาวิทยานิพนธ์ร่วม: ผศ.ภญ.ดร. รวงทิพย์ ตันติปิฎก, 199 หน้า

การวิจัยครั้งนี้มีจุดมุ่งหมายเพื่อวิเคราะห์ปัจจัยที่มีผลกระทบและสังเคราะห์ยุทธศาสตร์เพื่อเพิ่มประสิทธิภาพของระบบการนำเข้ายาแผนปัจจุบัน โดยเป็นการวิจัยเชิงคุณภาพที่ประกอบด้วยขั้นตอนการวิจัย ดังนี้ 1) การวิเคราะห์เนื้อหาจากเอกสารที่เกี่ยวข้อง 2) การสัมภาษณ์ผู้เชี่ยวชาญและผู้ปฏิบัติงานที่เกี่ยวข้อง 3) การศึกษากระบวนการและมาตรการต่างๆ ของระบบการนำเข้ายาที่ใช้อยู่ในปัจจุบัน และ 4) การวิเคราะห์สถานการณ์และสังเคราะห์ยุทธศาสตร์ ผลการวิเคราะห์สถานการณ์และปัจจัยที่มีผลกระทบต่อประสิทธิภาพของระบบการนำเข้ายาในปัจจุบันพบว่ายังคงมีข้อจำกัดในด้านจำนวนบุคลากร งบประมาณ และการประสานความร่วมมือระหว่างหน่วยงานที่เกี่ยวข้องได้แก่ กรมศุลกากร และสำนักงานคณะกรรมการอาหารและยา ผู้วิจัยจึงได้สังเคราะห์และนำเสนอยุทธศาสตร์เพื่อการพัฒนาระบบการนำเข้ายา กล่าวโดยสรุปคือ 1) ผลักดันให้มีการใช้ระบบ National Single Window 2) เพิ่มช่องทางการสื่อสาร เช่น จัดตั้งศูนย์ข้อมูลและระบบสื่อสารภายในและระหว่างองค์กร 3) จัดทำฐานข้อมูลของยาแผนปัจจุบันให้สมบูรณ์ 4) สร้างแรงจูงใจโดยการให้รางวัลแก่เจ้าหน้าที่ผู้ปฏิบัติงาน 5) จัดให้มีการฝึกอบรมและแลกเปลี่ยนความรู้และประสบการณ์ระหว่างบุคลากรของหน่วยงานที่เกี่ยวข้อง 6) จัดสร้างด่านอาหารและยาเพิ่มเติมและจัดให้มีเครื่องมือที่ทันสมัยสำหรับตรวจสอบคุณภาพยาที่นำเข้าในเบื้องต้นอย่างเพียงพอ 7) จัดตั้งคณะทำงานเฉพาะกิจเพื่อให้หน่วยงานที่เกี่ยวข้องดำเนินงานร่วมกันกรณีพบการกระทำความผิด 8) ผลักดันให้การพัฒนาระบบการนำเข้ายาเป็นหนึ่งในตัวชี้วัดของหน่วยงาน 9) พัฒนาระบบการตรวจประเมินภายหลังการอนุมัตินำเข้ายามาจำหน่ายภายในประเทศให้มีประสิทธิภาพยิ่งขึ้น 10) จัดทำคู่มือสำหรับเจ้าหน้าที่ประจำด่านศุลกากรและด่านอาหารและยา และ 11) ปรับปรุงกฎหมายและหลักเกณฑ์ต่างๆ ที่เกี่ยวข้องให้มีความเข้มงวดและครอบคลุมมากขึ้น ผลจากการวิจัยครั้งนี้ สามารถใช้เป็นข้อมูลพื้นฐานในการกำหนดยุทธศาสตร์อื่นเพิ่มเติม และหากมีการขยายขอบเขตการวิจัยให้ครอบคลุมผู้เกี่ยวข้องทุกภาคส่วน จะทำให้การกำหนดแนวทางการพัฒนาระบบการนำเข้ายาแผนปัจจุบันมีประสิทธิภาพมากยิ่งขึ้น

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The purpose of this research was to analyze the factors affecting current importing system for modern medicinal products and to synthesize strategies to improve the performance of system. The study designs used for this qualitative research included 1) content analysis 2) key informant interview 3) case study (by studying the processes and measurements used in the current importing system) and 4) situation analyzing and synthesis of strategies. The results from the analysis of current situation and factors affecting the effectiveness of the importing system found that the system still had the limitation on numbers of operators, budgetary as well as the cooperation among relevant organizations, i.e., the Customs and Thai FDA. The proposed strategies to improve the importing system were as followed; 1) to speed up the establishment of National Single Window 2) to increase communication channels by setting up the information center and promote inter- and intra-organizational communication 3) to complete database of modern medicinal products 4) to motivate the officers through the reward system 5) to improve the competency by sharing experiences among involved officers 6) to increase the number of ports of entry of FDA and the number of instruments for screening testing 7) to establish the task force among organizations for infringement detected at the port 8) to identify factors related to the improvement of importing system as key performance indicators 9) to develop more effective post-marketing surveillance system 10) to develop the operation procedure manual for officers working at port of entry and 11) to revise rules and regulations to carry higher penalty for illegal conducts. The result from the study could be inputs for further policy development. Future expansion of the scope of research to cover all sectors related to the importing system for modern medicinal product will provide a broader perspective and could establish more effective strategies respectively.

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LIST OF ABBREVIATIONS

FDA	The Food and Drug Administration
DCD	The Drug Control Division
DMSc	The Department of Medical Sciences
PIC/S	The Pharmaceutical Inspection Co-operation Scheme
WHO	World Health Organization
WCO	World Customs Organization
NRA	National Regulatory Authority
NCL	National Control Laboratories
HSA	Health Sciences Authority (NRA of Singapore)
HPRG	The Health Products Regulation Group, Singapore
A&L	Audit & Licensing Division, Singapore
TPD	The Therapeutic Products Division, Singapore
MAC	The Medicines Advisory Committee, Singapore
MCRC	The Medical Clinical Research Committee, Singapore
GMP	Good Manufacturing Practices
GDP	Good Distribution Practices
GSP	Good Storage Practices
GIP	Good Importer Practices
MRA	Mutual Recognition Arrangement
FTA	Free Trade Agreement
AFTA	ASEAN Free Trade Area
APEC	Asia-Pacific Economic Cooperation
ACMECS	Ayeyawady - Chao Phraya - Mekong Economic Cooperation Strategy
S	Strengths (Internal factor of SWOT analysis)
W	Weaknesses (Internal factor of SWOT analysis)
O	Opportunities (External factor of SWOT analysis)
T	Threats (External factor of SWOT analysis)

P	Political factor of PEST Model
E	Economic factor of PEST Model
S	Social factor of PEST Model
T	Technological factor of PEST Model
ACTD	ASEAN Common Technical Dossier
ACTR	ASEAN Common Technical Requirements
SOP	Standard Operating Procedures
AWB	Airway Bill
BL	Bill of Lading
COA	Certificate of analysis
APIs	Active pharmaceutical ingredients
ADR	Adverse drug reaction
KPIs	Key Performance Indicators
NSW	National Single Window
ASW	ASEAN single window
IFAS	Internal Factor Analysis Summary
EFAS	External Factor Analysis Summary
SFAS	Strategic Factor Analysis Summary
CAPA	Corrective Action and Preventive Action

CHAPTER I
INTRODUCTION

1.1 Rationale

Modern medicinal product is one of health products which much more useful for the patient who has got an ailment and needs the effective treatment to relieve the symptom of diseases. All of those should have more sufficient quality, safety, and efficacy. Therefore, the Food and Drug Administration (FDA), the government organization under control of the Ministry of Public Health responsible for controlling and monitoring all modern medicinal products being marketed in the country has required according to the Drug Act B.E. 2510 (1967) that any persons who wish to sell, manufacture or import the medicinal products into the Kingdom must obtain a license and the marketing authorization of each product from the licensing authority as the Drug Control Division (DCD).

Nowadays, the modern medicinal products supplied for the patients in Thailand usually come from the local manufacturers and also the importers. In case of local manufacturing plants, in which modern medicinal products are produced, should perform their operations to comply with the Good Manufacturing Practices (GMP) defined in the Ministerial Notification of GMP for modern medicinal products which had been notified and implemented since June 2003. For the imported medicinal products, only authorized licensees are qualified to apply for product registration and then import their medicinal products into Thailand.

The Import and Export Inspection Division, an organization under control of FDA responsible for controlling, monitoring, and sampling the imported medicinal products was established to ensure the quality and safety of those products prior to be imported and distributed to the patients in our country. Basic requirements for the importation of modern medicinal products are thoroughly defined and carried out by the Import and Export Inspection Division.

In addition, the importing system for modern medicinal products has been performed by the cooperation among many involved organizations both inside and

outside of FDA e.g. DCD, the Import and Export Inspection Division, the Department of Medical Sciences (DMSc), and the Customs.

Firstly, referring to the report for comparison between the manufacturing value and the importing value, published by DCD of FDA, the trend is shown that the manufacturing value is more than the importing value until B.E.2543, and then the importing value become greater than the manufacturing value during B.E.2544 - 2550[1], as the figure 1.1.

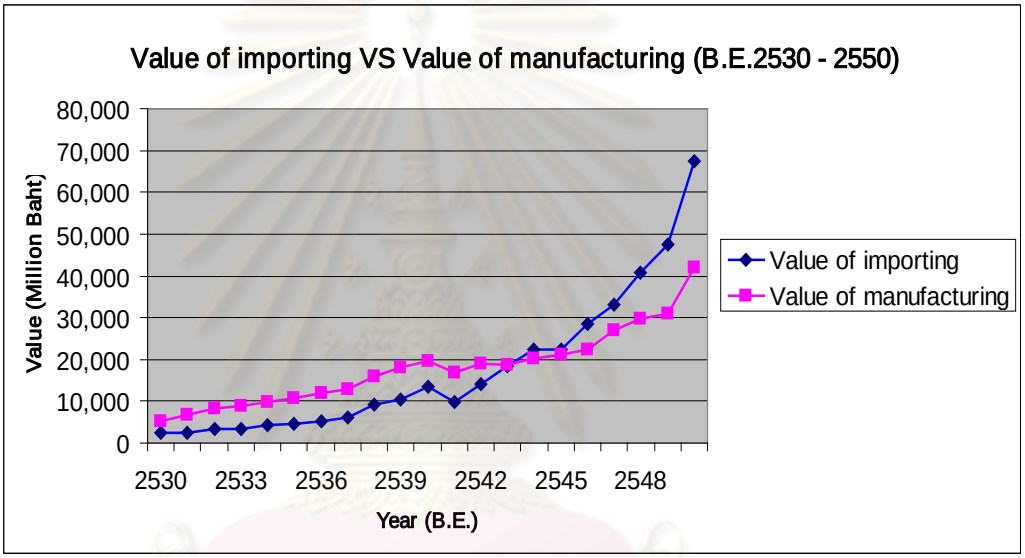

Figure 1.1 Trend for comparison between the importing and manufacturing value in B.E.2530 - 2550

According to the above information, it may be assumed that the quantity of modern medicinal products for patient used in Thailand comes from the importation from other countries more than the local manufacturing. Moreover, the patients may have to pay more money for their medical services, including the rising cost of medicines. Therefore, the quality, safety as well as efficacy of the imported medicinal products should be thoroughly concerned.

In order to ensure that all patients who have a chance or ability to access the imported medicinal products must obtain those products with high quality and safety, the importing system for modern medicinal products should be strictly performed and consistently strengthened.

Secondly, FDA has prepared and updated the information in “Safety Alert” which mentions on recall and rapid alert for modern medicinal products, published through the website of FDA, www.fda.moph.go.th[2]. Database of “Safety Alert” comes from the test results of the modern medicinal products which were taken sample from the local manufacturer, importer as well as the pharmacy regarding to annually sampling plan set up together by DCD, the Import and Export Inspection Division, and DMSc. Figure 1.2 presents the example of webpage of “Safety Alert”, including some items of the imported one.

Figure 1.2 The recall and rapid alert of medicinal products, published as “Safety Alert” through the website of FDA, www.fda.moph.go.th

Regarding to the published information shown in the above webpage, it consists of the details of products (e.g. lot, Mfg.date, expiry date, name of manufacturer and importer), the causes of recall or rapid alert (e.g. out-of-specification, sub-standard, non-registration), and the status or results (e.g. recalled already, in-process of recall, withdrawal of product registration).

In addition, some items of the recalled medicinal products in B.E.2551 – 2552 were the imported medicinal products with approved product registration. Most of people usually believe that the medicinal products produced and imported from other countries would have more quality and safety than the medicinal products produced by local manufacturers. However, the information indicated that the imported medicinal products may not be the best one. For instance, the table 1.1 showed the summary data of the imported modern medicinal products which were recalled from the market in B.E.2552 shown in the "Safety Alert."

Table 1.1 Raw data of the imported modern medicinal products recalled from the market in B.E.2552 shown in the "Safety Alert."

No	Trade name	Active ingredient	Lot/ Batch	Mfg.	Exp.	Origin	Recall date	Causes
1	Atmovin 1 g (2C 45/51)	Potassium clavulanate+ Amoxycillin trihydrate	BT9031	03/2009	02/2011	India	08/12/52	Dissolution failed
2	Acyclovir injection (1C 216/51)	Acyclovir Sodium	710156X V01	DEC 2008	JUN 2010	Pakistan	20/10/52	Weight (over spec.)
3	Duralyn-CR 200 mg (1C 90/47)	Theophylline anhydrous	E8002	21/02/08	20/02/11	India	12/05/52	Dissolution failed
4	Dolonil SR (1C 262/49)	Diclofenac Sodium 100 mg	AAU8007	SEP 2008	AUG 2011	India	12/05/52	Dissolution failed
5	Nicardia Retard 20mg (1C 192/45)	Nifedipine	A8032	MAR 2008	APR 2011	India	16/06/52	Dissolution failed
6	Tizan 4 (1C 9/47)	Tizanidine HCl	SK80846	05/2008	04/2011	India	14/05/52	Content of active ingredient failed
7	Zeptol CR 400 (1C 99/45)	Carbamaze-pine	SK80723	04/2008	03/2010	India	14/05/52	Dissolution failed

In case of the test results of sampled medicinal products were out-of-specification and also not comply with the law, the local manufacturers must follow the procedure for recall the products from the market and be punished according to the Drug Act B.E. 2510 (1967). They should investigate the root cause and then solve those problems in compliance with GMP. Moreover, they must be followed up through the special inspection by GMP inspectors of the DCD. On the other hand, the

importers must be punished also if the quality of their imported medicinal products was failed, and then the recall process should be immediately performed.

Nevertheless, FDA has no policy for the abroad on-site GMP inspection at the modern medicinal product manufacturers located in the origin countries where produce those products supplied into the market in Thailand. Besides, the Ministerial Notification of GMP for modern medicinal products does not define the responsibility of the competent authorities as the abroad GMP inspectors. Therefore, the measurement to follow up and control the quality of the imported medicinal products complying with GMP should be thoroughly considered.

Thirdly, the problem of counterfeit and smuggling of illegal medicinal products is one of the most important issues that FDA strongly concerns. Some counterfeit and smuggled medicinal products were found in the market, especially in the pharmacy located in the area for tourism both in Bangkok and other provinces such as Pattaya at Chonburi and Samui Island at Suratthani. Those illegal medicinal products would be presented as the picture with the details for observation in the website of FDA, in order to pass on the necessary information to the consumer.

Although there has some informal information indicated that most of illegal medicinal products usually be passed or imported into our country at the countryside boundaries without the formal port of entry under control of FDA, it still be difficult for the FDA officers to ensure that which place that those products will be transferred and when it happens. Therefore, this is one of the limitations of the measurement for solving these problems.

Only the post-marketing surveillance system for the modern medicinal products supplied in the market is not adequate. In addition, the importing system for modern medicinal products should be improved as more effective barrier, in order to detect the illegal medicinal products prior to be imported and distributed in our country.

In 2009, the smuggling of illegal medicinal products could be detected at the port(s) of entry[3]. For example, the Import and Export Inspection Division had announced through the media that an importer who carried the goods from Singapore but had no the license for importation of modern medicinal products issuing by FDA

was arrested on October 2, 2009 at the cargo of Suvarnnabhum airport together with non-registered modern medicinal products as Tationil® 600 mg/4 ml (contains Glutathione as the active ingredient) and its diluents in the amount of 1,000 boxes (1 box contains 1 vial of Tationil® and 1 ampoule of diluents) shown in below figure 1.3. This activity could be achieved because of the cooperation among relevant organizations, especially authorized persons from FDA and Customs.

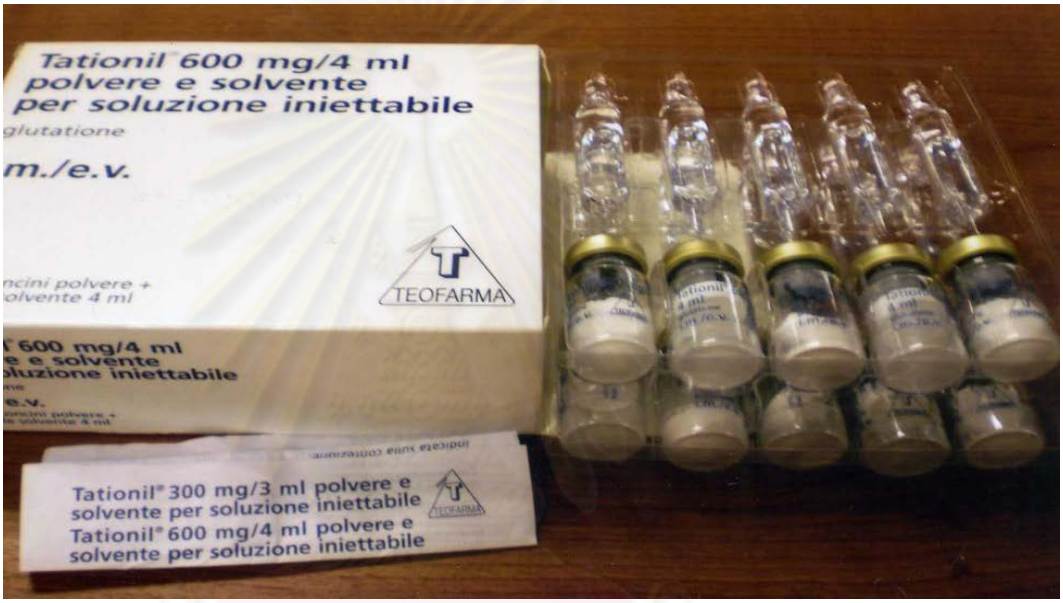

Figure 1.3 Non-registered modern medicinal products found at cargo of Suvarnnabhum airport on October 2, 2009

Nonetheless, most of activities that FDA by the Import and Export Inspection Division must perform are usually executed only as the corrective action which will correct and solve the problem case by case according to the content mentioned in the Drug Act B.E.2510 (1967). Although some specific requirements such as the procedure for importing approval has been followed in the present time, the additional preventive activities should be also set up and then performed to improve the importing system for modern medicinal products to get more effectiveness.

Therefore, to improve and increase the effectiveness of the importing system for modern medicinal products, all factors affecting the system should be identified and analyzed to know what the current situation of the system, and then the

appropriate strategies should be synthesized to improve the system performance. Furthermore, the result of this study should be proposed as the possibly practical measurement to FDA for consideration, and used as a guide for strategic development to improve the importing system for modern medicinal products respectively.

1.2 Significant of the problem

Modern medicinal product is much more useful for the patient who needs the effective treatment to relieve the symptom of diseases. All of those should have more sufficient quality, safety, and efficacy. Therefore, the Food and Drug Administration, the government organization responsible for controlling and monitoring all modern medicinal products being marketed in the country has required that all stakeholders who wishes to sell, manufacture or import modern medicinal products must obtain a license and the marketing authorization.

The trend for comparison between the importing and manufacturing value during B.E.2544 – 2550 shown that the importing value become greater than the manufacturing value. It may be assumed that the quantity of modern medicinal products for patient used in Thailand will increase, and the patients may have to pay more money for their medical services, including the rising cost of medicines. Thus the importing system for modern medicinal products should be strictly performed and consistently strengthened to ensure the quality and safety of those medicinal products.

Besides, there is the information in “Safety Alert” related to the test results of the modern medicinal products which were taken sample from the local manufacturer, importer as well as the pharmacy regarding to annually sampling plan shown that some imported modern medicinal products are sub-standard products and must be recalled. Since FDA has no policy for the abroad on-site GMP inspection at the modern medicinal product manufacturers at the origin countries and does not define the responsibility of the competent authorities as the abroad GMP inspectors in the law, the measurement to follow up and control the quality of the imported medicinal products complying with GMP should be thoroughly considered.

In addition, the problem of counterfeit and smuggling of illegal medicinal products is one of the most important issues that FDA strongly concerns. As only the post-marketing surveillance system for the medicinal products supplied in the market

is not adequate, the importing system for modern medicinal products should be more effective barrier to detect the illegal medicinal products prior to be imported and distributed in our country.

Therefore, this study will be performed to identify and analyze all factors affecting the importing system for modern medicinal products, and to synthesize the appropriate strategies to improve the system performance respectively.

1.3 Objectives

1. To analyze the current importing system for modern medicinal products.
2. To synthesize strategies to improve the performance of the importing system for modern medicinal products.

1.4 Expected contributions

1. Information and knowledge concerning factors affecting the effectiveness of the importing system for modern medicinal products could be used to improve the system performance.
2. The strategies to improve the importing system for modern medicinal products could be implemented as a part of the system infrastructure.

1.5 Research question

1. What are the problems of the importing system for modern medicinal products? and what is the magnitude of those problems?
2. Which factors affect the effectiveness of the current importing system for modern medicinal products?
3. Which approaches should be applied for improving the importing system for modern medicinal products?

1.6 Scope

The importing system that will be analyzed and synthesized the strategies for in this study covers only the importation of modern medicinal products being distributed for sale into the market. The study would include the importation process taken place at the port of entry by the Customs and the Import and Export Inspection Division of FDA.

1.7 Definition terms

1.7.1 Importing system

The system which has been established for the importation of medicinal products, particularly modern medicinal products, in order to control the process of importation in accordance with the relevant laws and regulations e.g. Customs' laws, FDA's laws, Commercial laws. There are several involved organizations in this system as

1) FDA : - Drug Control Division (DCD)
- The Import and Export Inspection Division
- The Legal Affairs Group

2) Customs

3) The Department of Medical Sciences (DMSc)

4) The Department of Foreign Trade, the Ministry of Commerce

The process of importing system

The importation of all kinds of products should follow the laws of the Ministry of Commerce. The contents of those laws mention that each product could be imported into the Kingdom of Thailand if the company or the importer completely follows the specific requirements or laws established to control that product.

In case of the modern medicinal product, it is required for an allowance from FDA. Any persons who wish to import the medicinal products into the Kingdom must obtain a license and the product registration of each product from the licensing authority as the DCD, one of the divisions under control of FDA.

<u>Company: Importers</u>

→ Licensing

- the license for importation of modern medicinal products must be approved by DCD under FDA.
- if the importer is a company, not a person, it is required for permission from the Ministry of Commerce to be a justice person.

Products: Modern medicinal products

→ Registration

- approval & issuing the product registration by DCD under FDA.

After that the importation of modern medicinal products should be followed each step of the process for approval. The overview of the relationship among all relevant organization in the importing system for imported modern medicinal products can be summarized base on its own responsibility and requirements in each step.

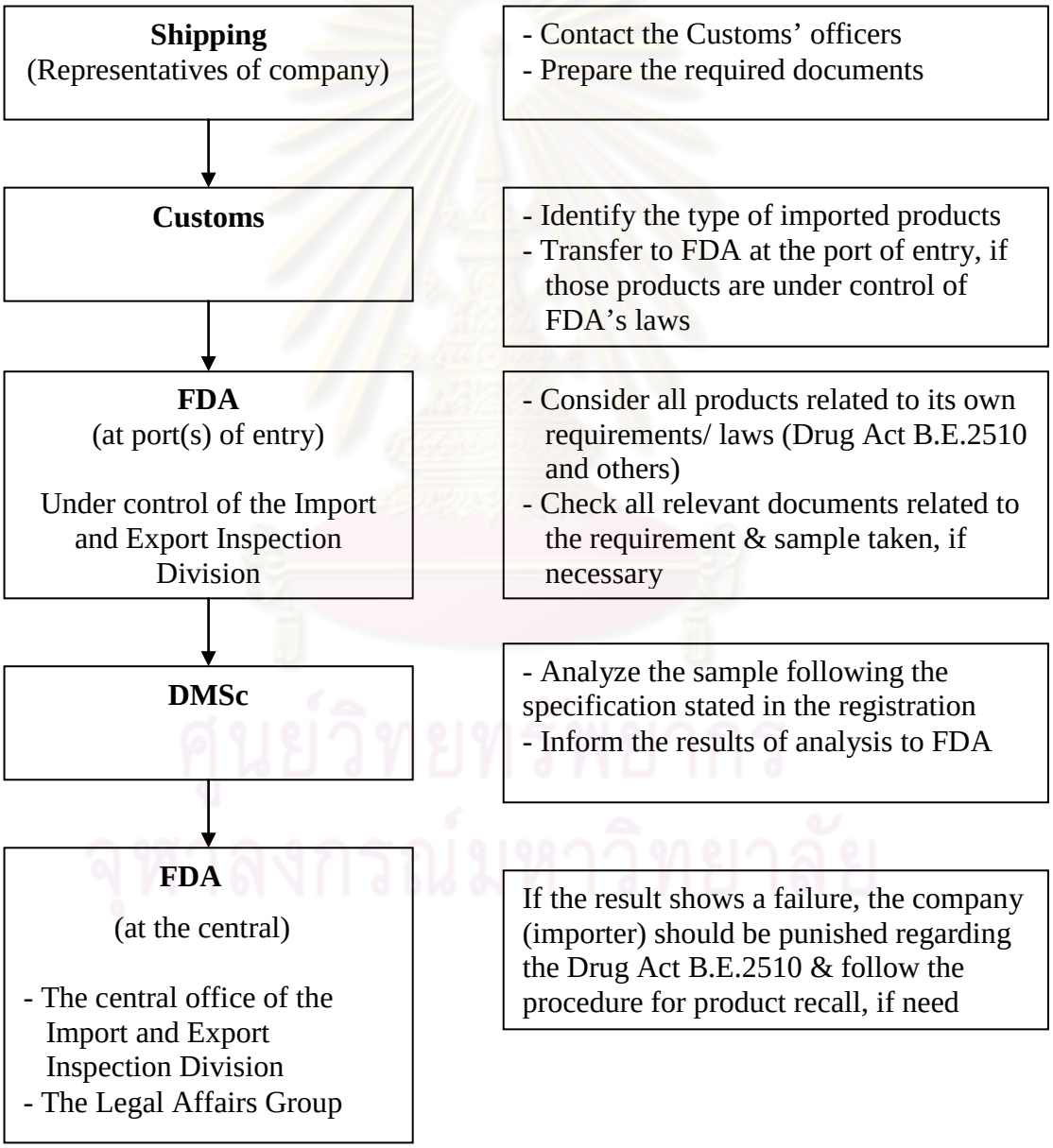

Figure 1.4 Relationship among involved organizations in the importing system for imported modern medicinal products

The post-marketing surveillance for the imported medicinal products

When the modern medicinal products have already been imported and distributed in the market, FDA will emphasize on the monitoring and controlling those products to ensure their quality and safety. **The Inspectorate Unit**, the post-marketing surveillance unit which is one of the units under control of the DCD of FDA is the main organization to be responsible for those purposes.

There is the annual sampling plan that mentions on the sampling of modern medicinal products in the market, including the medicinal products which was produced by local manufacturers and also imported from abroad. After sampling and sending those medicinal products to DMSc in order to test the quality of products, if the result presents that the failure was found, the owner who manufactures or import those medicinal products should be punished according to the Drug Act B.E.2510 as well as following the procedure for product recall respectively.

Besides, all other cases of the violation of the Drug Act B.E.2510 should be investigated and proposed for the prosecution by the officers of the Inspectorate Unit.

1.7.2 Modern medicinal product/ medicinal product = Modern drug

1.7.2.1 A definition regarding the Drug Act B.E.2510: "a drug intended for use in the practice of modern medicine or the cure of an animal disease" [4].

1.7.2.2 This study mentions on finished products only, not include the active pharmaceutical ingredients (APIs) or other chemicals.

1.7.3 Illegal medicinal products: cover all types of drug stated in Section 72 of the Drug Act B.E.2510[4] as follows;

1.7.3.1 Counterfeit/ fake drugs

Definition:

1) A drug or substance which is wholly or partly an imitation of a genuine drug

2) A drug which shows the name of another drug, or an expiry date which is false

3) A drug which shows a name or mark of a producer, or the location of the produce the drug, which is false

4) Drugs which falsely show that they are in accordance with a formula which has been registered

5) Drugs produced with active substances which quantity or strength are lower than the minimum or higher than the maximum standards prescribed in the registered formula by more than twenty percent

1.7.3.2 Sub-standard

Definition:

1) Drugs produced with active substances which quantity or strength are lower than the minimum or higher than the maximum standards prescribed in the registered formula to a degree less than twenty percent

2) Drugs produced so that their purity or other characteristics which are important to their quality differ from the standards prescribed in the registered formula or drug formulas which the Minister has ordered the drug formula registry

1.7.3.3 Deteriorated

Definition:

1) A drug the expiry date of which as shown on the label has been reached

2) A drug which has so denatured as to have the characteristics of a fake drug or a drug differing from the standard

1.7.3.4 Non-registered

Definition:

A drug which has not been registered

1.7.3.5 Formula registration cancelled

Definition:

Drugs whose formula registration has been cancelled for the licensee to produce drugs and licensee to import drugs into the Kingdom or drugs which the drug formula registry has been withdrawn for more than 6 months for the licensee to sell drugs

1.7.3.6 Withdrawn resulting from the minister's order

Definition:

Drugs whose formula registration has been ordered cancelled by the Minister

CHAPTER II
LITERATURE REVIEW

The importing system for modern medicinal products is the processes for importation of modern medicinal products from abroad in accordance with all relevant laws and requirements. Many organizations are involved in the importing system for modern medicinal products, and their responsibilities are different in each step of the process for importation approval. To achieve the objectives of this study, the appropriate theories; furthermore, should be used as a guide for situation analysis and as a tool for synthesizing the reasonable strategies to improve the performance of the importing system for modern medicinal products.

2.1 Organizations involved in the importing system

All organizations involved in the importing system for modern medicinal products consist of

2.1.1 Food and Drug Administration (FDA)

2.1.1.1 Drug Control Division (DCD)

a) The Pre-marketing Control Unit

b) The Inspectorate Unit (The Post-marketing Control Unit)

2.1.1.2 The Import and Export Inspection Division

2.1.1.3 The Legal Affairs Group

2.1.2 Customs

2.1.3 Department of Medical Sciences (DMSc)

2.1.4 Department of Foreign Trade, the Ministry of Commerce

2.1.1 The Food and Drug Administration (FDA)

The Food and Drug Administration (FDA) is one of the organizations under control of the Ministry of Public Health. The main role of the Thai FDA is to protect consumers' health, especially, to ensure safety, quality and efficacy of health products which include foods, drugs, psychotropic substances, narcotics, medical devices, volatile substances, cosmetics and hazardous substances available in the country, in accordance with national legislation and international agreements.

Vision[5]

The vision of the Thai FDA focuses on the increasing consumers' confidence in health products. It states that

"By the year 2007, the FDA will be the principal and most trusted organization in Thailand in public health protection by ensuring the quality and safety of health products and promoting proper consumer behavior through reliable scientific evidence and appropriate technology."

Mission[6]

1. Regulate and monitor health products to meet quality and efficacy standards.

2. Promote Good Manufacturing Practice in the production and quality control of health products to ensure consumer safety and to encourage exports.

3. Research and develop the effectiveness of the consumer protection system for health products.

4. Promote and support the capability of health product consumers and society to be able to protect themselves and be self-reliant.

5. Encourage and enable all stakeholders and non-government parties to share in the consumer protection role.

There are three main divisions involving in the importing system for modern medicinal products as followed;

2.1.1.1 Drug Control Division (DCD) [7]

The Drug Control Division (DCD) has set a vision as an institute with reliability and good reputation in consumer protection. The public is thus assured of accessibility to safe and efficacious marketed pharmaceutical products of standard quality, to reliable and adequate information, and to advance technology. The Division promotes the production capacity of local pharmaceutical industries to the extent that they are able to export medicines of standard quality.

The Division carries out its mission in consultation or cooperation with experts in science, medicine, pharmacy and public health, consumers, manufacturers, importers, distributors and retailers of drugs. It works closely with several other organizations (e.g. universities, industries, hospitals, health-care professional groups,

consumer groups, other relevant agencies and foreign governments) in the drug development and review processes.

National Drug Policy

1. Availability and accessibility of quality drugs, in term of therapeutic efficacy and safety to all at reasonable prices.

2. Encouragement on rational use of drugs in such a way that losses, shortage and over- consumption of drugs are minimized.

3. Upgrading and promotion of domestic pharmaceutical industry, leading toward self-reliance with particular emphasis on research and development as well as production for export.

4. Advocating on locally manufacturing of raw materials from locally available resources for local supply and for export.

5. Support of technical studies, research and development activities on disease prevention, general health care and potential therapeutic efficacy, safety and efficient utilization of herbs, herbal medicines, and traditional medicines.

6. Campaign on recognition and adoption of the National Essential Drug list in both government and private sectors.

7. Improvement of efficiency in legislative administration, strengthening on enforcement of laws, rules and regulations on drugs in favor of consumer protection.

a) The Pre-marketing Control Unit

The responsibilities of this unit consists of to control the manufacturing, importing, and drugstore facilities and to control product qualities before the production, importation or to launch the product to the market complying with laws and requirements. Two main activities of this unit as followed;

a.1) Licensing

The applications for licenses must be submitted to the licensing authority, and then the buildings and facilities will be inspected. A license will be issued after the inspection has confirmed that the applicant has adequate capabilities of doing such business, and he/she can secure appropriate facilities and personnel for that purpose.

a.2) Registration

The registration process is necessary to ensure quality, safety and efficacy of the drugs being marketed in the country. Only authorized licensees are qualified to apply for product registration.

b) The Inspectorate Unit (The Post-marketing Control Unit)

This unit is responsible for monitor and/or surveillance the facilities, product qualities which are available in the market to comply with the laws and requirements. Moreover, the activities concerning the importing system for modern medicinal products are composed of;

b.1) To take sample of imported medicinal products according to the annual sampling plan.

b.2) To ask company to follow the procedure of product recall, if the results of analysis are failed.

b.3) To follow the Drug Act B.E.2510 when the violation occurs, for example;

b.3.1) Post-marketing surveillance (on-site at the company) e.g. the retained sample was not kept in the adequate quantity, the reports of medicinal importation were not prepared and submitted to FDA regarding the requirement in law

b.3.2) Special cases e.g. the complaints informed by consumers about the quality of imported medicinal products which were distributed in the market

2.1.1.2 The Import and Export Inspection Division

The Import and Export Inspection Division is one of the organizations under control of FDA, the Ministry of Public Health. Its responsibility is to control the product quality and the process of importing for health products i.e. drug, food, narcotic, medical devices, cosmetic, and hazardous substances from abroad to Thailand regarding to the relevant laws[8].

Responsibilities [8]

1. To control the importation and exportation of health products at the port(s) of entry, in accordance with the relevant laws and requirements.

2. To investigate and follow the relevant laws in case of health products' smuggling and also to work together with other agencies to solve the narcotics problems.

3. To consider for approval of importation of health products.

4. To research and develop the standard for controlling the importation and exportation of health products to comply with the international standards.

5. To let the consumers understand more about the necessary information as well as the appropriate suggestion for the importation and exportation of health products.

6. To collaborate with or encourage the performance of other relevant agencies.

Current checkpoints or ports of entry [8]

To service the importers to gain more convenience to request for importing approval, and also to detect the smuggling of illegal products, the Import and Export Inspection Division has already established totally 35 checkpoints (ports of entry) covering all parts of Thailand.

Coordination with Other Agencies [9]

Without good working relationship among relevant agencies, effective import control cannot be achieved. There are many people involved in the process – officials from other divisions of the FDA, the Department of Medical Sciences (DMSc), the Customs, etc.

In addition, inputs from private companies are helpful in enhancing the efficiency of the work process at the checkpoints. One of the things to keep in mind is that "procedures taken at the checkpoints or ports of entry should not be too lengthy and burdensome to decent importers"

Strategies [8]

Furthermore, the Import and Export Inspection Division has the advance strategies for the importing control system as follows;

1. To check the merchandise (especially health products) packed in the containers, to ensure that there has no any illegal products hiding in the containers.

2. To take sample to analyze by DMSc and itself, only at the port(s) of entry where has the test equipment such as the test kits and IR spectrophotometer.

3. To detect the illegal health products prior to be imported and distributed in our country, and then do the prosecution according to the relevant laws respectively.

In conclusion, the activities of this division concerning the importing system for modern medicinal products consist of;

1. To check the imported medicinal products at the port(s) of entry

1.1 Physical/ Appearance of the products

1.2 Relevant documents as required e.g. the license to import the modern medicinal products, invoices, certificate of analysis

2. To take sample of the medicinal products being imported according to the annual sampling plan

2.1.1.3 The Legal Affairs Group

Most of persons who work for this unit are graduated for Bachelor in law. It is responsible for following the process of penalty stated in the Drug Act B.E.2510 if the violation of the laws was found and detected by the above two divisions, DCD and the Import and Export Inspection Division.

2.1.2 The Customs

When the medicinal products are imported through the port of entry, the Customs' officer will decide and transfer those products to the port of entry under control of FDA. After finishing of the approval process at FDA's port of entry, the revenue and tax rate according to the standard customs tariff will be defined and must be paid at the customs.

Furthermore, the Customs' requirement must be thoroughly followed. Each importer who would like to import all merchandises should understand the process for importing approval. A standard customs tariff always defines what kind of imported merchandises should be paid for the revenue in which rate. A tariff can be changed according to the agreement among the membership of AFTA [10].

Regarding to the contents of Customs' law, there has no any regulation to prohibit the importation or exportation. If any merchandises; therefore, must be

prohibited or particularly controlled in accordance with relevant laws, the Customs requires all importers have to follow those laws absolutely. Besides, some kinds of imported products must be approved to import or export by the officers who are responsible for, due to the relevant laws. If anyone does not follow this requirement, it means that one has already infringed the specific law for those products and also the Customs' law[10].

2.1.3 The Department of Medical Sciences (DMSc)

The major responsibility of DMSc concerning the importing system for modern medicinal products is to test or analyze all samples of medicinal products taken by FDA, and then reply its results to FDA, in order to make a decision complying with the contents of Drug Act B.E.2510.

2.1.4 The Department of Foreign Trade, the Ministry of Commerce

The importation of all kinds of products should follow the laws of the Ministry of Commerce. The contents of those laws mention that each product could be imported into the Kingdom of Thailand if the company or the importer completely follows the specific requirements or laws established to control that product [11].

For instance, the modern medicinal products are required for an allowance from the FDA, the organization that one of its responsibilities is to control the importation of those products. Moreover, some kinds of products such as the medicinal products, active pharmaceutical ingredients (APIs), salts of APIs, and semi-finished APIs has been defined in the laws for controlling the importation and exportation B.E.2522 that those products must have the product registration issued by FDA, and the importer should request the confirmation letter from FDA as one of the important documents submitted when those products are imported.

2.2 Laws and requirements

2.2.1 FDA's law[4] [12] [13] [14]

The important laws to control the importation for modern medicinal products consist of the Drug Act B.E.2510 and other Ministerial Regulations and Ministerial Notifications in accordance with contents in the Drug Act B.E.2510 as follows:

1. The Drug Act, Section 12: No person shall produce, sell or import the modern medicinal products into the Kingdom, unless he has obtained a license from the competent authority.

2. The Drug Act, Section 13(4) and 13(5): define that there has some exceptions for importation stated in Section 12 (the license for importation is not required) as in case of

2.1) Section 13(4): carrying the medicine for individual with an adequate amount to use for 30 days treatment, and also

2.2) Section 13(5): the importation by ministries, public bodies and departments which have a duty to prevent or treat disease, and by the Thai Red Cross, and pharmaceutical organization such as the Government Pharmaceutical Organization.

3. The Drug Act, Section 27: defines a duty of persons licensed to import modern medicinal products.

4. The Drug Act, Section 27 bis: All imported modern medicinal products should be thoroughly checked by the officers at each port of entry.

5. The Drug Act, Section 72: defines that no person shall produce, sell or import an illegal medicinal products into the Kingdom as follows;

5.1 Counterfeit/ fake drugs

5.2 Sub-standard

5.3 Deteriorated

5.4 Non-registered

5.5 Formula registration cancelled

5.6 Withdrawn resulting from the minister's order

6. The Drug Act, Section 79: Any person licensed to produce or import modern medicinal products or traditional medicines is required first to apply to the competent authority for registration of the formula. Upon receipt of a certificate of formula registration, those products can be produced or imported.

7. The Drug Act, Section 79 bis: defines that there has the exception of Section 79 for the samples that have received permission to produced or import into the Kingdom for application to register formula in accordance with the rules, regulations and conditions prescribed in Ministerial regulations.

8. The Ministerial Regulation No.14 (B.E.2532): defines the criteria and conditions for the imported medicinal products without formula registration required i.e. the importation for research, analysis, exhibition arrangement, and donation purposes [12].

9. The Ministerial Regulation No.16 (B.E.2525): defines the responsibilities of the licensee for importation of modern medicinal products as well as the required documents e.g. the format of application form and license, the lists of medicinal products which were imported and sold, the annual report which must be submitted to the competent authority[13].

10. The Ministerial Notification for establishment of port(s) of entry: defines the formal port(s) of entry of the Import and Export Inspection Division [14].

Nevertheless, there are some problems about an interpretation of the relevant laws; for instance, the contents in the Drug Act B.E.2510, Section 13(4): The license for importation of modern medicinal products has not been required for the person carrying the medicine for individual with an adequate amount to use for 30 days treatment. Some persons said that the intention of the Drug Act B.E.2510 should be thoroughly considered. The Drug Act intended to strictly control only the modern medicinal products imported for sale or for commercial benefits, and using for the majority of people. However, the importing of modern medicinal products in the less quantity, with the purpose of individual treatment might except to request for the license approval [15].

Nonetheless, some patients tried to import the modern medicinal products for their own treatment but did not carry with them who need to use those medicinal products. In some cases, most of people usually tried to carry the modern medicinal products using for treatment of chronic diseases, and sometimes those medicinal products were never supplied in our country. According to these cases, they must apply for approval of importation license following the content mentioned on the Drug Act, Section 12[15].

2.2.2 Custom's law

The main law of the Custom to control the importation and exportation for all kinds of products including health products is the Customs Act B.E. 2543, and the

additional procedures for importation and exportation approval must be followed. The imported products will be identified by the Customs' officer in accordance with the specific laws or requirements for those products, and then distributed to the office of each responsible organization's office at the port of entry.

2.2.3 Commerce's law

The Ministry of Commerce requires the importer who will import all kinds of products into the Kingdom of Thailand to follow the specific laws or requirements for each product issuing by the responsible organization.

Furthermore, all importation and exportation should be strictly followed the requirements stated in the international agreements e.g. Free Trade Agreement (FTA), ASEAN Free Trade Area (AFTA), Asia-Pacific Economic Cooperation (APEC), Ayeyawady - Chao Phraya - Mekong Economic Cooperation Strategy (ACMECS).

2.3 Process for importation approval

The procedure for how to check and control the importation and exportation of health products described the workflow how to consider and approve for importing of the health products, including the modern medicinal products. Furthermore, there are other procedures that describe in-depth details about the process for approval of importation of each health products e.g. modern medicinal products. The below diagram is the overview of workflow for the approval of importation of health products, including modern medicinal products.

The workflow shows each step in the process of importation approval. The first process is to identify the kind of imported products and issue the relevant documents by the Customs' officer. Then those products should be delivered by the shipping, a representative of the importer to the office at the port of entry of the other organizations responsible to control those imported products. For example, the modern medicinal products being imported must be transferred to the port of entry of FDA to consider for the compliance with FDA's law, the Drug Act B.E. 2510 and relevant laws, and also taking sample if needed. After that those medicinal products should return to the process for tax calculation, punishment if the law violation occurred and/or other processes as required before the importation approval by the Customs respectively.

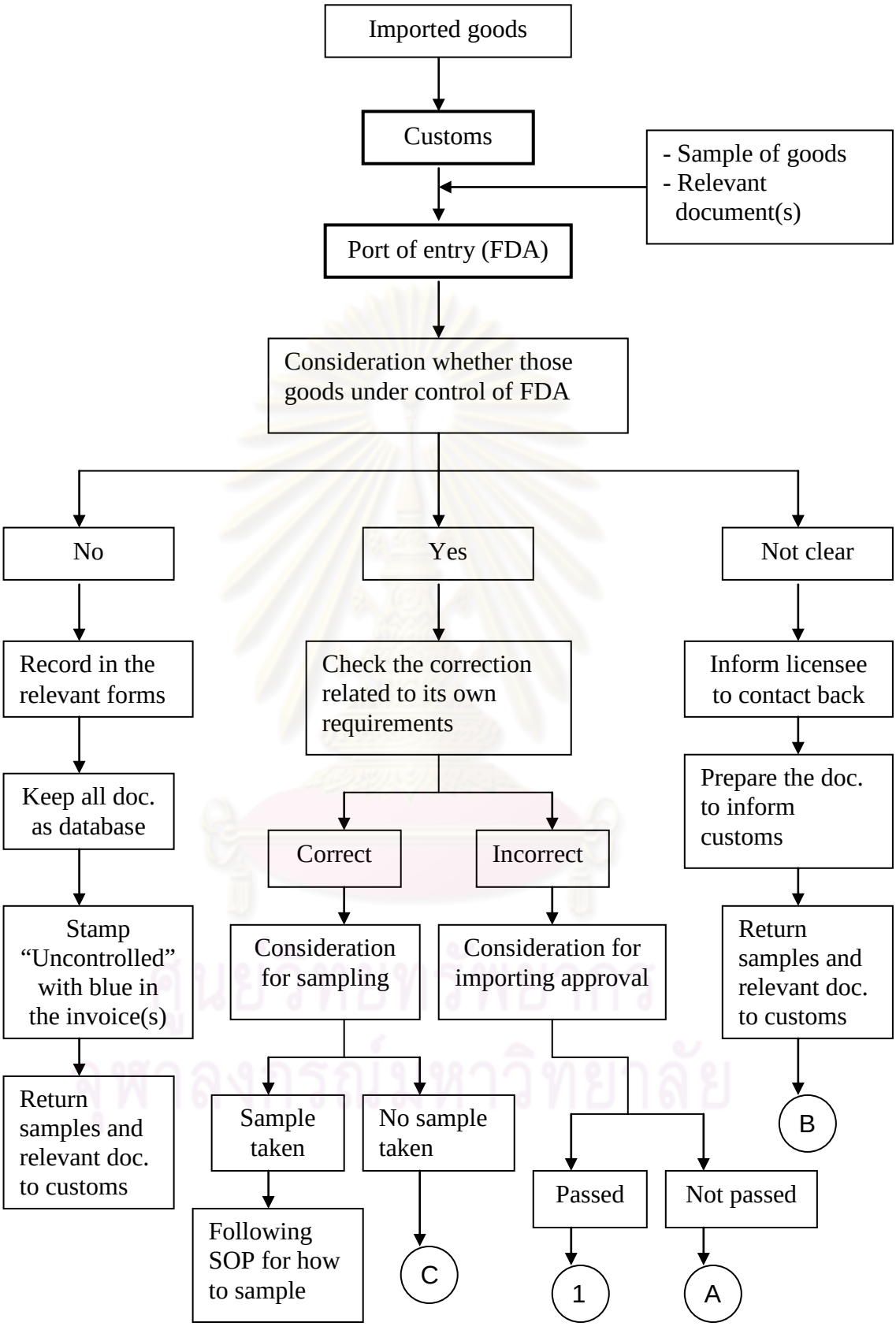

Figure 2.1 Workflow of importation approval for the health products, including the modern medicinal products

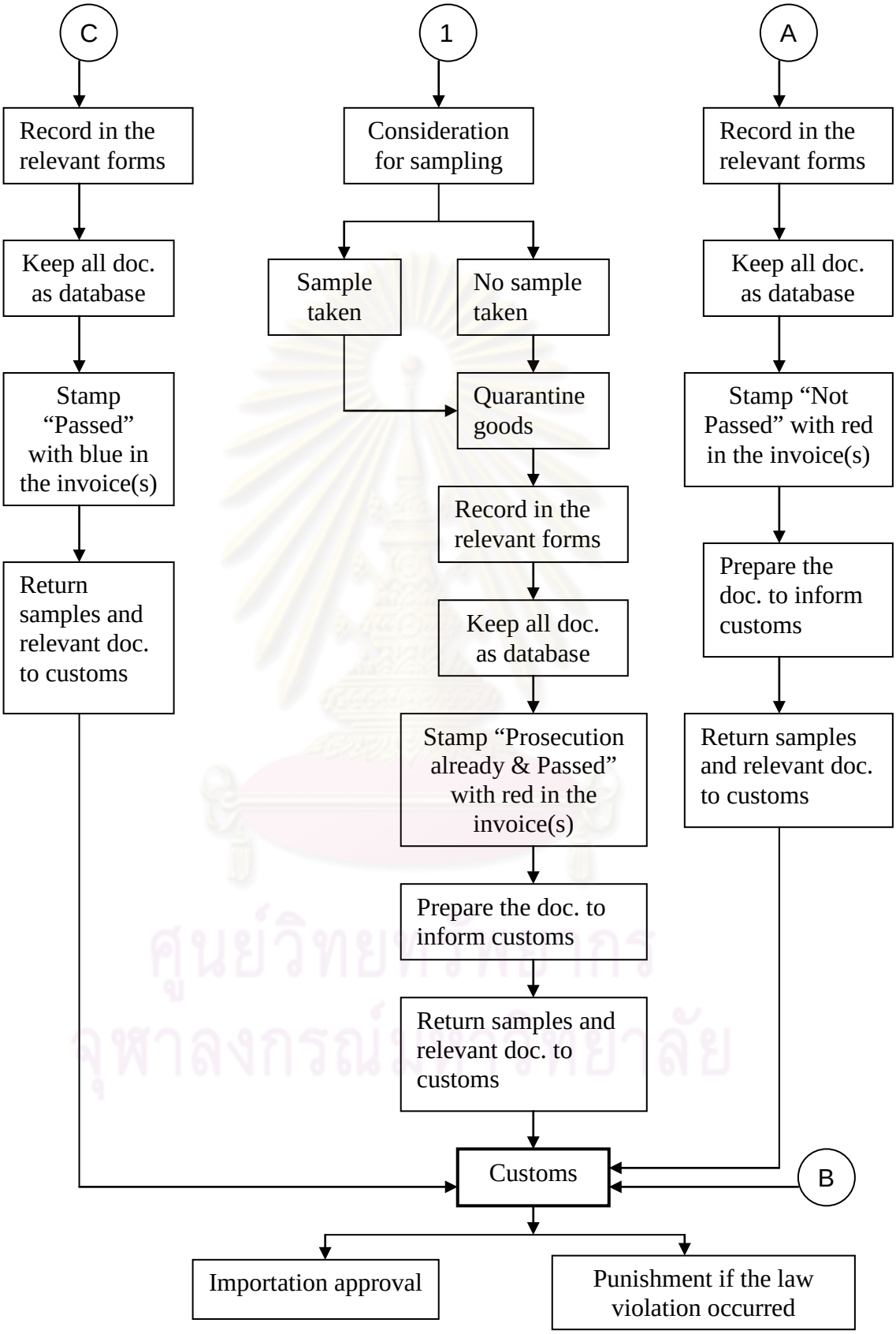

Figure 2.1 Workflow of importation approval for the health products, including the modern medicinal products (cont'd)

2.4 Theories used in this study

To achieve the objective of this study as to identify and analyze the factors affecting the importing system for modern medicinal products, the researcher decided to select the theory that mentions on which factor in the system should be identified. The main theory that the researcher has chosen is the Host Tor's Theory (1997): "The Organizational Pyramid". Besides, the Keidel's Theory (1995): "Seeing Organizational Patterns" and PEST Model will be used as the additional theory to identify the elements stated in the main theory as culture and environment respectively.

2.4.1 Host Tor's Theory (1997) : *"The Organizational Pyramid"* [16]

This theory focuses on identifying elements of an organization and be suitable for both managers and researchers to show relationships among organizational elements and their effects.

Normally, every organization consists of a consistent set of elements. Each organization usually has the different set of elements. Those elements are interdependent, so changing one has implications for others. Therefore, the researcher should concern about the nature and relationship among these elements.

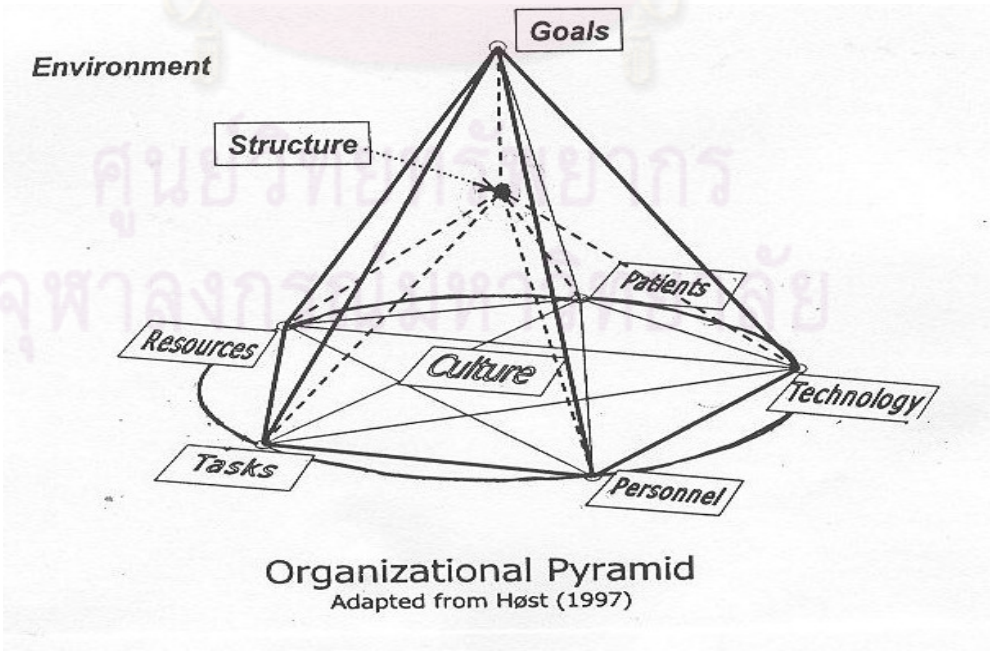

Figure 2.2 Host Tor's Theory (1997): The Organizational Pyramid

The main elements of the Organizational Pyramid are composed of;

1. Goals: What the organization aims to achieve
2. Structure: How elements are brought together
3. Resources: money plus lots more
4. Tasks: What is done
5. Technology: Physical (e.g. drugs, computers) and social (e.g. workflow)
6. Stakeholders: care recipients and participants
7. Personnel: Who does it
8. Culture: Collective values & beliefs of members
9. Environment: The organization's "sea"

Nevertheless, the limitation of Host Tor's Theory (1997) is that the organizations usually have many elements that interrelate with one another. Managers and researchers may design the changes without clear understand of what elements have been targeted or how those elements relate to other elements of the organization. That means the elements that the researcher must identify may not cover all above in the Organizational Pyramid. Only a few elements that have most affectation on the importing system for modern medicinal products should be mainly concerned and emphasized on as the first priority.

In addition, the pattern of the Organizational Pyramid is very useful for the researcher to identify the importing system for modern medicinal products following each element mentioned on Host Tor's Theory (1997) and use this theory as a guide to consider the system performance in the correct way, in order to achieve the objectives of this study.

The researcher has to review the written materials such as the standard operation procedures, records, laws and requirements, the technical documents, and the information uploaded on the website prepared by the organizations involved in the importing system i.e. FDA, Customs, DMSc and the Department of Foreign Trade, the Ministry of Commerce. After that the contents which are associated with the objectives of this study must be selected relating to each element of the Host Tor's Theory (1997). Moreover, some issues such as the culture of the organization involved in the importing system should be identified by using the alternatively additional

theory as Keidel's Theory (1995). And then the current situation analysis could be performed more effectively.

2.4.2 Keidel's Theory (1995) : "Seeing Organizational Patterns"

This theory emphasizes on the models of relationships within organizations. There are three basic forms of relationships in every organization as *control, cooperation and autonomy*. Each of those forms has important implications for an organization's structure and for its functioning. This theory can help managers to "see" their world & alternatives. Nonetheless, the different organizations usually focus on all basic forms of relationship in different degrees.

"*Seeing Organizational Patterns*" was provided by Robert W. Keidel, Ph.D., the principal of Robert Keidel Associates, based in Wyncote, Pennsylvania. A former senior fellow at The Wharton School, he works with major corporations, government agencies, and professional service firms as a consultant and an educator in organizational design and change [17].

Robert W. Keidel explained that most organizational issues are a balance of three variables: individual autonomy, hierarchical control, and spontaneous cooperation. It is a new prism for viewing organizational design that is neither simplistic nor unduly complicated. Moreover, *Seeing Organizational Patterns* converts organizational design into an art form of triangular patterns. It is a set of conceptual lenses that enables us to see organizations more clearly, systematically, and imaginatively than ever before.

In *Leadership and the New Science*, Margaret Wheatley argues that since nature consists essentially of relationships, it stands to reason that human organizations do as well. To take this idea a step further, *organizational design* may be defined as *the purposeful specification of relationships.* Organizations are inherently triadic because there are only three ways in which people can relate, without conflict, to each other – patterns that correspond to the three core design variables identified above: autonomy, control, and cooperation [18] as presented in figure 2.3.

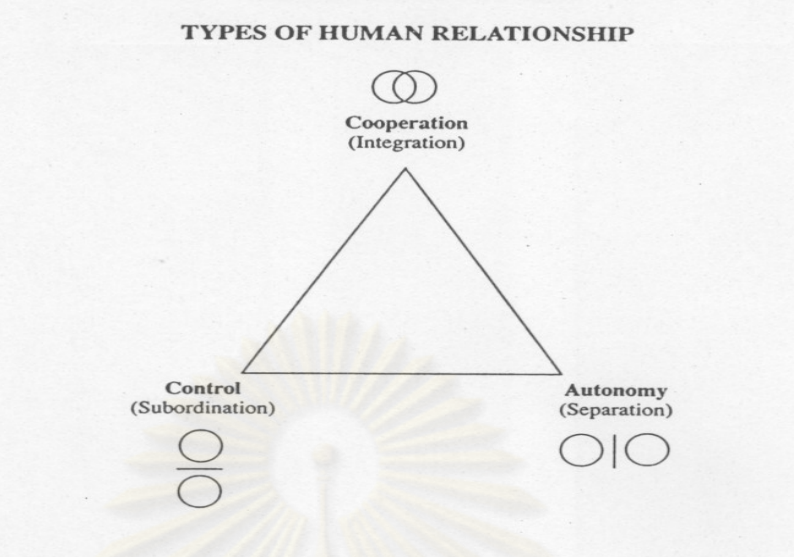

Figure 2.3 Type of Human relationship

Buckminster Fuller argues that nature has an underlying triangular structure: "Everything that you have ever recognized in [the] Universe as a pattern is re-cognited as the same pattern you have seen before. Because only the triangle persists as a constant pattern, any recognized patterns are inherently recognizable only by virtue of their triangularly structured pattern integrities. Recognition is as dependent on triangulation as is original cognition. Only triangularly structured patterns are regenerative patterns. Triangular structuring is a pattern integrity itself. This is what we mean by structure." [19]

Triangular design applies Fuller's perspective to human organization. It reflects Margaret Wheatley's conviction that "If nature uses certain principles to create her infinite diversity, it is highly probable that those principles apply to human organizations." Triangular design thus provides a way to balance – and continuously rebalance – any organization across multiple dimensions, each of which incorporates the autonomy/ control/ cooperation triad [18].

Organizational Design Profile [17]

1. Organizational strategy answers three fundamental questions: (1) *why* an organization exists, (2) *what* it is, and (3) *how* it competes. These respective issues are prior to those of organizational *structure* and *systems*. In other words, structure and systems are properly regarded as means for realizing organizational strategy.

Nevertheless, an organization may address issues of strategy, structure, and systems in any order – depending on its unique needs, opportunities, and inclinations.

Table 2.1 Organizational Design Profile: *Strategy*

Strategy	**Autonomy**	**Control**	**Cooperation**
Constituencies (for whose benefit does this org. exist?)	Customers/ Clients	Shareholders/ Subsidizers	Employee
Character (What is our essential nature?)	Player-oriented	Coach-oriented	Team-oriented
Capabilities (How do we compete?)	Differentiation (special)	Cost (affordable)	Flexibility (adaptable)

2. Organizational structure is the hard wiring of design. It – or, more often, part of it – is what one – variable thinkers typically have in mind when they conceive of organizational design. Indeed, "structure" for most corporate managers is typically that which is both concrete and clearly visible – the boxes and lines (and levels) that form the organization chart, the physical layout and location of various people and organizational units, and/or the actual work flow.

Table 2.2 Organizational Design Profile: *Structure*

Structure	**Autonomy**	**Control**	**Cooperation**
Organization chart (What is the form of our reporting relations?)	Flat/ Clear	Steep/ Clear	Flat/ Amorphous
Layout (What physical interaction does our design encourage?)	Independent action	Programmed interaction	Spontaneous interaction
Interdependence (How does our work/information flow?)	Pooled	Sequential	Reciprocal

3. Organizational systems constitute the soft wiring of design. They are the less visible aspects that nonetheless play a crucial role in determining organizational behavior and performance. Indeed, given the choice of manipulating either structure or systems, most experienced organizational consultants would probably choose the latter.

Table 2.3 Organizational Design Profile: *Systems*

Systems	**Autonomy**	**Control**	**Cooperation**
Reward system (What behaviors are reinforced financially and non-financially?)	Individualistic	Hierarchic	Mutual
Meeting system (for what reasons do people get together?)	Forum	Decision-making	Team-building
Decision system (How do we exercise authority?)	Decentralized (delegate)	Centralized (mandate)	Shared (collaborate)

The concept of triangular design has three features that go to the heart of management and organization – and language: incompleteness, integration, and stickiness. Triangular design is forever incomplete because there will always be new aspects of organization to pattern – as well as other ways to pattern existing aspects.

The situation analysis is very necessary for the researcher to understand more about the current situation, background, history, operation process, normal practices of the personnel, strength, weakness and some obstacles affecting the importing system for modern medicinal products. And then the appropriate tools should be selected and used to analyze the factors affecting the effectiveness of the current importing system for modern medicinal products as well as to synthesize the strategies to improve the system performance. The SWOT analysis and SWOT matrix (Confrontation matrix) are suitable to be used as tools for achieving the goals of this study.

2.4.3 SWOT analysis[20] [21] [22]

A SWOT analysis is a tool, used in management and strategy formulation. It can help to identify the Strengths(S), Weaknesses (W), Opportunities (O) and Threats (T) of a particular company.[20]

Strengths and weaknesses are **internal factors** that create value or destroy value. They can include assets, skills, or resources that a company has at its disposal, compared to its competitors. They can be measured using internal assessments or external benchmarking.[20]

Opportunities and threats are **external factors** that create value or destroy value. A company cannot control them. But they emerge from either the competitive dynamics of the industry/market or from demographic, economic, political, technical, social, legal or cultural.[20]

SWOT analysis was developed by the middle of the 1960s for large organizations to determine the strategic fit between an organization's internal, distinctive capabilities and external possibilities and to prioritize actions. SWOT stands for Strengths, Weaknesses, Opportunities and Threats. In the early 1950s, two professors of business policy at Harvard, George Albert Smith and C. Roland Christensen, began questioning whether a firm's strategy matched its competitive environment.[21]

In 1960, a number of large American enterprises commissioned a long range study at Stanford Research Institute to investigate why their long range planning efforts where was unsuccessful. SRI's research team -- Marion Dosher, Otis Benepe, Albert Humphrey, Robert Stewart and Birger Lie -- interviewed 5,000 managers at 1,000 companies over nine years. They found that the difference between what an organization planned to do and what they actually accomplished was about 35%. The problem was not the management team's quality of information, but their ability to reach a committed agreement on constructive objectives rather than settling for feeble compromises.[21]

Part of the team's methodology to make strategic decision making more explicit was to determine what the interviewees found positive and negative about the present and the future. The team developed SWOT for this purpose. The SWOT framework was first described in detail in the late 1960's by Edmund P. Learned, C. Roland Christiansen, Kenneth Andrews, and William D. Guth in Business Policy, Text and Cases.[21]

The acronym's definitions are: [22]

1. Strengths: attributes of person or company that is helpful to achieving the objective(s).

2. Weaknesses: attributes of person or company that is harmful to achieving the objective(s).

3. Opportunities: external conditions that is helpful to achieving the objective(s).

4. Threats: external conditions which could do damage to the objective(s).

Table 2.4 Typical examples of factors in a SWOT analysis diagram [20]

	Strengths	**Weaknesses**
INTERNAL	• Specialist marketing expertise • Exclusive access to natural resources • Patents • New, innovative product or service • Location of your business • Cost advantage through proprietary know-how • Quality processes and procedures • Strong brand or reputation	• Lack of marketing expertise • Undifferentiated products and service • Location of your company • Competitors have superior access to distribution channels • Poor quality of goods or services • Damaged reputation
	Opportunities	**Threats**
EXTERNAL	• Developing market (China, the Internet) • Mergers, joint ventures or strategic alliances • Moving into new attractive market segments • A new international market • Loosening of regulations • Removal of international trade barriers • A market that is led by a weak competitor	• A new competitor in your own home market • Price war • Competitor has a new, innovative substitute product or service • New regulations • Increased trade barriers • A potential new taxation on your product or service

Any organization must try to create a fit with its external environment. The SWOT diagram is a very good tool for analyzing the (internal) strengths and weaknesses of a corporation and the (external) opportunities and threats. However, this analysis is just the first step. To really create the fit with the external environment is often the most difficult work.

2.4.4 PEST Model

PEST analysis stands for "Political, Economic, Social, and Technological analysis" and describes a framework of macro-environmental factors used in the environmental scanning component of strategic management.[23]

The PEST model is decision making model used to measure a market, including competitors from the standpoint of a particular proposition or a business. When used as a tool, is works well to understand market growth or decline, such as potential and direction for a business. It is a model used to measure business, in terms of (P)olitical, (E)conomic, (S)ocial, and (T)echnological factors. The analysis uses four perspectives, in logical construct or matrix format. The format helps the readers to understand, and those using it to easily format and discuss. During its growth and conclusion, it is a tool which simplifies decision-making.[24]

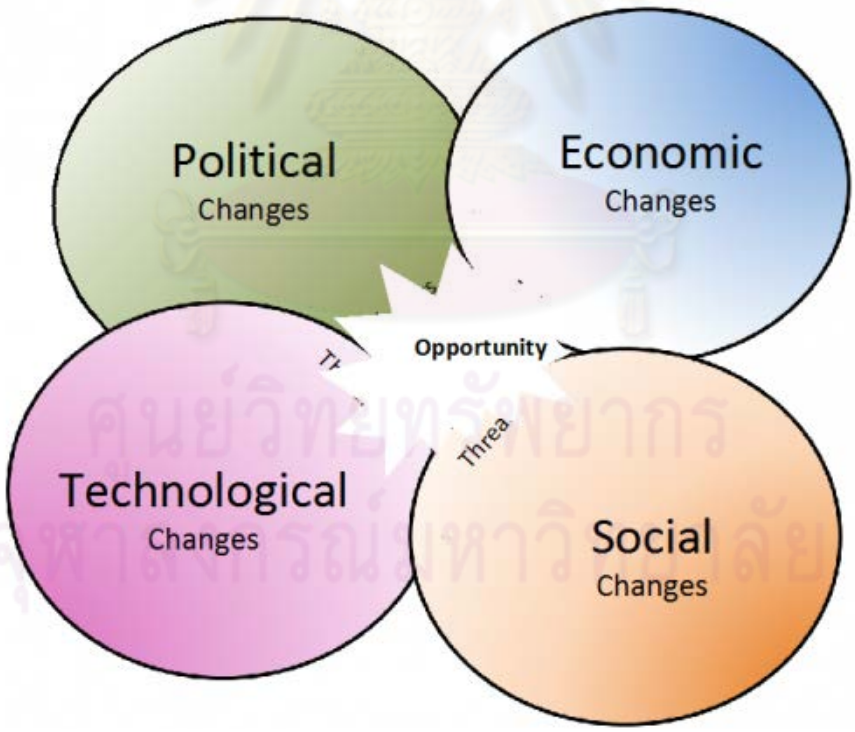

Figure 2.4 PEST Model

Composition[23]

- **Political** factors, are how and to what degree a government intervenes in the economy. Specifically, political factors include areas such as tax policy, labour law, environmental law, trade restrictions, tariffs, and political stability. Political factors may also include goods and services which the government wants to provide or be provided (merit goods) and those that the government does not want to be provided (demerit goods or merit bads). Furthermore, governments have great influence on the health, education, and infrastructure of a nation.

- **Economic** factors include economic growth, interest rates, exchange rates and the inflation rate. These factors have major impacts on how businesses operate and make decisions. For example, interest rates affect a firm's cost of capital and therefore to what extent a business grows and expands. Exchange rates affect the costs of exporting goods and the supply and price of imported goods in an economy

- **Social** factors include the cultural aspects and include health consciousness, population growth rate, age distribution, career attitudes and emphasis on safety. Trends in social factors affect the demand for a company's products and how that company operates. For example, an aging population may imply a smaller and less-willing workforce (thus increasing the cost of labor). Furthermore, companies may change various management strategies to adapt to these social trends (such as recruiting older workers).

- **Technological** factors include technological aspects such as R&D activity, automation, technology incentives and the rate of technological change. They can determine barriers to entry, minimum efficient production level and influence outsourcing decisions. Furthermore, technological shifts can affect costs, quality, and lead to innovation.

- **Environmental** factors include ecological and environmental aspects such as weather, climate, and climate change, which may especially affect industries

such as tourism, farming, and insurance. Furthermore, growing awareness of the potential impacts of climate change is affecting how companies operate and the products they offer, both creating new markets and diminishing or destroying existing ones.

Use of PEST analysis with other models[23]

The PEST factors, combined with external micro-environmental factors and internal drivers, can be classified as opportunities and threats in a SWOT analysis.

2.4.5 SWOT matrix (Confrontation matrix) [20]

A tool to combine the internal factors with the external factors is the SWOT matrix (Confrontation matrix).

Table 2.5 SWOT matrix (Confrontation matrix)

	Opportunities (O)	**Threats (T)**
Strengths (S)	**(SO)** **Offensive** make the most of these	**(ST)** **Adjust** restore strengths
Weaknesses (W)	**(WO)** **Defensive** watch competition closely	**(WT)** **Survive** turn around

Often in reality the two columns of the SWOT diagram are pointing in opposite directions. Strategists must still deal with the paradox of creating alignment. This can be done via Outside-in strategy formulation (market-driven strategy) or Inside-out strategy formulation (resource-driven).

The steps in the common three phase SWOT analysis process are: [25]

Phase 1: Detect strategic issues

1. Identify external issues relevant to the firm's strategic position in the industry and the general environment at large with the understanding that opportunities and threats are factors that management cannot directly influence.

2. Identify internal issues relevant to the firm's strategic position.

3. Analyze and rank the external issues according to probability and impact.

4. List the key strategic issues factors inside or outside the organization that significantly impact the long-term competitive position in the SWOT matrix.

Phase 2: Determine the strategy

1. Identify firm's strategic fit given its internal capabilities and external environment.

2. Formulate alternative strategies to address key issues.

3. Place the alternative strategies in one of the four quadrants in the SWOT matrix. Strategies that combine:

3.1 Internal strengths with external opportunities are the most ideal mix, but require understanding how the internal strengths can support weaknesses in other areas;

3.2 Internal weaknesses with opportunities must be judged on investment effectiveness to Determine if the gain is worth the effort to buy or develop the internal capability;

3.3 Internal strengths with external threats demand knowing the worth of adapting the Organization to change the threat into opportunity;

3.4 Internal weaknesses with threats create an organization's worst-case scenario. Radical Changes such as divestment are required.

4. Develop additional strategies for any remaining “blind spots” in SWOT matrix. Select an appropriate strategy.

Phase 3: Implement and monitor strategy

1. Develop action plan to implement strategy;
2. Assign responsibilities and budgets;
3. Monitor progress;
4. Start review process from beginning.

For this study, SWOT analysis will be used as a tool to analyze each factor affecting the effectiveness of the importing system for modern medicinal products, in order to know what the strengths, weaknesses, opportunities, and threats are. Moreover, the SWOT matrix (Confrontation matrix) will be used to synthesize the

appropriate strategies to improve the performance of the importing system for modern medicinal products respectively.

This study will adapt the SWOT analysis following **Phase 1: Detect strategic issues** and **Phase 2: Determine the strategy**, not include **Phase 3: Implement and monitor strategy.**

2.5 Health Sciences Authority (HSA), Singapore [26][27][28]

The government organization which is the National Regulatory Authority (NRA) of Singapore is the Health Sciences Authority (HSA). The organization structure consists of four main groups as

1. **Health Products Regulation Group**

The Health Products Regulation Group (HPRG) ensures that drugs, innovative therapeutics, medical devices and health-related products in Singapore are wisely regulated to meet appropriate standards of safety, quality and efficacy.

Three divisions under this group include

1.1) Pre-marketing

1.2) Vigilance, Compliance and Enforcement

1.3) Audit and Licensing (A & L)

2. **Blood Services Group**

The Blood Services Group, as the national blood service, secures the nation's blood supply by ensuring a safe and adequate blood supply and providing specialist transfusion medicine services.

There are two divisions under this group. It consists of

2.1) Blood supply

2.2) Patient service

3. **Applied Sciences Group**

The Applied Sciences Group represents the national forensic medical and scientific, analytical and laboratory expertise to support regulatory and other compliance agencies in the administration of justice and the safeguarding of public health.

There are six divisions under this group. It consists of

3.1) Forensic Medicine

3.2) Forensic Science
3.3) Illicit Drugs and Toxicology
3.4) Pharmaceutical
3.5) Food safety
3.6) Chemical metrology

Membership of PIC/S

With effect from 1 January 2000, Singapore has become the first Asian country to accede to the Pharmaceutical Inspection Co-operation Scheme (PIC/S). Accession to PIC/S (which is based in Geneva, Switzerland), would bring about many benefits to Singapore and the pharmaceutical manufacturing sector. These include the enhancement of the status of Singapore as a regional pharmaceutical and life sciences hub, the facilitation of the process of mutual recognition on GMP inspection with PIC/S countries and the global acceptance of the quality of pharmaceutical products manufactured and exported from Singapore.

WHO Certification on Quality of Pharmaceutical Product

Singapore is a party to the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce. HSA is the competent authority for Singapore for the granting of a Certificate of a Pharmaceutical Product and the Certificate of Licensing Status of a Pharmaceutical Product in accordance with the WHO Certification Scheme.

ASEAN Sectoral Mutual Recognition Arrangement for GMP Inspection of Manufacturers of Medicinal Products

An ASEAN Sectoral Mutual Recognition Arrangement (MRA) on Good Manufacturing Practice (GMP) Inspection of manufacturers of medicinal products was signed on 10 April 2009 in Pattaya Thailand by the Economic Ministers of the 10 ASEAN Member States.

The scope and coverage of this Sectoral MRA is for medicinal products in finished dosage forms, and excludes products such as biopharmaceuticals, radiopharmaceuticals, traditional medicines and investigational medicinal products. Under this Sectoral MRA, a party whose inspection service is listed under this Sectoral

MRA will have its inspection reports and GMP certificates, in respect of a facility manufacturing medicinal products in its territory, recognized and accepted by other ASEAN member states. In order for an inspection service to be listed under this Sectoral MRA, the inspection service shall operate a Pharmaceutical Inspection Cooperation Scheme (PIC/S) GMP inspection system, as demonstrated by PIC/S membership or adherence to any other equivalent standard. As Singapore is already a PIC/S member, it would mean that Singapore HSA would become one of the Listed Inspection Service under the Sectoral MRA. As such, other ASEAN Member States would therefore recognize and accept HSA's GMP certificates and inspection reports of the local manufacturers of medicinal products, without the need to conduct another audit on those local manufacturers.

Regulatory Guidelines and Standards

Licensing

Manufacturer’s license for medicinal product

All medicinal products are regulated under **the Medicines Act** and its subsidiary legislations. Under the Medicines Act, all local manufacturing facilities engaged in the manufacture or assembly of medicinal products must be licensed with Health Sciences Authority (HSA). Thus, no person shall manufacture or assemble any medicinal product except in accordance with a license grant for the specific purposes (referred to in the Medicines Act as a Manufacturer's License).

The GMP Audit and Licensing Unit of Audit & Licensing Division (A&L) in Health Sciences Authority is responsible for the audit and licensing of medicinal product manufacturers and assemblers in accordance with current international Good Manufacturing Practice (GMP) standard. A manufacturer's license would only be granted when the manufacturing facilities has been assessed, audited and found to comply with the Pharmaceutical Inspection Convention/Co-operation Scheme (PIC/S) Guide to Good Manufacturing Practice (GMP) for Medicinal Products. The holder of a manufacturer's license shall comply with all the standard provisions and licensing conditions for a manufacturer's license under the Medicines Act.

Import's license for medicinal product

Under the Medicines Act, importers of medicinal products who do not hold the relevant product licenses may apply for an import license to import registered medicinal products. The import license can be separated into two kinds as followed;

(1) Import license (for authorized agent) for medicinal products will only be issued to local importers who have been authorized by the product license holders to import licensed products on their behalf. The importers must demonstrate their compliance with HSA's GDP standard before the granting of the Import License would be considered. The products authorized for importation would be listed in the license.

(2) Import license (On Consignment Basis) for medicinal products is issued to importers who are not product license holders or authorized agents. The license allows the import of a registered medicinal product on a per consignment basis after the importer has satisfied the licensing authority that the product to be imported is in all respects the same as the medicinal product registered in Singapore.

Wholesale Dealer's license for medicinal products

Wholesale dealing is defined under the Medicines Act as selling (a product) to a person who buys it for the purpose of selling or supplying it in the course of a business carried on by that person except that it does not include any such sale by the person who manufactured it. Therefore, any person (except for licensed manufacturers) who intends to sell registered medicinal products to others for purpose of resale will have to apply for a Wholesale Dealer's license for medicinal products.

The granting of the Wholesale Dealer's license would be considered when the company has been audited and found to comply with HSA's GDP standard. Licensed wholesale dealers can only deal in registered medicinal products and are not allowed to deal in medicinal products of which the product licenses are no longer valid.

Moreover, applicants for all kinds of license should submit the online application forms through the e-service system namely Pharmaceutical Regulatory Information System (PRISM).

Product license (Product registration)

All medicinal products imported or sold in Singapore are required to be licensed by the Health Products Regulation Group, Health Sciences Authority. A medicinal product is defined in the Medicines Act as "any substance which is to be used for administration to human beings and animals for the diagnosis, prevention or treatment of ailments including preparations intended for the promotion of health, for anesthesia or for contraception". The onus of applying for a product license rests with the license holder, i.e. a locally registered company that is responsible for the safety, quality and efficacy of the product.

The Therapeutic Products Division (TPD) is responsible for the registration of medicines and the continual review of approved medicinal products. TPD will facilitate the timely introduction and availability of new and innovative quality medicines in Singapore and the region, including medicines targeted for diseases prevalent in the region.

The main activities relating to the control of medicinal products include:

- Evaluation and approval of applications for new product licenses, amendment and renewal of existing product licenses, as well as the continual review of registered medicinal products.
- Evaluation and approval for import of unregistered medicinal products on a named patient basis.
- Approvals for the import of medicinal products for the purpose of re-export.
- Evaluation and approval of applications for licenses for the purpose of importation of registered medicinal products on a per consignment basis.
- Evaluation, approval and monitoring of clinical trials on medicinal products.
- Secretariat support for the Medicines Advisory Committee (MAC) and the Medical Clinical Research Committee (MCRC).

Furthermore, the ASEAN registration of pharmaceuticals for human use has required the licensee to submit the documents in compliance with the ASEAN Common Technical Dossier (ACTD) and also the ASEAN Common Technical Requirements (ACTR).

Good Distribution Practice (GDP) Standard

Good Distribution Practice is a quality system which ensures that medicinal products are stored and handled consistently under appropriate conditions as required by the marketing authorization or product specification so that the quality of the products will be maintained during storage and distribution.

Importers and Wholesale Dealers of Medicinal Products are required to comply with the HSA GDP standard. The Regulatory Inspectors of HSA will audit the company in accordance with the HSA Guidance Notes on Good Distribution Practice. This guidance has already prepared by referring to the Good Distribution Practices for Pharmaceutical Products of World Health Organization (WHO) 2006, EU Guidelines on Good Distribution Practice of Medicinal Products for Human Use (94/C 63/03) and the Pharmaceutical Inspection Co-operation Scheme (PIC/S) Guide to Good Manufacturing Practice (GMP) for Medicinal Products.

The scope of the audit will cover the following area where applicable:

- Personnel
- Premise and facilities
- Stock handling and stock control
- Disposal of products
- Documentation
- Product complaints
- Product recall
- Returned materials
- Counterfeit products
- Self-inspection
- Contract activities

Certifications

1. The Good Manufacturing Practice (GMP) certificate

The GMP certificate issued by HSA is a certificate relating to the manufacture of a medicinal product, an active pharmaceutical ingredient or a cosmetic product attesting to its conformity with the relevant GMP Standard as appropriate.

The GMP certificate is granted when the manufacturing facility has been audited and found to demonstrate satisfactory compliance with the required GMP standard. The name and address of the manufacturing site and the scope of the certification will be defined on the GMP certificate. The scope of certification would normally be determined by the scope of the actual audit that was performed at the manufacturing facility and the types of dosage forms/range of products being manufactured. A GMP certificate would normally be valid for 2 years for a medicinal product manufacturer and 3 years for a cosmetic product manufacturer.

The certificate would be issued in the name of the local firm/company registered with the Accounting and Corporate Regulatory Authority, Singapore. The person making the application should be authorized by the company to do so as the person responsible (e.g. managing director, QA/QC manager, production manager).

2. Good Distribution Practice (GDP) certification

This is a voluntary scheme for interested companies to seek official certification from HSA. A GDP certificate is a certificate relating to the storage and distribution of medicinal products or active pharmaceutical ingredients attesting to its conformity with the HSA's GDP Standard. A GDP certificate is issued when the company's quality system has been audited and found to comply with HSA's GDP Standard.

3. The Certificate for Exporter of Medicinal Product (Certificate of Pharmaceutical Product, CPP)

The CPP certificate issued in the format as recommend by the WHO is a document that is internationally recognized by national drug regulatory authorities for establishing the status of medicinal product under a national drug product licensing system. The medicinal product has to be produced under a comprehensive system of quality assurance, conforming to GMP standards as mandated by WHO.

The certificate is specific for one product as well as one country of import. Among other information, the certificate specifies whether or not a product is sold in Singapore. Where a product is limited to export, a standard comment would be included in the certificate to define the reason. Product details, such as the formulation, are also provided in the certificate.

The certificate can be issued for medicinal products controlled under the Medicines Act of Singapore as well as those that are exempted from licensing control. The certificate will be prepared in English and transmitted to the requesting authority through the applicant. The applicant will be responsible for providing a notarized translation that may be required by the requesting authority. The competent authority in the requesting country could request a copy of the certificate directly from HSA for the purpose of verifying its authenticity.

The certificate will normally expire 24 months or 6 months from the date of issuance for licensed medicinal products and medicinal products exempted from licensing control respectively. Upon expiry, a new application must be submitted. The certificate cannot be renewed or re-issued.

GMP Conformity Assessment of Overseas Manufacturers of Medicinal Product

With effect from 1 April 2004, all new overseas manufacturers who intend to register their "western" medicinal products in Singapore will be subjected to a GMP Conformity Assessment by HSA.

Manufacturers which have been previously audited and found to conform to GMP standards by a PIC/S member authority or any of the HSA's benchmark GMP inspection authorities may submit GMP evidence e.g. a valid GMP Certificate, for evaluation. Such manufacturers need not be audited by HSA if the submitted evidence is found to be acceptable.

Manufacturers who do not meet the above criteria will be subjected to an on-site audit by HSA's GMP auditors to assess their compliance to the PIC/S GMP standard. An application to request for an overseas audit has to be filed together with the submission of a quality system dossier, which is essentially a collation of documents and information that provides a comprehensive overview of the manufacturing site, facilities and the quality system of the manufacturing operations.

Service Charges

GMP Evidence Evaluation	$600 *per manufacturing site*
Quality System Dossier (QSD) Evaluation	$4500 *per manufacturing site* *(one time payment)*

On-site GMP audit of a manufacturer located in*:	
(a) an ASEAN country	$18,000 *per manufacturing site*
(b) an Asia country (other than ASEAN)	$20,000 *per manufacturing site*
(c) a country outside of Asia	$24,000 *per manufacturing site*

Service charges varies according to the geographical location of manufacturer

Note:

1. Payment should be made payable to Health Sciences Authority by either cheque or GIRO
2. All service charges paid will not be refundable
3. Please refer to the Guidance Notes on GMP Conformity Assessment of an Overseas Manufacturer for further information.
4. The GMP conformity assessment of overseas manufacturer will be implemented with effect from 1 April 2004.

Safety Information & Recalls

Guidance for industry and applicants

Guidance for Industry: Safety Reporting Requirements for Registered Medicinal Products (October 2008)

This document applies to license holders who are responsible for introducing registered western medicinal products into Singapore. It provides guidance to license holders on the submission of relevant safety information relating to registered western medicinal products to the Vigilance Branch. It addresses the types of documents to be submitted, the timelines and the requirements for reporting drug safety information.

Guidelines on product defect reporting and recall procedures

Objective

When products are suspected of being potentially harmful to users due to their defective quality, safety or efficacy, they may be subjected to a recall and all related information must be reported to the Enforcement Branch of HSA.

The following guidelines are intended to ensure that in the event of a necessary recall, the recall operations are effectively and efficiently carried out by the product

owner/license holder, manufacturer or importer (hereinafter known as the "company") responsible in order to safeguard public health.

Definitions

Product defect

A suspected deficiency which may produce an impact, whether directly or indirectly, on the continuing safety, quality and efficacy of a product.

Product recall

A permanent removal of the affected products from the market OR a temporary removal for product correction, after which the corrected products may be returned to the market for sale.

A specified timeline will be given by HSA to a Company to recall the affected product from the market.

The classification and level of recall will depend on the potential hazard of the defective product and the extent of product distribution. These are determined after consultation between the Company and HSA.

Assessment of recall

(a) Classification of Recall

A recall will be classified as a Class 1 recall or Class 2 recall depending on the potential hazard of the defective product.

Class 1 Recall

Initiated when the product defect poses a life-threatening situation to users. Some examples of defects that will result in Class 1 recall are non-sterile injections, contamination with toxic substances and products with major labeling errors.

Class 2 Recall

Initiated when the problem or defect is unlikely to cause serious harm to users. Some examples of defects that will result in Class 2 recall include products with minor labeling errors or products which fail to meet product specification or pharmacopoeia standards but are likely to cause minimal hazard to users.

(b) Level of recall

There are 3 levels of recall, namely: Wholesale, Retail and Consumer. Each recall will be assigned the appropriate level of recall depending on the nature of defect, the distribution networks of the product and the extent of distribution.

Recall to wholesale level includes

All parties involved in wholesale sale and may include wholesalers and retail pharmacies

Recall to retail level includes

- All restructured and private hospital pharmacies
- Retail pharmacies
- Medical, dental and other healthcare practitioners' establishments
- Nursing homes and other related institutions
- Clinical trial centres
- Other retail outlets e.g. health food stores, supermarkets
- Wholesale level

Recall to consumer level includes

- Patients
- Other consumers
- Wholesale and retail levels

Initiation of recall

(a) Recall initiated by company

Recall may be initiated by the Company as a result of defective reports from various sources such as manufacturers, wholesalers, retailers, medical practitioners, hospital and retail pharmacists, end-users and members of the public.

(b) Recall initiated by HSA

Recall may also be initiated by HSA as a result of adverse drug reaction monitoring, product quality surveillance or defective reports from reputable sources.

Responsibilities of the company

(a) Informing HSA's Enforcement Branch

It is the prime responsibility of the company to inform HSA's Enforcement Branch on receipt of any product defect information, regardless of whether the surfaced information may, or may not lead to a subsequent recall of the product. On receipt of such information, the company has to undertake to inform HSA's Enforcement Branch recall officer within 24 hours.

The company is also fully responsible for recalling the defective products and notifying all customers, and if necessary, healthcare professionals and the general public, to alert them about the recall.

(b) Maintenance of sales records

The Company must maintain and keep proper wholesale records for each product for a minimum period of two years from the date of the last entry. All records should be readily available so as to expedite a recall when necessary.

(c) Establishment of Standard Operating Procedures (SOP) for product recall

The company should establish proper SOP for effective recall of product in the event that such action becomes necessary. All staff likely to be involved in a product recall should be trained in the relevant procedures and have access to a copy of the Company's SOP whenever they are required to act.

(d) Implementation of recall

The following flowchart acts as a guide for the company when it receives product defect information.

Company receives product defect information. Company to alert enforcement branch must recall to the recall officer within 24 hours. Classification, level and strategy of recall to be finalized after discussion with HSA.

In the event that a recall is deemed necessary, the company has to:

1. Cease all sales of defective products immediately
2. Quarantine all defective stocks
3. Inform all affected wholesalers/ distributors/ retailers to do likewise first through verbal communication and followed by the recall letter

Arrangement for collection of defective stocks from affected wholesalers/ distributors/ retailers for collation and quarantine in warehouse

1. Complete the recall and submit full recall report using RR2/007 to HSA's Enforcement Branch recall officer within 3 weeks from the date of initiation of recall
2. Submit proof of action taken on recalled stocks (re-export documents or certificate of destruction) within 3 months from the date of completion of recall
3. Submit proposal of corrective action(s) for approval (if any)
4. Institute corrective action(s) on approval (if any)

(e) Maintenance of up-to-Date contact details

Contact details for the company should be maintained up-to-date at all times. It is the responsibility of the company to contact HSA proactively whenever there are any changes in the contact details, such as the person responsible, telephone number, fax number, address and email address.

Contact HSA's Enforcement Branch

All enquiries or necessary information pertaining to a product defect or recall should be forwarded to:- Enforcement Branch, Enforcement Division, Health Products Regulation Group, Health Sciences Authority.

When there is a risk of significant hazard to consumers and the distribution has been extensive, the Company responsible is required to employ all possible mass communication media available including newspaper, radio and television broadcast to disseminate the recall information to the consumers.

In circumstances when a media release is required, companies are to consult HSA prior to release of any recall information.

For the conclusion, companies are responsible for the quality, safety and efficacy of their products. All efforts must be made to ensure that recall operations are carried out as efficiently and effectively as possible. Appropriate follow-up actions must also be taken to prevent future recurrence of similar problems.

2.6 Conceptualization and operationalization of concepts

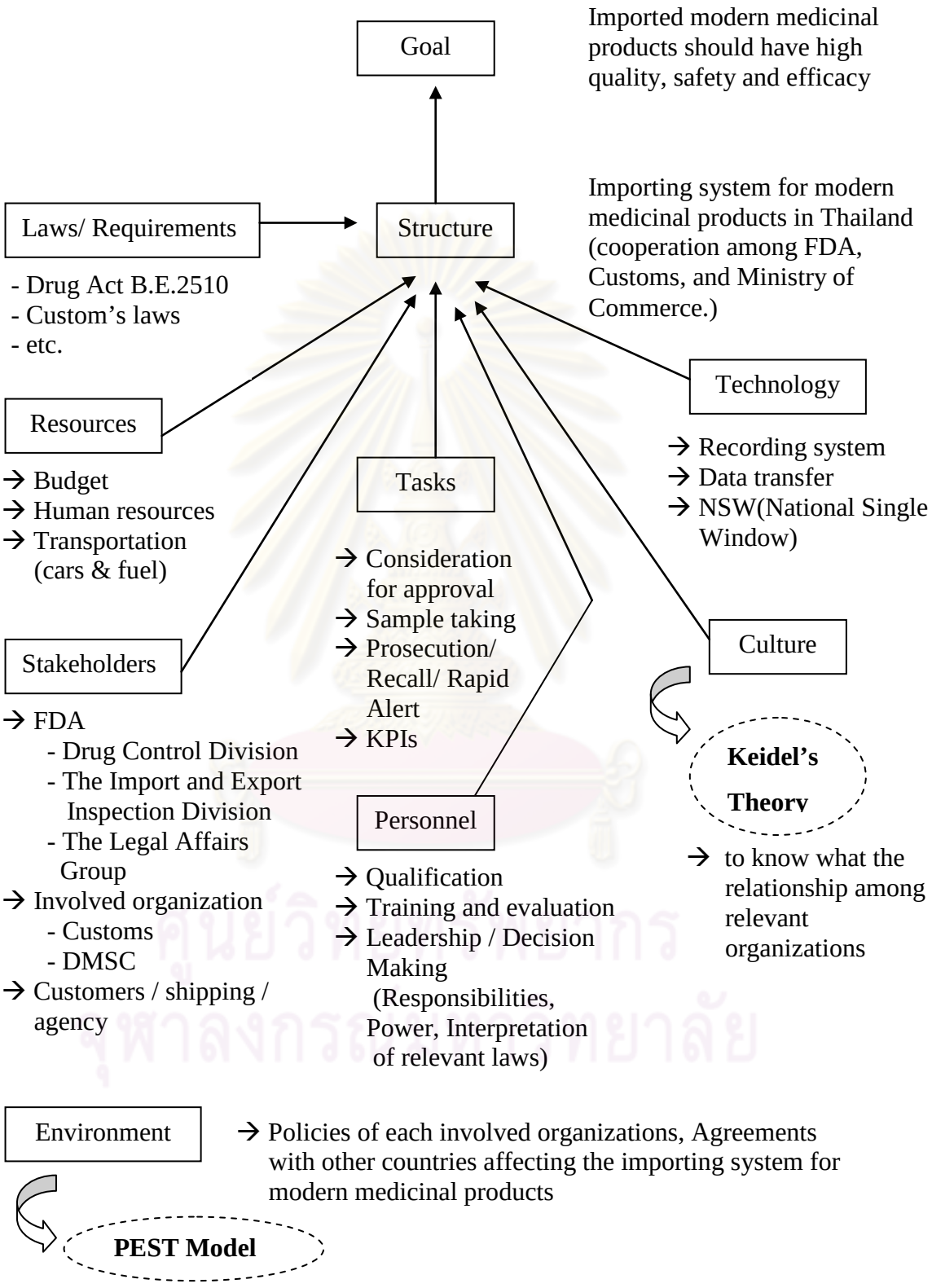

Figure 2.5 Conceptual framework of study (developed from Host Tor's Theory (1997): The Organizational Pyramid)

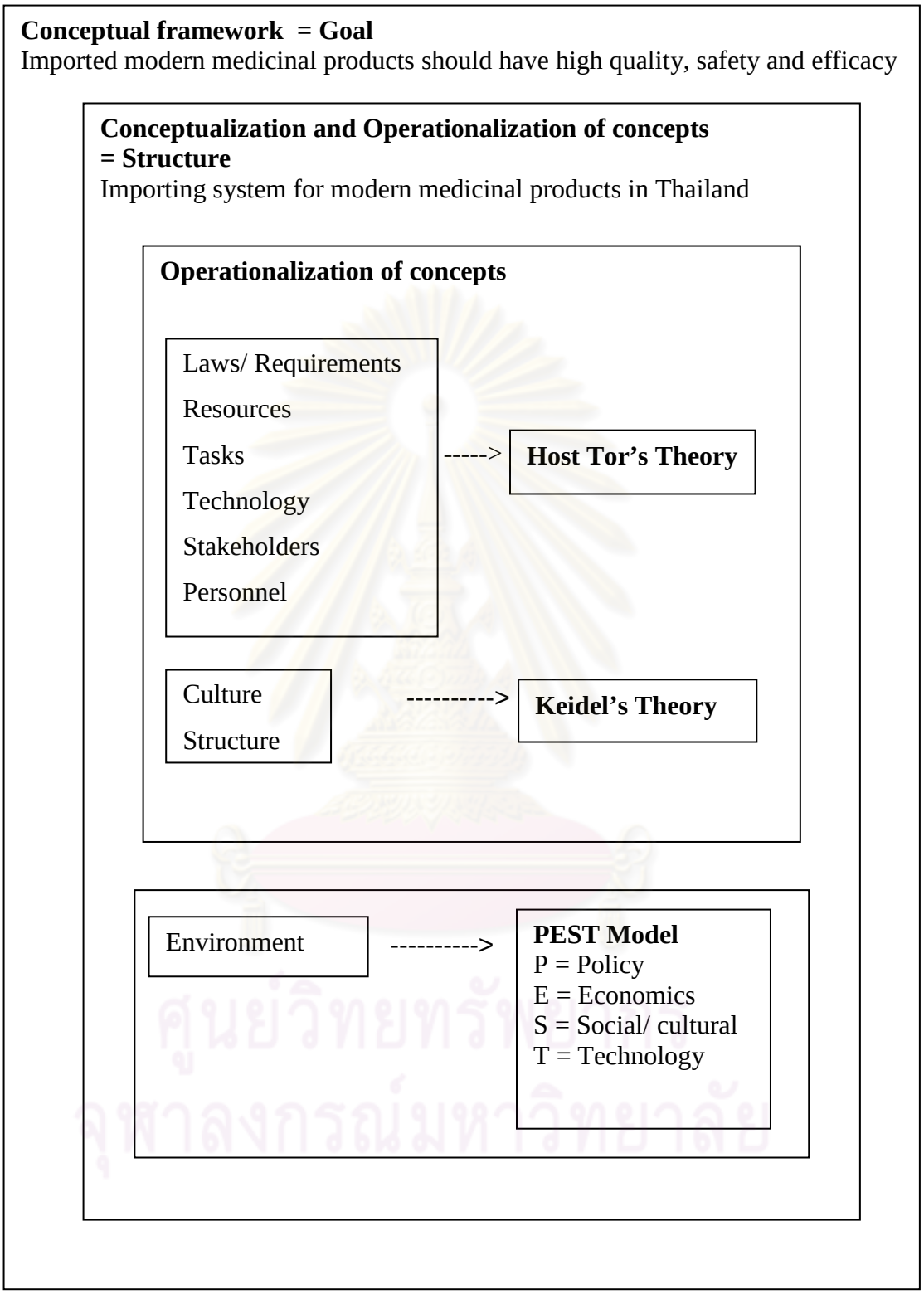

Figure 2.6 Conceptual framework of study

CHAPTER III
RESEARCH METHODOLOGY

Since this study would be separated into two mainly different steps in accordance with the objectives as to analyze the importing system for modern medicinal products and to synthesize strategies to improve the system performance, the research methodologies were selected to be appropriate for each step.

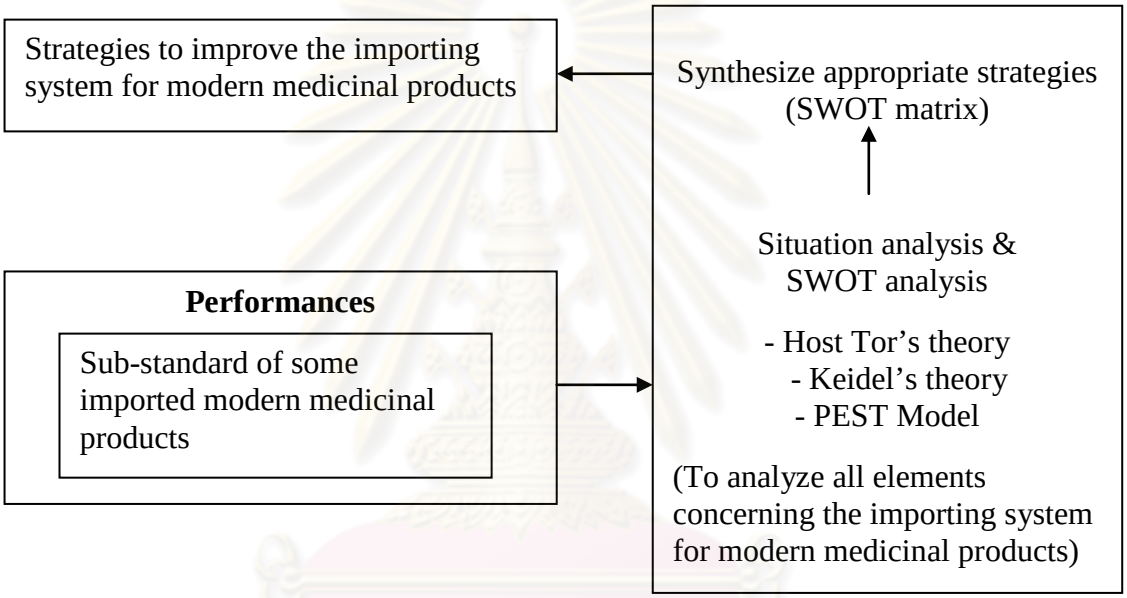

Figure 3.1 Research process for this study

3.1 Study Design

This study comprised 2 steps with different study designs as followed:

3.1.1 <u>Step I</u> : to analyze the current importing system for modern medicinal products (Situation analysis)

All factors affecting the effectiveness of current importing system for modern medicinal products were analyzed by using the combination of three theories including ***Host Tor's Theory (1997)*** as the main theory and ***Keidel's Theory (1995)*** and ***PEST Model*** as the supplementary theory.

Data collection

Situation analysis was considered and performed following each element stated in Host Tor's Theory (1997) as the first step by using all below methods to collect data as much as possible.

1) Content analysis

All relevant written documents were reviewed and analyzed, in order to understand more about the background, history, operation process, normal practices of the personnel, strength, weakness as well as some obstacles affecting the current importing system for modern medicinal products. The example of written documents that were reviewed as followed;

1. Laws and requirements
2. Standard operation procedures
3. Records
4. Technical documents prepared by the officers or experts of each involving organization e.g. the Import and Export Inspection Division, the Customs
5. An information uploaded on the website of organizations involved in the importing system for modern medicinal products

In addition, the importing system of modern medicinal products of Health Sciences Authority (HSA), the national regulatory authority of Singapore was reviewed and selected some parts as data to adapt in some proposed strategies to improve current importing system of our country respectively.

2) Key informant interview

Key personnel involved in or responsible for each issue were observed at the operation site and interviewed with the opened questions, in order to gain more details of each issue in-depth, and then the current situation could be extracted. The persons who were selected to be interviewed as the participants for this study include

1. The director and 9 key persons of the Import and Export Inspection Division of FDA
2. The director and 4 key persons of DCD of FDA
3. The Customs' officer - the expert who had been operated at the airport and pier for more than 10 years

The research spent approximately 8 hours in the office to observe the operation and then interview the key persons following the approved topic for key informant interview. Moreover, their opinion about what the factors most affecting the system performance of the importing system of modern medicinal products was used in the process of prioritization for strategies respectively.

3) Case study

From data of recall and rapid alert of medicinal products presented on the FDA's website as "Safety Alert", to publicize as the safety information for the consumer, some of those data were selected to be the case study in order to recheck the activities following the current process of importation of modern medicinal products from beginning to the end.

A modern medicinal product imported from abroad shown in the "Safety Alert" was selected. And then its history was reviewed from the process of approval for its registration, being imported, sample be taken, the failure in quality of product found until the process to punish the importer regarding the contents of penalty stated in the Drug Act B.E.2510 and also other additional measurement.

The study selected 2 imported medicinal products that had been presented in the "Safety Alert" webpage as (1) ENVAS 5 Reg.no.1C 235/44 (Each tablet contains: Enalapril Maleate USP 5 mg) and (2) ZEPTOL CR 400 Reg.no.1C 99/45 (Each film coated controlled release tablet contains: Carbamazepine BP 400 mg).

Data analysis

To analyze all data collected by the above methods, **SWOT analysis** was selected.

All collected data following each element of Host Tor's Theory (1997) should be identified to conclude what the strengths (S), weaknesses (W), Opportunities (O), and threats (T) of the current importing system for modern medicinal products. The internal factors and external factors that could affect the importing system of modern medicinal products were identified. The internal factors included the strengths (S) and weaknesses (W), and the external factors consisted of the Opportunities (O) and threats (T).

3.1.2 Step II : purpose to synthesize strategies to improve performance of the importing system for modern medicinal products

After finishing of step I, all elements of the main theory, the Host Tor's Theory (1997) consisting of resources, tasks, technology, stakeholders, personnel, culture, environment, and laws/requirements were analyzed. The next processes were composed of 2 processes, prioritizing and proposing the strategies to improve the system performance.

1) Prioritize strategies

The SWOT derived from step I were selected based on key informants' opinion. These selected were proposed for the expert review to prioritize. The prioritization was conducted using weighing and rating for each selected factor.

In this process, all selected SWOT was separated into 2 tables including the table of Internal Factor Analysis Summary (IFAS) and the table of External Factor Analysis Summary (EFAS). The internal factor consisted of the strengths (S) and weaknesses (W) must be identified by using IFAS, and the external factor consisted of the Opportunities (O) and threats (T) must be shown in EFAS respectively. Both IFAS and EFAS must define the weight and rating for each selected factor.

The weight stands for the feasibility of success of each factor. The factor that could be performed easier and had the possibility to reach a goal faster than another factor must be weighed with higher number. Total weight of each table, IFAS and EFAS must be 100 absolutely. However, the total weight of S must be 50 and total weight of W must be 50 in the table of IFAS. It was the same for factor O and T in the table of EFAS.

For the rating, the expert must consider for the importance of selected factor and then prioritize by using the number 1 to 5. The no.1 means that the factor was the least important factor affecting the importing system of modern medicinal products and the no.5 means that the factor was the most important factor that could mainly affect the performance of the importing system.

Furthermore, the current situation of the importing system of modern medicinal products could be identified by using the result of totally weight scored of SWOT. The cut point between the total weight scored of internal factors and those of

external factors in one of the four quadrants of the SWOT matrix was used for assuming the current importing system.

In addition, the experts who reviewed and prioritized the selected factors consisted of the expert from each organization concerning the importing system of modern medicinal products as the DCD and the Import and Export Inspection Division of FDA, and the Customs.

2) Propose strategies

From IFAS and EFAS, SWOT with the rating of 5 and 4 were selected. However, some SWOT with the rating of 3 was selected under the decision making by the focus group.

The components of the focus group included

- 5 key personnel from the Import and Export Inspection Division
- The Chief of the Inspectorate Unit, DCD of FDA
- 1 expert from the Customs

After that all selected SWOT were analyzed through the Strategic Factor Analysis Summary (SFAS). In the table of SFAS, the rating of each selected factor should be the same as mentioned in IFAS and EFAS. Moreover, the duration as the expected time to reach the achievement was also identified as S = short time, M = medium time, and L = long time.

From SFAS, the ***SWOT matrix (Confrontation matrix)*** was used as a tool for developing the strategies for improving the importing system for modern medicinal products. The members of focus group had widely discussed and then considered for the feasible specific strategies that would be used to improve the system performance of the importing system of modern medicinal products.

CHAPTER IV
RESULTS

This study was separated into two steps following Step I, the situation analysis (to analyze the current importing system for modern medicinal products) and Step II, synthesize strategies (to prioritize and propose the strategies to improve performance of the importing system for modern medicinal products). Therefore, the results would be chronological described for each step according to the study design as followed;

4.1 Results of Step I : The situation analysis

4.1.1 Data collection

4.1.1.1 Content analysis

4.1.1.2 Key informant interview

4.1.1.3 Case study

4.1.2 Data analysis

→ SWOT analysis

- Internal factors (Host Tor's Theory (1997) and Keidel's Theory (1995))
- External factors (PEST Model)

4.2 Results of Step II : Synthesize strategies

4.2.1 Prioritize strategies

- Internal Factor Analysis Summary (IFAS)
- External Factor Analysis Summary (EFAS)

4.2.2 Propose strategies

- Strategic Factor Analysis Summary (SFAS)
- SWOT matrix (Confrontation matrix)

4.1 Results of Step I : The situation analysis

4.1.1 Data collection

To understand the current situation of the importing system for modern medicinal products, the process of the content analysis and key informant interview were performed. Each factor concerning the importing system for modern medicinal product was identified and collected its relevant data regarding the element of the ***Host Tor's Theory (1997)*** as a main guide, and also ***Keidel's Theory (1995)*** and ***PEST Model*** was used as the supplementary theory. Furthermore, a case study was conducted to recheck the real activities following the process for the importation of modern medicinal products.

Moreover, the reviewing of the importing system of modern medicinal products of Health Sciences Authority (HSA), the national regulatory authority of Singapore was performed, and selected data was presented in Chapter II: Literature review.

4.1.1.1 Content analysis

The results from the reviewing of all relevant written documents e.g. laws and requirements, standard operation procedures, records, the information uploaded on the website, and the technical documents prepared by the officers or experts of each organization involved in the importing system for modern medicinal products such as the Import and Export Inspection Division, the Drug Control Division, and the Customs had been collected relating to each element of the ***Host Tor's Theory (1997)***. Besides, the element of culture had been considered according to the concept of the ***Keidel's Theory (1995)*** and the element of environment was considered through ***PEST Model***.

4.1.1.2 Key informant interview

Before the beginning of the interviewing key personnel involved in each issue, the researcher would inform him/her and to know more about the objectives, the study design, and to understand the reason why he/she was selected as a participant in this study. Moreover, the researcher would request him/her to sign the consent form and ask him/her for permission to interview first as he/she had to lose some times for the interview. All participants were interviewed with the opened questions following the attached interview document. The persons who were selected

as the participants for this study include the director and nine key persons of the Import and Export Inspection Division, the director and four key persons of the Drug Control Division as well as at least two key persons of the Customs.

4.1.1.3 Case study

To recheck all activities following the current processes of the importing system for modern medicinal products including the post-marketing surveillance as well as the prosecution if the law violation occurred, some imported medicinal products which were recalled from the market because of the quality defects and also published on the FDA's website as "Safety Alert" was selected to follow up. It consisted of (1) ENVAS 5 Reg.no.1C 235/44 (Each tablet contains: Enalapril Maleate USP 5 mg) and (2) ZEPTOL CR 400 Reg.no.1C 99/45 (Each film coated controlled release tablet contains: Carbamazepine BP 400 mg)

FDA has already established "Procedure of consideration for the testing result analyzed by DMSc". The criteria to identify the type of illegal medicinal products in this procedure were stated as follow;

1. Sub-standard

Category no. 1

Example :-

1) Drugs produced with active substances which quantity or strength are lower than the minimum or higher than the maximum standards prescribed in the registered formula to a degree less than twenty percent

2) Sterile medicinal product which its testing results presented a failure on sterility test, Pyrogen test, and toxicity

3) High quantity of degradation product which could be harmful for human use

Category no. 2

Example :-

1) Drugs produced so that their purity or other characteristics which are important to their quality differ from the standards prescribed in the registered formula or drug formulas which the Minister has ordered the drug formula registry

2) Drugs which its testing results presented the out-of-specification in any item stated in its finished product specification e.g. weight variation, disintegration, dissolution, pH, etc.

2. Counterfeit/ fake drugs

Example :-

1) Drugs produced with active substances which quantity or strength are lower than the minimum or higher than the maximum standards prescribed in the registered formula by more than twenty percent

2) Drugs which show that it has already been registered, but its testing result presented the incorrect active ingredient

3. Deteriorated

Example :-

1) A drug which has so denatured as to have the characteristics of a fake drug or a drug differing from the standard

Moreover, this procedure mentions that if the testing result of sampled medicinal product could be identified as one type of illegal medicinal products,

1) For the first time, the licensee must be asked to meet the authorized officer to get the warning and also ordered by FDA to recall those products from the market and then report the result of recall in timely manner (15 days or 30 days). Finally the recalled products would be destroyed through the appropriate methods, under control of the authorized person who was appointed by FDA.

2) For the next time, the licensee must be prosecuted in case of importing of the sub-standard drugs into Thailand according to the content in the Drug Act B.E.2510. Besides, the licensee will be ordered by FDA to recall the product from the market, and follow the process of product recall respectively.

<u>Example 1</u> : ENVAS 5 Reg.no.1C 235/44

(Each tablet contains: Enalapril Maleate USP 5 mg)

The importer: Pharmaland (1982) Co.,Ltd. **License no. จ.** 14/2526

Product register no. 1C 235/44 (issue date: 21st December 2001)

Manufacturer/ Origin: CADILA PHARMACEUTICALS LIMITED, INDIA

Type: Dangerous drug

Dosage form: Compressed tablet

Characteristics: White, flat, round, beveled edged, uncoated tablets with the breakline on one side

Indication: Hypertension, Heart failure (combined with Digitalis and/or Diuretics)

Packaging: Aluminium foil, 1 unit contains 10 tablets

Shelf-life: 2 years

Storage condition: Store below 30°C

Port of entry: Bangkok Pier

Table 4.1 Summary data of the imported medicinal product - ENVAS 5 Reg.no.1C 235/44

No.	Sampling/ Importation date	Lot	Mfg	Exp	Recall date	Causes	Deficiencies	Punishment
1	1 AUG 07	E7007	MAY 07	APR 09	28 NOV 07	Dissolution failed	Sub-standard (Category no. 2)	Warning & Recall
2	12 DEC 07	E7022	OCT 07	SEP 09	27 MAR 08	Content uniformity failed	Sub-standard (Category no. 2)	Prosecution regarding the Drug Act B.E.2510
3	10 JAN 08	E7028	NOV 07	OCT 09	1 AUG 08	Content uniformity failed	Sub-standard (Category no. 2)	Warning & Recall
4	20 MAR 08	Y57E8001	JAN 08	DEC 09	19 SEP 08	Content uniformity failed	Sub-standard (Category no. 2)	Prosecution regarding the Drug Act B.E.2510

Example 2 : ZEPTOL CR 400 Reg.no.1C 99/45

(Each film coated controlled release tablet contains: Carbamazepine 400 mg)

The importer: Pharmaland (1982) Co.,Ltd.

License no. จ. 14/2526

Product register no. 1C 99/45 (issue date: 25th June 2002)

Manufacturer: SUN PHARMACEUTICAL INDUSTRIES LTD., INDIA

Type: Dangerous drug

Dosage form: film coated controlled release tablet

Characteristics: A brown colored circular biconvex film coated tablets having breakline one side and plain on the other side

Indication: Anti-epileptics

Packaging: Aluminium foil, 1 unit contains 10 tablets

Shelf-life: 3 years

Storage condition: Store below 30°C

Port of entry: Suvarnnabhum Airport

Table 4.2 Summary data of the imported medicinal product - ZEPTOL CR 400 Reg.no.1C 99/45

No.	Sampling/ Importation date	Lot	Mfg	Exp	Recall date	Causes	Deficiencies	Punishment
1	4 DEC 07	SK71740	10/2007	09/2009	11 JUN 08	Dissolution failed	Sub-standard (Category no. 2)	Warning & Recall
2	10 MAR 09	SK80723	04/2008	03/2010	14 MAY 09	Dissolution failed	Sub-standard (Category no. 2)	Prosecution regarding the Drug Act B.E.2510

Conclusion

Thai FDA has been developed and followed the specific procedure to consider for the suitable methods that should be performed after the issuing of testing result from DMSc. Nevertheless, there are some problems that should be identified and solved respectively.

1) In case of the licensee who infringes the law repeatedly, there has no any law or measurement to adopt for this case. The penalty according to the Drug Act B.E. 2510 could be performed case by case only. That means this procedure should be revised and mentioned that how to consider for the prosecution according to the repeated failure on testing results of the sample taken by FDA.

2) Some licensees could not recall their products which must be recalled from the market in time, or did not report the progress of recall to FDA. That means the products with low quality still be distributed in the market, and it could be a risk for any person who used those products. Therefore, the system for monitoring and follow-up the result of product recall should be strengthened.

4.1.2 Data analysis

To complete the current situation analysis of the importing system for modern medicinal products, the collected data from above should be analyzed by using the ***SWOT analysis*** to identify the internal factors as the strengths (S) and weaknesses (W), and also the external factors as the opportunities (O) and threats (T) of the current importing system for modern medicinal products.

Internal factors

For the internal factors, the researcher had considered through 6 elements of the ***Host Tor's Theory (1997)*** as laws/requirements, resources, tasks, technology, stakeholders, and personnel. Moreover, the structure and culture of importing system for modern medicinal products has been analyzed by the concept of the ***Keidel's Theory (1995)***. So the totally 8 issues that were thoroughly considered as the internal factors according to SWOT analysis consist of

1) Laws/ Requirements
2) Resources

3) Tasks
    3.1) Licensing
    3.2) Registration
    3.3) Approval process for imported modern medicinal products
    3.4) Sample taking
        3.4.1) Sampling plan
        3.4.2) Persons who take sample
        3.4.3) Instruments/ Laboratories
    3.5) Storage area and condition for keeping the imported medicinal products
    3.6) Post-marketing surveillance system for the imported medicinal products
    3.7) Prosecution/ Recall/ Rapid Alert
    3.8) Key Performance Indicators (KPIs)
4) Technology
5) Stakeholders
6) Personnel
7) Structure and 8) Culture

    - using the principle of "*Keidel's Theory (1995)*"

External factors

According to "environment" which is one of elements of the *Host Tor's Theory (1997)*, the researcher had considered this element through the concept of the ***PEST Model*** and identified as the external factors of SWOT analysis. The 4 elements of PEST Model consist of policy, economics, social/cultural, and technology.

The result of SWOT analysis for each element had been presented as below information and also prepared as the summary table of internal factors and external factors as Table 4.3 and Table 4.4. In addition, the summary table to identify the resource of data for each factor i.e. content analysis, key informant interview, and case study was presented in Table 4.5.

4.1.2.1 SWOT analysis: Internal factors

Host Tor's Theory (1997)

Element 1: Laws/ Requirements

From content analysis

The main organization involving in the importing system for modern medicinal products has been established and performed its own responsibility following the laws and requirement of each organization. Therefore, the importation for modern medicinal products should follow the laws of relevant organizations including;

The Food and Drug Administration (FDA) : is the National Regulatory Authority (NRA) responsible for controlling the importation of modern medicinal products from abroad.

The Drug Act B.E. 2510 mentions that any persons who wish to import the medicinal products into the Kingdom must obtain a license and the product registration of each product from the licensing authority as the Drug Control Division (DCD), one of the divisions under control of FDA. In addition, the licensee to import the modern medicinal products into Thailand is required to submit an annual report concerning the importation in the form prescribed in the Ministerial Regulations within the 31st March of the following year.

Moreover, the modern medicinal products imported from abroad are required that all those products must be checked by the officer at the port of entry of the Import and Export Inspection Division, FDA**.**

The Customs : establishes the Customs' law as the Customs Act B.E. 2543 and procedure for controlling the importation and exportation for all kinds of products, including health products. However, the other organizations that responsible to control each product should inform the Customs to know more about the relevant laws or requirements. The imported products will be identified by the Customs' officer and then distributed to the office of each responsible organization's office at the port of entry.

In case of the modern medicinal products, the Customs' officer will inform the officer at the port of entry of the Import and Export Inspection Division, FDA to check those products complying with the procedure for importation approval and the relevant law as the Drug Act B.E. 2510. After that those modern medicinal products must be

returned to the Customs' officer in order to consider for tax calculation related to a customs tariff for each product following the customs protocol.

The Department of Medical Sciences (DMSc) : is the National Control Laboratory (NCL) responsible for testing the sample of modern medicinal products which were taken a sample by FDA and other agencies such as the regional offices of DMSc. The test results would be informed directly to FDA, in order to consider for the violation and penalty according to the Drug Act B.E. 2510 respectively.

The Ministry of Commerce : requires the importers who will import all kinds of products into the Kingdom of Thailand should follow the specific laws or requirements for each product issuing by the responsible organization.

Furthermore, the agreement among many countries e.g. Free Trade Agreement (FTA), ASEAN Free Trade Area (AFTA), Asia-Pacific Economic Cooperation (APEC), Ayeyawady - Chao Phraya - Mekong Economic Cooperation Strategy (ACMECS) should be thoroughly considered. The Department of Foreign Trade, the Ministry of Commerce must cooperate with all relevant organizations, in order to set up the appropriate policies for each agreement. Finally, each organization must establish or improve its policy and laws to comply with those agreements.

From key informant interview and case study

There are some issues concerning the importing system for modern medicinal products that should be thoroughly considered and improved as followed;

1. In case of the importer who infringes the law repeatedly, there has no any law or measurement to adopt for this case. The penalty according to the Customs Act B.E. 2543 and Drug Act B.E. 2510 could be performed case by case only.

For instance, if the testing results of imported modern medicinal products show that those medicinal products were failed or out-of-specification, the importer X must be punished regarding the content of penalty stated in the Drug Act B.E. 2510. The Import and Export Inspection Division will record the details of operation as the history of importer X, and then add the group of medicinal products and the name of importer X into the annual sampling plan for special case. After that the modern medicinal products imported by importer X, particularly the same product which there is the problem about its quality must be taken sample for all shipments. If the test

results show that its quality was failed, the importer X should be punished according to the Drug Act B.E. 2510 again. However, there has no particular measurement for the importer who has violated the law repeatedly.

2. The laws used in the importing system for modern medicinal products could not be promptly implemented or up-to-date.

For instance, the e-service with paperless system is new trend that many organizations should be adapted to use for its own activities. However, the Drug's law did not allow Thai FDA to consider and issue the license or the certificate through electronic system. Therefore, the information network among the government organizations e.g. Customs, FDA could not be effectively performed in the present time.

3. There has no the specific measurement with the cooperation among all relevant organization e.g. the Customs, FDA and product owner, when the violation could be detected at the port of entry. Nowadays, the Customs and FDA will follow its laws and requirement if the violation occurred. However, the product owner should have more activities together with the officers of the Customs and FDA to establish the appropriate measurement, in order to decrease the number of cases of violation at the port of entry respectively.

4. The full enforcement of the laws and requirement concerning the importing system for modern medicinal products usually could not be performed. For example, the importer who has a history of many times of violation of the FDA's laws as the Drug Act B.E. 2510 will be punished only case by case. The content defined in the Drug Act B.E.2510 about the suspension and withdrawal of the license for importation of the modern medicinal product could not be used effectively and immediately. FDA must follow the recommendation of the Drug Committee. The Drug Committee always take more times to handling the consideration, interpretation of the content in law and then conclusion whether that importer will be suspended or withdrawn its license. Therefore, FDA could not fully implement of this issue regarding the Drug Act B.E. 2510.

Result of SWOT analysis

Strengths (S)

S1) Each relevant organization has already established and had full power to implement its laws.

Weakness (W)

W1) There has no law or measurement in case of the repeated violation.

W2) The laws used in the importing system for modern medicinal products could not be promptly implemented or up-to-date e.g. in case of e-paperless service.

W3) There has no the specific measurement to adopt by all relevant organizations when the violation detected at the port of entry.

W4) The full enforcement of the laws and requirements usually could not be performed e.g. suspension and withdrawal of the license for importation of the modern medicinal product.

Element 2: Resources

The main resources that influence the importing system for modern medicinal products consist of budget, human resources, and number of port of entry.

2.1) Budget

From content analysis

All organizations involving in the importing system had already encouraged the fiscal budget for each year. Nevertheless, the additional budget should be thoroughly considered in order to be used for improving the importing system for necessary issues e.g. the employment for recruited officers, the expenses to develop the new logistics system.

From key informant interview

For instance, the Import and Export Inspection Division had already proposed the new project to the board of Ministry of Public Health in the beginning of a year 2010. The project was about to increase the number of ports of entry at least equal to those of the Customs within five years. Thus the budget for the building construction as well as for officer's monthly salary must be supported. For this case, the board of Ministry of Public Health decided to approve the project, and in the process of budget arrangement.

2.2) Human resources

From content analysis

Since the relevant organizations in the importing system include the Ministry of Commerce, the Customs, FDA, and DMSc, the total number of officers involving in the importing system could not be absolutely summarized. However, the information which the researcher had already collected and analyzed showed that

2.2.1) The Ministry of Commerce

The Department of Foreign Trade is the department under control of the Ministry of Commerce that was appointed to be responsible for the commercial cooperation between Thailand and other countries including the importation and exportation.

Most of their responsibilities always coordinate with among organizations to follow the policies regarding the international agreements, and control the overview of commercial situation of Thailand. So the number of officers might not be the cause of resources' problem in this department.

2.2.2) The Customs

The number of Customs' officer in each port is quite sufficient based on the workload of that port. If there are so many rounds of importation per day e.g. at the airport or pier, the Customs will support appropriate number of officers for those ports.

2.2.3) The Department of Medical Sciences (DMSc)

Normally, most of samples must be queued for testing e.g. samples regarding the annual sampling plan; however, some emergency or crucial cases e.g. the sample taken by FDA in case of the violation of Drug Act B.E. 2510 could be requested to do the testing first.

This organization has many scientists who expertise in their responsibilities, especially performing all testing for modern medicinal products. Each person will be appointed to do only some specific tests, not all tests as required. For example, they are separated into two groups. One is responsible for chemical testing and another is responsible for microbiological testing. The time management of this organization is quite effective, so there may not have the problem of inadequate operators.

From key informant interview

2.2.4) The Food and Drug Administration (FDA)

The officers of FDA who involve in the importing system could be separated into two major groups as followed;

2.2.4.1) The officers working for the Drug Control Division (DCD), both in Pre-marketing Control Unit and the Inspectorate Unit

There was the problem of insufficient human resources. In Pre-marketing Control Unit, each officer must be responsible for reviewing and considering all data submitted by the licensees, in order to follow the process of approval for the product registration. One officer must have many the requests for product registration in his hands. Moreover, the recruitment for new pharmacists or educational persons as the government officials could not be now performed according to the government policy on the limitation of the officer recruitment, so it is necessary to hire too many temporary employees to help the formal officers for some works, especially to record all relevant information into the database. Nonetheless, the significantly important problem about current situation is that the possibility of some mistake during the process for product registration approval could be occurred resulting from the human error, especially from the temporary employees since the pharmacist working in the Pre-marketing Control Unit could not recheck all activities assigned them to perform.

Besides, the officers working at the Inspectorate Unit have got the same problem. They must do the post-marketing surveillance as well as conducting GMP inspection in parallel, with only 15 pharmacists. Overload is the main problem that may be a cause of an inadequate controlling and monitoring for the imported modern medicinal products distributed in the market.

2.2.4.2) The officers working for the Import and Export Inspection Division

Only 35 of 43 government officers in this division are the educational officers as pharmacists and persons who graduated for Bachelor in other fields such as in science. They were distributed to work at the ports of entry and at the central office as well.

Because of the limitation of officer recruitment, the number of officers who have to work at the port of entry was inadequate. So there has no the officers of the Import and Export Inspection Division of FDA working at some port(s) of entry. Nowadays, there are only 15 ports of entry where FDA can support its own officers, while the 20 remaining ports of entry must request the provincial offices to arrange for.

Although FDA supports the budget for employment, the officers who work at 20 ports of entry are recruited by the provincial offices and it is difficult for FDA to control their operation. In fact, the officers who will work at all ports of entry should be under control and supported by FDA because it will ease to monitor and evaluate their work following the procedures as required.

2.3) Number of port of entry

From key informant interview

In the present, the number of Customs' port and the ports of entry of FDA in Thailand consist of 62 and 35 ports respectively. However, the importation of health products, including modern medicinal products could be done at all 62 Customs' ports. At the port of entry without FDA, the Customs will take action to check and approve the importation of modern medicinal products instead of FDA. So the ports of entry of FDA should be increased at least equal to the number of Customs' ports in the near future, in order to ensure that all imported medicinal products will be clearly checked regarding the Drug Act B.E. 2510.

Besides, the boundary line of Thailand is too long and there has a chance that the importation at the informal port(s) can be done. However, the port of entry of both the Customs and FDA does not cover the route that any goods could be imported and also smuggled into Thailand.

2.4) Materials and Equipment

From key informant interview

The Customs has already arranged the high technology equipment such as the mobile scanner that used to scan the container which contains several kinds of imported product. The illegal products that were smuggled could be detected by this

process. However, the competency, expertise and experience of the Customs' officers are the most important to achieve a goal of the detection of the illegal products.

The port of entry of FDA has already prepared the specific and high technology instruments e.g. IR spectrophotometer, RAMAN Spectrophotometer, in order to check the correction of the active ingredients compared with a detail of the label of the imported medicinal product. It is the first step to ensure the quality of the imported medicinal product before being distributed into the market.

Result of SWOT analysis

Strengths (S)

S2) Each organization has been encouraged the fiscal budget to conduct their activities.

S3) Each organization has arranged its own officers to do all activities at the port of entry.

S4) Both the Customs and FDA has already arranged high technology instrument using at the port of entry e.g. mobile scanner of the Customs used for scanning of the container, and RAMAN Spectrophotometer of FDA used for checking the active ingredients without opening the container.

Weakness (W)

W5) The boundary line of Thailand is too long and there has a chance that the importation at the informal port(s) may occur.

W6) The number of port of entry of FDA is not sufficient, and not equal to the number of port of entry of the Customs.

W7) Because of the limitation of FDA's officers, there has no the officers of the Import and Export Inspection Division of FDA working at some port(s) of entry.

Element 3: Tasks

The importing system for modern medicinal products should include the step of approval for the license as well as the product registration, and then the control processes when the modern medicinal products are imported. Moreover, the control system after those imported medicinal products were distributed in the market should be a part of the importing system.

From the reviewing of relevant data and also interviewing key persons, the researcher has analyzed and concluded the results in each part of the importing system as followed;

3.1) Licensing

From content analysis

The requirement defined in the Drug Act B.E. 2510 for the person or company who want to import the medicinal product into Thailand is that those must be licensed by Thai FDA first. The Pre-marketing Control Unit, under control of DCD, FDA acts as the licensing authority and responsible for consideration and issue the license for importation of modern medicinal product. After submit the applications, the pre-approval inspection should be performed by the authorized officers and its requirement is that the buildings and facilities of the applicant must be inspected to ensure that the applicant has adequate capabilities of doing its business, and the storage area will be appropriate for keeping the imported medicinal products in the condition as required.

From key informant interview

Nevertheless, the pre-approval inspection has not yet covered some important activities e.g. the temperature/ humidity control devices, the cold chain management system for the temperature sensitive medicinal products and vaccines, the sanitary system, the traceable inventory system.

In addition, there has no the requirement to do the additional on-site inspection when the licensee(s) request FDA to add other types of medicinal products that would be imported in their existing license for importation of modern medicinal product. For example, the licensee who would like to import some kinds of vaccine should prepare the storage area with appropriate condition e.g. cold room (2 – 8 °C), and then inform the FDA to consider for approval. Nevertheless, the on-site pre-approval inspection for this case would not be done. Nowadays, the applicant is required to submit only the photograph of its buildings and facilities for consideration.

Result of SWOT analysis

Strengths (S)

S5) License for import of modern medicinal products has required by FDA regarding to the Drug Act B.E. 2510.

Weakness (W)

W8) Pre-approval inspection has not yet covered some important activities e.g. the cold chain management system for the temperature sensitive medicinal products and vaccines, the traceable inventory system.

W9) There has no the requirement to do the on-site inspection before adding other types of medicinal products in existing license for importation of modern medicinal product.

3.2) Registration

From content analysis

Only authorized licensees are qualified to apply for product registration. The licensee who has already had the license for importation of medicinal product should request the Thai FDA to consider and issue the product registration for each medicinal product that would be imported and distributed into Thailand according to the Drug Act B.E. 2510.

At the present time, all licensees who want to request for product registration should follow the ASEAN Common Technical Dossiers (ACTD) and the ASEAN Common Technical Requirement (ACTR).

The ACTD consists of

(1) Organization of the Dossier

(2) Glossary used for the ACTD and ACTR

(3) Part II: Quality

(4) Part III: Non-clinical Document

(5) Part IV: Clinical Document

(6) Clinical Check List for Product Classification

In addition, the ACTR includes relevant ASEAN guidelines as

(1) ASEAN Guideline on Submission of Manufacturing Process Validation Data for Drug Registration

(2) ASEAN Guidelines for Validation of Analytical Procedures

(3) ASEAN Guideline on Stability Study of Drug Product

(4) ASEAN Guidelines for the Conduct of Bioavailability and Bioequivalence Studies

(5) ASEAN Guideline on Process Validation Q&A

Besides, the important information as well as relevant forms could be available through the website of the Drug Control Division of the FDA.

Reviewing of product registration

From content analysis

The reviewing of product registration of the modern medicinal product would be routinely performed by the authorized officers of the Pre-marketing Control Unit of the Drug Control Division. The database used for the reviewing of product registration consists of the result of the project for study the quality of some kinds of medicinal product such as Tolperisone which has always had a problem about the related substances, the report of quality defect and product recall from the Inspectorate Unit and the Import and Export Inspection Division.

From key informant interview

However, the reviewing of product registration could not be done up to date and spent more times to finish all processes because of the large number of product registration and the limitation of human resource.

Sample analysis

From content analysis

When the licensee(s) would like to apply for the product registration of each medicinal product, they would be asked for submission of the sample of those medicinal products and then the FDA will send those samples to DMSc to test its quality as required.

From key informant interview

Nonetheless, the sample analysis for some kinds of medicinal product, especially anticancer could not be done since the DMSc's laboratory is not ready in a

part of facilities and instrument to do the analysis for hazardous medicinal products. So the consideration for approval of the product registration of anticancer requires only the documents e.g. COA, process validation, stability study, etc.

Result of SWOT analysis

Strengths (S)

S6) Product registration for each medicinal product has required by FDA regarding to the Drug Act B.E. 2510.

Weakness (W)

W10) Reviewing of product registration could not be done up to date and spent more times to finish all processes because of the large number of product registration and the limitation of human resource.

W11) Sample analysis for some kinds of medicinal product, especially anticancer could not be done since the DMSc's laboratory is not ready in a part of facilities and instrument to do the analysis for hazardous medicinal products.

3.3) Approval process for imported modern medicinal products

From content analysis

The import inspection process has been defined for the importation of all products into Thailand. The Customs is the organization that responsible to both facilitate and also control the import and export of all kinds of product. Furthermore, the taxation for the import and export products should be performed correctly. On the other hand, the FDA is the organization that responsible to monitor and control the quality of imported health products, including the modern medicinal products. The importer should be licensed by FDA, and its own imported products should have more quality, safety and efficacy according to the requirement for each product.

When the modern medicinal products are imported at the port of entry, the Customs' officers are responsible for consideration of the type of products being imported as followed;

1. The goods that must be prohibited to import into Thailand such as the narcotic drugs

2. The goods that must be controlled by some organizations with the relevant laws

All organizations responsible to control each product should inform the Customs to know more about the relevant laws or requirements. If the imported products could be identified as the first type, the importation of those products should be rejected immediately and the importer will be punished according to the Custom's law. If; moreover, those imported products were identified as the second type, they will be calculated the tax with a rate that defined in the customs tariff of those products, and then distributed to the office of each responsible organization's office at the port of entry. For the modern medicinal products, they are identified as the second type and the importer should contact the port of entry of FDA to request for checking their medicinal product being imported according to the Drug Act B.E.2510 respectively.

The shipping/ agency, the representative of the importer should coordinate with the Customs and FDA's officers in order to follow the process for the customs clearance and the importation approval process. If there has no any violation of the laws, the Customs will check the submitted documents and consider for tax calculation related to a customs tariff for each product first.

The Customs must follow the international requirement notified by the World Customs Organization (WCO) for the customs clearance and also how to identify the customs tariff for each product. A customs tariff is a tool for product identification. Each product is identified as the code related to its customs tariff and the tax rate will be different for each product.

From key informant interview

However, some kinds of products could not be identified its customs tariff because the definition notified by the Customs usually not comply with the contents in the relevant laws. Therefore, the Customs have to coordinate with among relevant organization to verify that all products under control of each organization have already been correctly stated in the list of the customs tariff. Moreover, the Customs always communicate with all organization through the training programme that will be held

particularly, in order to clarify and harmonize the information on the customs tariff together.

Besides, the additional measurement in case of the product which could not be identified its customs tariff has been established by the Customs as followed;

1) The importer could inquire what the customs tariff of its own product through the website of the Customs as well as telephone to the responsible officers

2) The Customs has already appointed the working group to do the consideration and analysis for the product that could not be clearly identified

3) The importer(s) could argue the result of the customs tariff identification done by the Customs if they disagree

In case of the imported modern medicinal products, they will be identified and concluded as one of the health products which under control of FDA. After the taxation has already done, the Customs will issue the documents for importation as (1) Import Entry and/or Notification to Collect International Postal Items, and (2) Invoices, and ask the shipping/ agency to transfer all documents as well as the sample of all items and all lots of the modern medicinal products which was imported in each shipment, to the officers at the port of entry of FDA.

At the port of entry of FDA, if the sample of imported products could not be identified as the modern medicinal products, the officer will contact the relevant division of FDA such as the Drug Control Division (DCD), the Food Control Division (FCD) to get more details about those products. If each division could not identify what those imported products are, the officer at the port of entry will ask the shipping/ agency to contact the licensee to know the problem, and then the licensee should go to the FDA, in order to seek for the conclusion.

If there has no the problem about the product identification, the officer at the port of entry of FDA must thoroughly consider the imported medicinal products according to the Drug Act B.E. 2510 and relevant laws. Furthermore, all documents related to the importation as required must be submitted to the officers at the port of entry of FDA as followed;

(1) Request form for modern medicinal importation

(2) The license for modern medicinal importation

(3) The product registration

(4) Import Entry and/or Notification to Collect International Postal Items

(5) Invoices

(6) Airway Bill (AWB) or Bill of Lading (BL)

(7) Packing list

(8) Certificate of Analysis (from the manufacturer)

(9) GMP Certificate

(10) Certificate of free sale

The decision making of the officers at the port of entry of FDA could be done as followed;

1. The imported medicinal products comply with the Drug Act B.E. 2510 and relevant laws

The officer at the port of entry should make a decision for taking a sample of all items and all lots of the imported medicinal products in each shipment, in order to do the visual inspection by checking the correction of the labeling according to its product registration and the requirement defined in the Drug Act B.E. 2510. If any items of imported modern medicinal products are stated in the annual sampling plan, it must be taken sample and its testing results must be used for evaluating the current situation of the quality of those medicinal products distributed in the market. Besides, the relevant documents for importation request must be reviewed and then approved when there has no any violation of the laws.

After that the shipping/ agency must return to the Customs together with the approved importation documents. The Customs will recheck all documents and then release those modern medicinal products to be imported and distributed in our country respectively.

2. The imported medicinal products do not comply with the Drug Act B.E. 2510 and relevant laws

If the violation of the law defined the penalty as the civil suit (only pay a fine) e.g. the improper details on label, the officer at the port of entry of FDA would prepare the letter to inform the Customs about the violation occurred, in order to

follow the procedure for punishment according to the Customs' law. The importer who infringed the FDA's laws in this case must pay a fine in the rate defined by the Customs. Moreover, all imported medicinal products with improper details on label should be sequestered at the store of importer until the label has been corrected and then the importer must inform the officer at the Import and Export Inspection Division in order to re-check the new label and allow the importer to distribute its imported medicinal products respectively. Besides, the officer at the port of entry may decide to take sample if necessary.

If the violation of the law defined the penalty as the criminal case which includes the imprisonment e.g. importing of counterfeit or non-registered, all those medicinal products must not be allowed to import into Thailand and the importer should be punished according to the Drug Act B.E. 2510 and also the Custom's law.

After the imported medicinal products had been sampled and having no any violation of the Drug Act B.E. 2510 and other relevant laws, the importer will be allowed to import its products into Thailand and keep those products at the store, with the appropriate storage condition.

Since the analysis usually takes more time, all the imported medicinal products taken sample at the port of entry of FDA could be moved from the Customs' cargo to its own storage area because the expenses to rent the Customs' cargo are quite expensive. Those products could be distributed in the market immediately. Nevertheless, the importer must strictly follow the procedure for product recall and also be punished according to the Drug Act B.E. 2510 if the testing result analyzed by DMSc showed that the quality of its imported medicinal products was failed.

Nevertheless, there are some limitations which can be the causes of error in the import inspection system for modern medicinal products as followed;

1. All kinds of products imported from abroad should be categorized or filtered by the Customs before informing the other organizations to check those products regarding the relevant laws or requirements. Nevertheless, the import inspection system of the Customs could not be completely performed in some cases. For instance, some kinds of product that were declared as only a sample, not the

finished product, the importer can import those products without the license for importation. However, if those imported products are the modern medicinal product, the importer should be strictly followed the procedure that required by FDA. Furthermore, it is difficult to detect if the passenger intend to smuggle some products by packing together with their own luggage. That means it is possible that some imported medicinal products will be passed without transfer to the port of entry of FDA.

2. The officers at the port of entry of FDA have to approve the importation of modern medicinal products before the issuing of testing results by DMSc. If the testing results showed that the imported modern medicinal products taken sample at the port of entry are failed or out-of-specification, the importer must promptly recall its products from the market. However, those failed medicinal products had already distributed in the market for a long time before issuing the conclusion of testing results. That means there has a risk for the consumer or patients who access those medicinal products at that time.

3. The required documents in the process of the importation approval that the importer presented to the FDA's officers at the port of entry might not be reliable. For example, the copy of Certificate of analysis (COA) issued by the manufacturer; sometimes, could not prove whether it is the real one.

Result of SWOT analysis

Strengths (S)

S7) The process for the importation approval has been performed following the written procedure(s). The duty and responsibility of each organization has been clearly identified.

S8) The additional measurement to clarify the customs tariff of unclearly identified product has been established and operated by the Customs.

Weakness (W)

W12) After taking sample, FDA must approve the importation of modern medicinal products before the issuing of testing results by DMSc.

W13) The import inspection system of the Customs could not be completely performed in some cases e.g. products declared as a sample only, smuggled products by packing with passenger's luggage.

W14) Some required documents to consider for importation approval might not be reliable e.g. copy of COA.

3.4) Sample taking

The imported modern medicinal products must be taken sample as an important step in the importing system.

3.4.1) Sampling plan

From content analysis

The annual sampling plan emphasized on the sampling of modern medicinal products being distributed in the market among those produced by local manufacturers, sold at the pharmacy, and imported from abroad has been prepared by the involved divisions of FDA as the DCD, the Import and Export Inspection Division, the Technical and Planning Division, and DMSc. The objective of the annual sampling plan is to monitor the quality of modern medicinal products before and after being imported and distributed into the market. Moreover, the criteria for setting the annual sampling plan based on scientific and/or pharmacological information include the collective data of each medicinal product about the quality defect and the adverse drug reaction (ADR) occurred in the past time, and the stability data. The sample of finished medicinal products being distributed in the market must be taken from the warehouse used as finished product stock, and also from the retained sample if necessary. Nevertheless, the annual sampling plan could not define covering all kinds of medicinal product being distributed in the market because of the limitation of budget and the high expenses for sample analysis.

The modern medicinal products will be sampled following the sampling plan by the responsible organizations. For the central part, the officers of the Inspectorate Unit must do the sample taking of the medicinal products being distributed in the market at the local manufacturers, the importer, and the pharmacy located in Bangkok, while the officers of the Import and Export Inspection Division have to take samples the imported modern medicinal products at the port(s) of entry).

For the regional part, the Rural and Local Consumer Health Products Protection Promotion Division, the organization under control of FDA is appointed to contact the provincial offices to request them to take samples following the sampling plan at the pharmacy located in their provinces. After all samples are sent back to the Rural and Local Consumer Health Products Protection Promotion Division, they will be sent continuously to the Inspectorate Unit to pass through them to the DMSc to do the testing following its specification respectively.

Moreover, there are two types of the sampling plan for the imported modern medicinal products. Firstly, a sampling plan aims to collect data and then evaluate the current situation for some kinds of products including the imported medicinal products, but do not concern about the violation of the law. Secondly, a sampling plan for special cases, particularly the medicinal products of the "Hot issues" that may affect the consumer protection policy will be set up based on the situation at that time, and the violation of law must be prosecuted regarding the content of penalty in the Drug Act B.E. 2510.

In addition, the Inspectorate Unit has established the year plan for routine inspection with sample taking if necessary for post-marketing surveillance purpose at the importer and/or distributor as well as the sample taking in case of the violation of the laws.

From key informant interview

In fact, the FDA could not completely follow the number of sample stated defined in the annual sampling plan since it depends on the frequency and quantity of importation for the modern medicinal products during a fiscal year by each importer. Furthermore, the Drug Act B.E. 2510, section 85 defined that any medicinal product which has been registered but not imported into Thailand for two consecutive years, the product registration shall be withdrawn. Therefore, most of importers usually import some items of modern medicinal products which were not quite popular in the market in the small amount every year. Those medicinal products will be kept as the retained sample only but not distributed into the market. If those medicinal products are one of products required in the sampling plan, they will not be sampled as its objective of importation was not to distribute into the market for patient treatments.

That means the number of sample. Finally, the kind and number of sample(s) of imported modern medicinal products taken by all involved organization cannot achieve a goal.

Result of SWOT analysis

Strengths (S)

S9) The annual sampling plan has been defined based on scientific and/or pharmacological information.

Weakness (W)

W15) FDA could not completely follow the number of sample defined in the annual sampling plan. It depends on the frequency and quantity of importation for the modern medicinal products during a fiscal year by each importer.

W16) Annual sampling plan could not define covering all kinds of medicinal product being distributed in the market because of the limitation of budget and the high expenses for sample analysis.

3.4.2) Persons who take sample

From key informant interview

The FDA's officers at the port of entry who responsible for taking a sample were graduated for Bachelor in science, and well-trained following the written procedure.

For sampling process of the modern medicinal products, the shipping/ agency must carry the samples to the port of entry of FDA, and then submit those medicinal products to the officers. However, the officers who work at the port of entry of FDA do not go to the containers or shipment to take sample by themselves because of the limitation of the number of officers, the workload based on the frequency of importation and also the difficulty to distinguish the imported modern medicinal products from other items in the same container.

Result of SWOT analysis

Strengths (S)

S10) The officer responsible for taking sample at the port of entry of FDA were graduated for Bachelor in science, and well-trained following the written procedure.

Weakness (W)

W17) The officers who work at the port of entry of FDA do not go to the containers or shipment to take sample by themselves because of the limitation of the number of officers.

3.4.3) Instruments/ Laboratories

From key informant interview

Nowadays, some ports of entry of FDA e.g. the Suvarnnabhum airport (cargo), Bangkok Pier have already established the laboratory and also sampling boot used for testing of some items of imported medicinal products. Those laboratories have been already passed the accreditation and then certified by the DMSc, the National Control Laboratories (NCL) of Thailand.

Furthermore, all ports of entry of FDA have been supported the test kits for some health products. In addition, the specific and high technology instrument has been arranged in some ports of entry e.g. RAMAN Spectrophotometer which could be used to identify the active ingredients of the modern medicinal products without opening the container. It will be useful for rapid identification at the port of entry, and the officer can use the result from this rapid identification to consider for importation approval respectively.

Nonetheless, the number of laboratories and high technology instrument as RAMAN spectrophotometer are still inadequate at the present time.

Result of SWOT analysis

Strengths (S)

S11) The quality control laboratories at the port(s) of entry have been accredited by DMSc.

Weakness (W)

W18) The number of laboratories and high technology instrument as RAMAN spectrophotometer are still inadequate at the present time.

3.5) Storage area and condition for keeping the imported medicinal products

From content analysis

When the modern medicinal products are imported, the importer will be allowed to move those products to keep in the store after the consideration for importation approval. The licensee always provides the storage area with appropriate condition, in order to keep and maintain the quality of those medicinal products according to its storage condition and shelf-life defined in the product registration of each imported modern medicinal product.

Nowadays, the importers always employ other company as the distributor in order to distribute their imported modern medicinal products into the market. The responsibility of distributor is to keep the imported medicinal products at the store as well as deliver those products under the storage condition as required for each product.

Moreover, the environmental control during the transportation should be concerned, in order to ensure that the imported medicinal products will be kept under the suitable condition always and then the quality of those medicinal products can be maintained until transferring to the consumer.

The Good Distribution Practices (GDP) and Good Storage Practices (GSP) are the useful principle to control, monitor, and assess the effectiveness of the operation of transportation and storage for modern medicinal products. At the present time, the guide for GDP and GSP had already prepared as a draft version, and in the process of simulation test of the possibility and effectiveness of those guides.

From key informant interview

Since the GDP and GSP are not now required as the laws, and there has no the penalty regarding the Drug Act B.E. 2510 in case of transportation and storage the medicinal products under inappropriate condition, some importers and distributors did not strictly concern about those issues. If the testing results of the modern medicinal products taken sample following the annual sampling plan or special cases show that

the quality of those medicinal products still be in specification, FDA cannot punish the importer or distributor although they did not keep their medicinal products under the condition as required.

Result of SWOT analysis

Strengths (S)

S12) Normally the licensee of medicinal product importation always provides the storage area with appropriate condition, to maintain the quality of their imported medicinal products according to its product registration.

Weakness (W)

W19) There has no the penalty regarding the Drug Act B.E. 2510 in case of transportation and storage the medicinal products under inappropriate condition; therefore, some importers and distributors did not strictly concern about those issues.

3.6) Post-marketing surveillance system for the imported medicinal products

From content analysis

According to the post-marketing surveillance system for the imported medicinal products, both the Customs and FDA are established its own system. Moreover, the officers responsible for conducting the post-marketing surveillance of both the Customs and FDA are well-trained and very skillful in their field.

The Customs not only provide the facilitation for import and export any goods but also control the correction of goods in compliance with the relevant law and requirement for each product. The inspection system for imported products has been established based on a principle of risk management. Furthermore, the post-audit system is another system that the Customs has defined as the post-marketing surveillance system to ensuring the effectiveness of the customs clearance and also the correction of releasing process for the imported products.

The FDA by the Inspectorate Unit of DCD is responsible for controlling and monitoring the quality of medicinal products being distributed in the market to ensure that the consumer will access any medicinal product with high quality, safety, and efficacy. Moreover, if there has any violation of the Drug Act B.E.2510, the officers of

the Inspectorate Unit will strictly take action in order to collect all data as the evidence or witness. After that the licensee should be punished regarding the Drug Act B.E.2510 and following the procedure for product recall as well.

From key informant interview

However, the FDA has no policy for the abroad on-site GMP inspection at the modern medicinal product manufacturers located in the origin countries where produce those products supplied into the market in Thailand. The objective of abroad on-site GMP inspection is to ensure that those manufacturers could produce the modern medicinal products complying with the reliably international standard, and more quality and safety for human used. Nonetheless, the Ministerial Notification of GMP for modern medicinal products does not define the responsibility of the competent authorities as the abroad GMP inspectors.

In addition, there has no effectively systematic measurement that should be established by both the Customs and FDA to investigate and promptly detect the illegal medicinal products which were smuggled and distributed in the market, without passing through the port of entry of FDA.

Result of SWOT analysis

Strengths (S)

S13) The officers responsible for conducting the post-marketing surveillance of both the Customs and FDA are well-trained and very skillful in their field.

S14) The inspection system and post-audit system for imported products based on a principle of risk management has been established by the Customs to ensure the effectiveness of the customs clearance.

Weakness (W)

W20) There has no policy for the abroad on-site GMP inspection at the manufacturers located in the origin countries.

W21) There has no effectively systematic measurement established by both the Customs and FDA to investigate and promptly detect the illegal medicinal products which were not passed through the port of entry of FDA.

3.7) Prosecution/ Recall/ Rapid Alert

In the importing system for the modern medicinal products, there has the measurement for prosecution the importer who infringe the relevant laws as followed,

From content analysis

3.7.1) The Customs' law

Any importers who violate the Customs' law as well as other relevant laws must be punished according to the penalty mentioned in the laws. For example, the importer who imported the modern medicinal products with wrong labels should be punished by paying a fine at the rate defined in the Customs' law since the fine rate for this case stated in the Customs' law is more than in the Drug Act B.E.2510. The importer should be punished following the most powerful law.

3.7.2) FDA's law and the additional measurements

3.7.2.1) The Drug Act B.E.2510 and relevant laws

The importer who wishes to import the modern medicinal products into Thailand should know its responsibility regarding the Drug Act B.E.2510.

Any violation of Drug Act B.E.2510 should be considered for prosecution according to the content of penalty defined in this law. Furthermore, the testing results related to the annual sampling plan or the violation of the laws show that the quality of imported medicinal products was failed or out-of-specification, the importer must be punished regarding the Drug Act B.E.2510.

3.7.2.2) Recall system

This system has been required for all local manufacturers and importers whose modern medicinal products were failed or having a risk for the patients use. It consists of two main options as followed;

(1) Recall with FDA's order

If there has any data shown as the serious cases that affect or might be risk for the patient use, the working group to consider for quality defect and recall of medicinal products should thoroughly consider for those cases immediately. If the resolution is to require the company to recall its medicinal products from the market, the secretariat of the working group must prepare and submit the formal recall letter to the Secretary General of FDA to sign in the letter.

And then the recall letter should be sent to the company rapidly. The company should follow the recall procedure in order to ask its clients to return the recalled medicinal products and the company is finally required to report the conclusion of recall to FDA. After that FDA will appoint the responsible officers at least two persons to observe and control the operation for destroying the recalled medicinal products. All recalled medicinal products should be destroyed with the appropriate methods in order to ensure that those medicinal products cannot be returned for use.

For example, the testing result of product Z, aseptically prepared sterile product which was taken sample regarding the annual sampling plan shows that there has the visible particle and the microbiologists of DMSc had already tested and confirmed that it was the fiber of mold. The data would be transferred from DMSc to FDA promptly, and proposed into the working group meeting first. After that FDA will send the formal recall letter to the company related to the resolution of the meeting of the working group. Moreover, the company must follow the recall procedure strictly, and those recalled medicinal products should be destroyed under control of the officers appointed by FDA respectively.

(2) Voluntary recall

If the company has got the information shown that the quality of its medicinal products has a possible trend to be out-of-specification, the company can take action following its own recall procedure, in order to protect the consumer as soon as possible from any risk resulting from using its medicinal products.

For example, the company had already updated the details of insert in part of precaution for product Y, the pediatric drops for children imported from abroad and the formal insert must be changed. However, the company found that the new version of insert still remains about 300 pieces. That means the insert of some packages of product Y did not be changed. So the company informs its clients to return product Y, and send the new one with new version of insert instead. In this case, the company may inform FDA about the reason why product Y must be recalled, and all recall processes that the company followed.

From key informant interview

Although there has penalty stated in the Drug's law for the company that could not recall its products in time or ignore to follow the recall procedure as FDA required, the effectiveness of recall system should be thoroughly concerned, particularly the monitoring system for product recall. After the FDA asked the company to recall its products from the market in time as required, the FDA must only wait for the report of product recall from the company, without any more effective system to monitor the result of product recall. In the present time, the FDA's officer has to stimulate the company by phone. However, the limitation of this method is that the phone number may be not available and the change of responsible person could be a cause of the slowness of monitoring of the result of product recall.

From content analysis

3.7.2.3) Rapid Alert

The FDA has already established the webpage as "Safety Alert" published through the website of FDA, www.fda.moph.go.th to inform the consumer to know more and beware of the quality of health products, including the imported modern medicinal products distributed in the market. In case of medicinal products, the Inspectorate Unit is the organization appointed from FDA to prepare and update the information on the webpage of "Safety Alert".

"Safety Alert" will be always updated and mentioned on recall and rapid alert for each health product, including modern medicinal products. There has the specific webpage for modern medicinal products as well. Database of "Safety Alert" comes from the test results of the modern medicinal products which were taken sample from the local manufacturer, importer as well as the pharmacy according to the annual sampling plan and some special cases with violation of the Drug Act B.E.2510.

The published information shown in "Safety Alert" consists of the details of medicinal products (e.g. lot, Mfg. date, expiry date, name of manufacturer and importer), the causes of recall or rapid alert (e.g. out-of-specification, sub-standard, non-registration), the status or results (e.g. recalled

already, in-process of recall, withdrawal of product registration), the organization who taking sample (the Import and Export Inspection Division, the Inspectorate Unit).

In addition, some items of the recalled medicinal products presented in “Safety Alert” were the imported medicinal products with approved product registration. Most of people usually believe that the medicinal products produced and imported from other countries would have more quality and safety than the medicinal products produced by local manufacturers. However, the information indicated that the imported medicinal products may not be the best one.

3.7.2.4) Working group

(1) The Committee to consider for prosecution in case of the violation of the Drug Act B.E.2510

This working group has been established by FDA. It consists of many experts in the field of pharmaceuticals such as the Secretary General of FDA, the experts working for the Ministry of Public Health, and the lawyer of the Legal Affairs Group of FDA. The responsibility of this working group is to thoroughly consider for the prosecution and penalty of the violator who infringed the law for health products, including the Drug Act B.E. 2510.

(2) The ADR working group

This working group has been established by FDA and the Technical and Planning Division is the division act as the focal point and responsible to perform the activities of this working group. In case of the adverse drug reaction (ADR) occurred in the patient who used the health products including the medicinal products, this working group would consider and conclude the resolution for each case. And then they inform the Inspectorate Unit of the Drug Control Division (DCD) to follow the process for recall as well as rapid alert respectively.

(3) The Quality Defect working group

This working group has been established by FDA. The member of this working group is composed of the experts and the officers of the Drug Control Division who have more knowledge and experience such as the lead inspectors and head of the compilation group of the Inspectorate Unit, and the head of the Licensing Unit.

If there has any data shown the risk for patient use resulting from the quality defect of the medicinal products, this working group should thoroughly consider for those cases immediately. If the resolution is to require the company to recall its medicinal products from the market, the process of recall would be done step by step according to the procedure for recall prepared and published by the FDA. Moreover, the rapid alert could be performed in parallel if needed.

From key informant interview

Nevertheless, the Quality Defect working group has not had the experts or specialists in several fields of expertise or from other organizations, particularly from DMSc. The cooperation among all involved persons who have different expertise is very necessary and useful for issuing the appropriate and correct conclusion.

In the present time; however, there has no the specific criteria to distinguish the difference between the quality defect and adverse drug reaction (ADR) issues. If details of the problem of medicinal products were transferred into an incorrect channel, it would take more times to change the channel for consideration. For instance, the problem comes to FDA in the ADR channel and the resolution from the ADR working group shows that a cause of problem is the quality defect issue. This issue must be sent back to the Quality Defect working group to do the consideration respectively. During this long processes, the consumer might get a risk from accessibility of those low quality medicinal products which still be distributed in the market at that time.

Nonetheless, the FDA has already established this specific working group in year 2010, but not ready to work out now since it is in the process of discussion for its responsibilities and action plan.

Result of SWOT analysis

Strengths (S)

S15) The penalty and prosecution was defined in all relevant laws. Moreover, recall and rapid alert system has been established and strictly followed regarding its procedure.

Weakness (W)

W22) The measurement to monitor the result of product recall is not effective.

W23) Members of the Quality Defect working group do not cover the experts or specialists in several fields of expertise or from other organizations, particularly from DMSc.

W24) There has no the specific criteria to distinguish the difference between the quality defect and adverse drug reaction (ADR) issues.

3.8) KPIs

Key Performance Indicators (KPIs) defined by each organization concerning the importing system for modern medicinal products should be considered based on the appropriateness and its function that should represent the overview of all responsible works of the organization. KPIs should be used as a tool for controlling all involved persons to perform their own activities effectively and for achieving a goal of the organization related to the importing system for modern medicinal products.

From key informant interview

3.8.1) <u>The Customs</u>

The major KPI defined by the Customs is that the taxation for the products being both imported and exported must be complete and correct. In addition, the detection and prosecution for the violation of copyright, patent and also trademark should be absolutely performed.

The result of KPIs in year 2009 presented that the Customs' officers could reach a goal of each KPI. And then the result of KPIs will be considered the improvement of a system for taxation and also measurement to detect any violation respectively.

From content analysis

3.8.2) <u>Food and Drug Administration (FDA)</u>

The FDA is the main organization that must be directly responsible for monitoring and controlling the imported medicinal products to comply with the Drug Act B.E.2510. Therefore, the KPIs of each organization under control of FDA should be suitable defined, in order to achieve a goal of consumer protection.

3.8.2.1) The Drug Control Division

The result from reviewing the KPIs of the Pre-marketing Unit as well as the Inspectorate Unit in the fiscal year of 2010 shows as followed;

3.8.2.1.1) The application for issuing the license that was considered and approved in timely manner should not be less than 92%

3.8.2.1.2) The application for issuing the product registration that was considered and approved in timely manner should not be less than 91%

3.8.2.1.3) The number of medicinal products both being imported and distributed in the market that were taken sample should not be less than 85%

3.8.2.1.4) The number of licensees that were inspected following the year plan should not be less than 85%

3.8.2.1.5) The number of any complaints from consumer that were inspected regarding relevant laws in time should not be less than 80%

From key informant interview

From 3.8.2.1.1) and 3.8.2.1.2), both of KPIs were represented the performance of the FDA's officers that could follow the written procedure for issuing the license and product registration in timely manner. However, there had no the evaluation of those result of KPIs related to the importing system for medicinal products. For instance, If a number of the application for issuing the license for importation of modern medicinal product or a number of the application for issuing the product registration has significantly increased, it could be assumed whether the importation for modern medicinal product was activated and it would affect the local market of modern medicinal product or not.

From 3.8.2.1.3) to 3.8.2.1.5), all KPIs could be used to improve the importing system for modern medicinal products. The testing result of the sample of imported medicinal product in 3.8.2.1.3) could be used as the raw data of consideration for setting of the annual sampling plan for the medicinal products in next fiscal year. The result of 3.8.2.1.4) and 3.8.2.1.5) could inform the FDA to know

more about the behavior of each licensee, and then the post-marketing surveillance plan will be prepared based on the history of licensees.

From content analysis

3.8.2.2) The Import and Export Inspection Division

The result from reviewing the KPIs in year 2008 – 2010 shows that the KPIs were separated into two types i.e. the quantitative and qualitative KPIs respectively as followed;

3.8.2.2.1) The quantitative KPIs

(1) The number of the consideration for importation approval for the health products should not be less than 50,000 items

(2) The number of the imported health products that were sampled for inspection according to the relevant laws should not be less than 500,000 items

3.8.2.2.2) The qualitative KPIs

(1) The imported health products that were sampled for inspection having more quality regarding its specification should not be less than 95%

From key informant interview

Some KPI was not appropriate and could not be the representative of the achievement of the organization. For instance, the KPI in 3.8.2.2.2) mentioned that "the imported health products that were sampled for inspection having more quality regarding its specification should not be less than 95%" might not be reasonable. The limitation was that the FDA's officers could not control whether the testing results of all products that were taken sample following the annual sampling plan would comply with the specification stated in each product registration. Since the sampling plan for the Import and Export Inspection Division could not defined the name of importer, just only the list of medicinal products being taken sample stated in the sampling plan; therefore, in order to pass the KPI as required, the officers working at the port of entry may make biased decision to take sample of imported medicinal products which was the products of the reliable importer who had no the history of violation of the FDA's

law such as the Drug act B.E. 2510. That means the sampling of imported medicinal products at the port of entry could not be the real representative and not achieved a goal of sample taken.

Result of SWOT analysis

Strengths (S)

S16) Each organization has defined the KPIs, in order to control and monitor the officers whether they could follow the procedures and do their works effectively.

S17) The result of KPIs is usually evaluated and used for improving the previous activities.

Weakness (W)

W25) Some KPI was not appropriate and could not be the representative of the achievement of the organization.

Element 4: Technology

From content analysis

Nowadays, both the Customs and FDA has published and transferred the information that the consumer should know and do understand by using the modern technology and media, particularly through the internet e.g. website of the Customs (www.customs.go.th) and FDA (www.fda.moph.go.th).

Furthermore, the data recording system has already established for collecting the important data concerning the importing system for medicinal products e.g. The DCD of FDA has already used the data recording system to prepare the database of all licensees and product registrations.

Besides, the data recording system through the specific programme has been provided for the officers of the Customs and also the FDA working at the port of entry. The recording system of the Customs can collect and evaluate data of importation and exportation in the real time.

On the other hand, the FDA has established the data recording system through the intranet, in order to achieve the campaign of paperless. In parallel, the ports of entry in Bangkok and also in the other provinces must transfer all hard copies which are the evidences for importation approval to the central office every month.

From key informant interview

Nevertheless, because of the increasing of quantity and frequency of importation of the medicinal product, the officer working at the port of entry of FDA could not record all data of imported medicinal products completely in the real time. Therefore, the evaluation for the current situation of the imported health products, including modern medicinal products could not be performed immediately.

Result of SWOT analysis

Strengths (S)

S18) Both the Customs and FDA has published the important information through the modern technology and media e.g. website of each organization.

S19) The data recording system has already setup for collecting the data concerning the importing system for medicinal products e.g. the data recording system of DCD prepared as database of all licensees and product registrations.

Weakness (W)

W26) Data record of FDA could not perform as the real time so the evaluation for the current situation of the imported medicinal products could not be done immediately. On the other hand, the Customs can collect and evaluate data of importation and exportation in the real time.

Element 5: Stakeholders

From content analysis

All stakeholders in the importing system for modern medicinal products have to follow their own duty and responsibilities according to the relevant laws, requirement, and procedures of each organization. The involved organization and/or personnel consists of

5.1) Customs

Its responsibility is to facilitate the importer and exporter and also follow the procedure for customs clearance regarding a guide or requirement issued by World Customs Organization (WCO). Moreover, a system to check up and control the imported products has been established and strictly performed.

5.2) Food and Drug Administration (FDA)

- Drug Control Division (Pre-marketing Unit and Inspectorate Unit)
- The Import and Export Inspection Division
- The Legal Affairs Group

This organization is the National Regulatory Authority (NRA) of Thailand. For the modern medicinal products being imported and distributed in Thailand, FDA is the main organization to ensure the quality of imported medicinal products by setting a system to control and monitor all activities of the licensees and also the quality of their own products in compliance with the Drug Act B.E. 2510 and other relevant laws.

5.3) Provincial Health Office

For the port(s) of entry at other provinces, FDA has requested the Provincial Health Office(s) to conduct the importation approval for health products including modern medicinal products. Thai FDA supports them the budgetary for all activities.

5.4) Department of Medical Sciences (DMSc)

This organization is the National Control Laboratory (NCL) of Thailand. Its responsibility is to do the sample analysis in order to ensure that the medicinal products taken sample at the port(s) of entry and from the market still have a quality, safety and efficacy complying to its own product registration approved by FDA. The testing result from DMSc will be used as the important evidence that FDA can use it to consider any prosecution or punishment of the violator who infringed the Drug Act B.E. 2510.

5.5) Shipping/ Agency

This organization acts as the representative of the importer and exporter. The operator from the company for shipping/ agency will coordinate with the Customs and FDA's officers at the port of entry, in order to follow the process for the customs clearance and the importation approval process. Their responsibility is that they must do all processes as the Customs and FDA required until finishing the process of releasing the products.

From key informant interview

5.6) Forwarder

This organization is the company who was employed by the importer to carry out the products from the origin countries to Thailand. It has not been controlled by FDA.

Nevertheless, when they carry out the product being imported into Thailand, there are many kinds of products contained in the same containers. Sometimes, the small amount of medicinal products may be overlooked or identified as only a sample of product. The Customs may make a decision to release them without transferring to the port of entry of FDA to check its correction regarding the Drug Act B.E. 2510 before releasing by the Customs respectively.

Result of SWOT analysis

Strengths (S)

S20) Each organization has prepared the procedure for its activities, regarding the laws and other relevant requirements.

Weakness (W)

W27) Forwarder who was employed by the importer to carry out many kinds of product from the origin countries to Thailand has not been controlled by FDA. Sometimes, the small amount of medicinal products may be overlooked and released without the approval by FDA.

Element 6: Personnel

From content analysis

This study focused on the persons who work for the Customs and FDA only. The results from the key informant interview could be summarized as followed;

6.1) Qualification

6.1.1) The Customs' officers

The person who could work as the government official at the Customs should be graduated at least in Bachelor's Degree. However, the person who could be selected to work at the Customs in the other positions e.g. the secretariat, the

temporary employees for doing some works such as record data in the computerized system.

6.1.2) The FDA's officers

The person who could work as the government official in the position of pharmacists and scientists at the Import and Export Inspection Division and the Drug Control Division should be graduated in Bachelor's Degree in Pharmacy or in Science. For the employees working in other positions, the degree of education might be varied e.g. Bachelor's degree in other field, high school education, depends on the responsibility of each position.

From key informant interview

6.2) Competency and training

6.2.1) The Customs' officers

The officers who work for the Customs, particularly at the customs port must be well-trained, to do understand and be able to do their own activities effectively. They always improve their competency regularly and also expert in their field based on the experiences on the position that they were responsible for. Moreover, skill for investigation and detection of the abnormal products is very strong, and lead the officers' Customs to reject all incorrect products before being imported into Thailand.

6.2.2) The FDA's officers

The persons working at the Import and Export Inspection Division (both at the port(s) of entry and at the central) and the Drug Control Division (both at the Pre-marketing Control Unit and the Inspectorate Unit) always be well-trained. In addition, the internal and external training were defined in the annual plan. There are always the experts from other organizations in Thailand and also from abroad to be the instructors for some training courses. They have more competency and expertise in their field and own activities.

6.3) Work improvement

In the present time, the officers of the Customs and FDA at the port of entry have already been accessed all relevant information including the procedure(s) for any activity, the update main laws and additional requirement through the

communication system. However, the current communication system to provide the necessary knowledge and update laws to the officers or employee is now not effective and must be re-considered and improved. There are some technical difficulties that affect the accessibility of the information stated in this communication system. Besides, the interpretation of the laws and requirements by each officer should be thoroughly considered.

The international agreements could be a cause of dramatically increasing of quantity and frequency of the importation for health products including modern medicinal products into Thailand. Therefore, the officers have no more time to improve their own expertise and also develop their own activities

Result of SWOT analysis

Strengths (S)

S21) The officers had been well-trained. They have the expertise in their field as the specialists based on their experiences.

Weakness (W)

W28) Although there was communication system to provide the necessary knowledge and update laws to the officers working at the port of entry, the interpretation of the laws by each officer still be thoroughly considered.

W29) The officers have no more time to improve their own expertise and also develop their own activities because of dramatically increasing of quantity and frequency of the importation resulting from the international agreements.

Element 7: Structure and Element 8: Culture

From key informant interview

In order to know what the structure and relationship among relevant organizations concerning the importing system of modern medicinal products, the researcher separated the consideration following the principle of ***Keidel's Theory (1995)*** into two sessions consisting of 1) the Customs and FDA and 2) FDA and the Provincial Health Offices as followed;

(1) The Customs and FDA

Strategy

	Strategy	Type of organization	Characteristics
1.	Constituencies	Autonomy	Customers/ Clients
2.	Character	Autonomy	Player-oriented
3.	Capabilities	Autonomy	Differentiation (special)

1. Constituencies = Customers/ Clients

Consumers and the import-export business owners are the main group of persons who get the most benefit from all organizations concerning the importing system of the medicinal products.

2. Character = Player-oriented

Each organization pushes its work by itself, regarding to its responsibilities.

3. Capabilities = Differentiation (special)

The officers working for each organization has more competency and expertise in their field.

Structure

	Structure	Type of organization	Characteristics
1.	Organization chart	Autonomy	Flat/ Clear
2.	Layout	Autonomy	Independent action
3.	Interdependence	Autonomy + Cooperation	Pooled + Reciprocal

1. Organization chart = Flat/ Clear

Each organization has its own clear organization chart and job description of the officers who must work concerning the importation approval. The officers in each organization must directly report to its top management, but would not report their work to another organization.

2. Layout = Independent action

The activities performed by the officers of each organization are independently distinguished. The officers of each organization always work independent and having no closely relation with the others.

3. Interdependence = Pooled + Reciprocal

3.1 Pooled

The information flow for the importation approval of the modern medicinal products has to be pooled at the Custom, in order to consider and make a decision to finish the importation approval.

3.2 Reciprocal

The work flow for the importation approval of the modern medicinal products must be followed to the procedures and requirements of each relevant organization. The Custom and Thai FDA have to exchange or transfer the relevant documents with another before the finalization of the importation approval process. However, during the process for importation approval, the shipping usually acts as the messenger to transfer the relevant documents between the Custom and FDA.

Systems

	Systems	Type of organization	Characteristics
1.	Reward system	Autonomy	Individualistic
2.	Meeting system	Autonomy + Cooperation	Forum + Team-building
3.	Decision system	Autonomy	Decentralized (delegate)

1. Reward system = Individualistic

Reward for the officers should be paid by using the budgetary of each organization based on the evaluation of the effectiveness of their work.

2. Meeting system = Forum + Team-building (partial)

2.1 Forum

Normally when the representatives of each organization participate in the meeting, they can share the idea, inform the necessary data to the others and finally get the conclusion together. Nevertheless, some resolutions from the forum meeting could not be practically done, and the representatives from each organization could not lead or ask another to follow those resolutions.

2.2 Team-building

The team-building between the Customs and FDA could be set up for specific purpose or case by case only e.g. to combat the counterfeit products.

3. Decision system = Decentralized (delegate)

Each organization has the individual authority, the power and responsibility defined in its own laws.

(2) FDA and the Provincial Health Offices

Strategy

	Strategy	Type of organization	Characteristics
1.	Constituencies	Autonomy	Customers/ Clients
2.	Character	Autonomy	Player-oriented
3.	Capabilities	Autonomy	Differentiation (special)

1. Constituencies = Customers/ Clients

Consumers and the import-export business owners are the main group of persons who get the most benefit from all organizations concerning the importing system of the medicinal products.

2. Character = Player-oriented

Each organization pushes its work by itself, regarding to its responsibilities.

3. Capabilities = Differentiation (special)

The officers working for each organization has more competency and expertise in their field. Thai FDA has requested the Provincial office(s) to conduct the importation approval for health products, including modern medicinal products. Therefore, the officers of the Provincial Health Office(s) must be improved their competency in compliance with the procedure for importation approval.

Structure

	Structure	Type of organization	Characteristics
1.	Organization chart	Autonomy + Cooperation	Flat/Clear + Flat/Amorphous
2.	Layout	Autonomy + Control	Independent action + Programmed interaction
3.	Interdependence	Autonomy + Cooperation	Pooled + Reciprocal

1. Organization chart = Flat/ Clear + Flat/ Amorphous

1.1 Flat/ Clear

Each organization has its own clear organization chart and job description of the officers who must work concerning the importation approval. The officers in each organization must directly report to its top management, but would not report their work to another organization.

1.2 Flat/ Amorphous

The port(s) of entry at other provinces, particular at the border of Thailand, the Provincial Office(s) would be responsible for conducting the importation approval for health products including modern medicinal products as requested by Thai FDA. Thai FDA supports them the budgetary; however, Thai FDA does not have the authority to control, standardize and evaluate their works at the port of entry.

2. Layout = Independent action + Programmed interaction

2.1 Independent action

The activities performed by the officers of each organization are independently distinguished.

2.2 Programmed interaction

Any health policy or campaign, done by the Provincial offices must be periodically followed-up through the annual supervision conducted by the health expert team from the ministry.

3. Interdependence = Pooled + Reciprocal

3.1 Pooled

The information flow for the importation approval of the modern medicinal products would be pooled at the Import and Export Inspection Division of Thai FDA, in order to conclude the overall of the importation for modern medicinal products.

3.2 Reciprocal

The work flow for the importation approval of the modern medicinal products at the provincial port(s) of entry is that the Provincial offices must be followed the procedures and requirements of Thai FDA. And then they could finish the importation approval by themselves, together with the Custom. Only in some cases that the Provincial offices could not make a decision by themselves for the importation

approval, they usually contact to the Thai FDA to share the information and ask for the conclusion.

Systems

	Systems	Type of organization	Characteristics
1.	Reward system	Autonomy	Individualistic
2.	Meeting system	Autonomy + Cooperation	Forum + Team-building
3.	Decision system	Autonomy	Decentralized (delegate)

1. Reward system = Individualistic

Reward for the officers should be paid by using the budgetary of each organization based on the evaluation of the effectiveness of their work.

2. Meeting system = Forum + Team-building

2.1 Forum

Normally the representatives from Thai FDA and the Provincial offices would participate in the meeting to share the idea, inform the necessary data and get the conclusion together. However, some resolutions from the forum meeting could not be practically done.

2.2 Team-building

Sometimes, the team-building between FDA and the Provincial Health Office(s) could be set up for specific purpose in case by case.

3. Decision system = Decentralized (delegate)

Each organization has the individual authority, the power and responsibility defined in its own laws.

Result of SWOT analysis

Element 7: Structure

Strengths (S)

S22) Each organization has its own clear organization chart and job description of the officers who work concerning the importation approval.

S23) The cooperation among relevant organizations has been established in some cases e.g. smuggling of illegal medicinal products.

Weakness (W)

W30) Work flow for the importation approval of the modern medicinal products requires the shipping/agency to carry out the relevant documents between the Customs' office and the port of entry of FDA. The releasing process of those products may take more times.

W31) FDA has supported the budgetary to the Provincial Health Office(s) for conducting the importation approval for health products but FDA does not have the authority to control, standardize and evaluate their works at the port of entry.

Element 8: Culture

Strengths (S)

S24) The officers of each organization perform their work by themselves, regarding to the duty and responsibilities of their organization.

S25) Reward system has been established in each organization to motivate their officers.

S26) Each organization has the individual authority, the power and responsibility defined in its own laws.

Weakness (W)

W32) The officers of each organization always work independently and having no closely relation with the others.

4.1.2.2 SWOT analysis: External factors

PEST Model

Element 1: Policy

From content analysis

The top management of each organization involved in the importing system for modern medicinal products aims to encourage any policy that can improve and develop the importing system to get more effective.

Besides, the government always supports the budgetary for using in the project which has been established to develop the system of importation and exportation of our country. So the additional budget will be thoroughly considered for the important project only.

Furthermore, the Ministry of Public Health has conducted the periodic programme to follow-up the achievement of any health policy or campaign, under responsibility of the Provincial Health Office(s).

From key informant interview

For example, the new project proposed by the Import and Export Inspection Division of FDA to the board of Ministry of Public Health, in order to increase the number of ports of entry of FDA at least equal to those of the Customs within five years, to set up the new laboratories as well as to purchase new instrument e.g. RAMAN spectrophotometer in an adequate quantity. This project has already been approved, and in the process of budget arrangement.

On the other hand, the result of agreements used as the non-tariff barrier such as the Free Trade Agreement (FTA), ASEAN Free Trade Area (AFTA) is that any products from the other countries could be imported into Thailand without tax calculation. The quantity and frequency of the importation for health products including modern medicinal products into Thailand would be dramatically increased. Moreover, the policy of government to encourage our country to be “Hub of logistics” as well as the international requirement for the customs clearance notified by the World Customs Organization (WCO) that requires a period of time for releasing of the goods within 1/2 hours could affect the personal performance and the effectiveness of the consideration for importation approval by the officers of the Customs and the FDA, especially at the port of entry.

Result of SWOT analysis

Opportunities (O)

O1) The top management of each organization encourages any policy to improve and develop the importing system for modern medicinal product.

O2) The government always supports the budgetary used for developing of the importation and exportation system.

O3) The Ministry of Public Health has conducted the periodic programme to follow-up the achievement of any health policy or campaign, under responsibility of the Provincial Health Office(s).

Threats (T)

T1) The result of agreements used as the non-tariff barrier e.g. FTA, AFTA is that any products from the other countries could be imported into Thailand without tax calculation. Therefore, the quantity and frequency of the importation for health products including modern medicinal products would be dramatically increased, and then it could affect the personal performance and the effectiveness of the consideration for importation approval.

Element 2: Economics

From key informant interview

To get more market sharing during currently economic situation, the medicinal product owners should compete with the others by improving their capacity and reliability e.g. using more effective logistics' system that can keep the modern medicinal products under the appropriate condition and transport in shorter time and also providing the better customer services, with the lower prices. And then the customers will have more alternative way to select the most cost-effectiveness medicinal products for use.

Nevertheless, the government notified a policy for limitation of the number of officers in each governmental organization. The personnel recruitment as the govern officers could not be done. Therefore, all organization involving in the importing system for modern medicinal products must encounter to a circumstance of lack of qualified officers.

Result of SWOT analysis

Opportunities (O)

O4) The product owners would improve their capacity and reliability e.g. using more effective logistics' system to reduce a time for transportation and provide the better customer services, to get more market share.

Threats (T)

T2) The government notified a policy for limitation of the number of officers in each governmental organization. So the lack of qualified officers in each organization might affect the operation.

Element 3: Social/ cultural

From key informant interview

Nowadays, the consumers have more knowledge and always concern about their health. Therefore, the quality, safety and efficacy of the medicinal products are the main issues that the consumers consider.

However, some consumers still believe that the modern medicinal products produced and imported from other countries would have more quality and safety than the medicinal products produced by local manufacturers. In fact, the medicinal products produced by local manufacturer where follows the requirement of Good Manufacturing Practice (GMP) should also have a quality, safety, and efficacy in compliance with its product registration.

Result of SWOT analysis

Opportunities (O)

O5) Nowadays, the consumers have more knowledge and always concern about their health.

Threats (T)

T3) Attitude on the imported medicinal product of some consumers still presents that medicinal products imported from abroad have more quality and safety than those produced by local manufacturers.

Element 4: Technology

From content analysis

The government provided the policy for all organizations concerning the importation and exportation to establish and use the Logistics & National Single Window (NSW) as one of the export promotion campaign, in order to reduce the steps and times for the importation approval process. Moreover, the top management of the Customs and FDA had already signed the MOU about the policy for development of the logistics system for all health products including modern medicinal products. In the present time, it is in the process of establishment for data network system among all organizations involving in the importing system, especially for medicinal products.

In order to improve the importing system of Thailand to get more effectiveness and can compete with other countries, the Customs has already developed the single window e-logistics (National Single Window: NSW) which is the e-paperless system to link the data used for consideration of importation approval in the same window. It is the data network system used for exchanging the information among international levels. The World Customs Organization (WCO) notified that the ASEAN single window (ASW) should be established and completely performed by 2015.

The cabinet has already thoroughly considered and concluded that both importation and exportation must be done by using the NSW, and appointed the Customs as a focal point for this issue. All government agencies must develop their own database about the licensing and/or certification of products under control of each organization, and then link those data with the e-licensing system of the Customs. Moreover, each government agency must recheck a custom tariff for products under control of its law, and send back the confirmation to the Customs, in order to set up the customs tariff system. The NSW to develop the control system of the license and certificate through e-logistic system was shown as figure 4.2

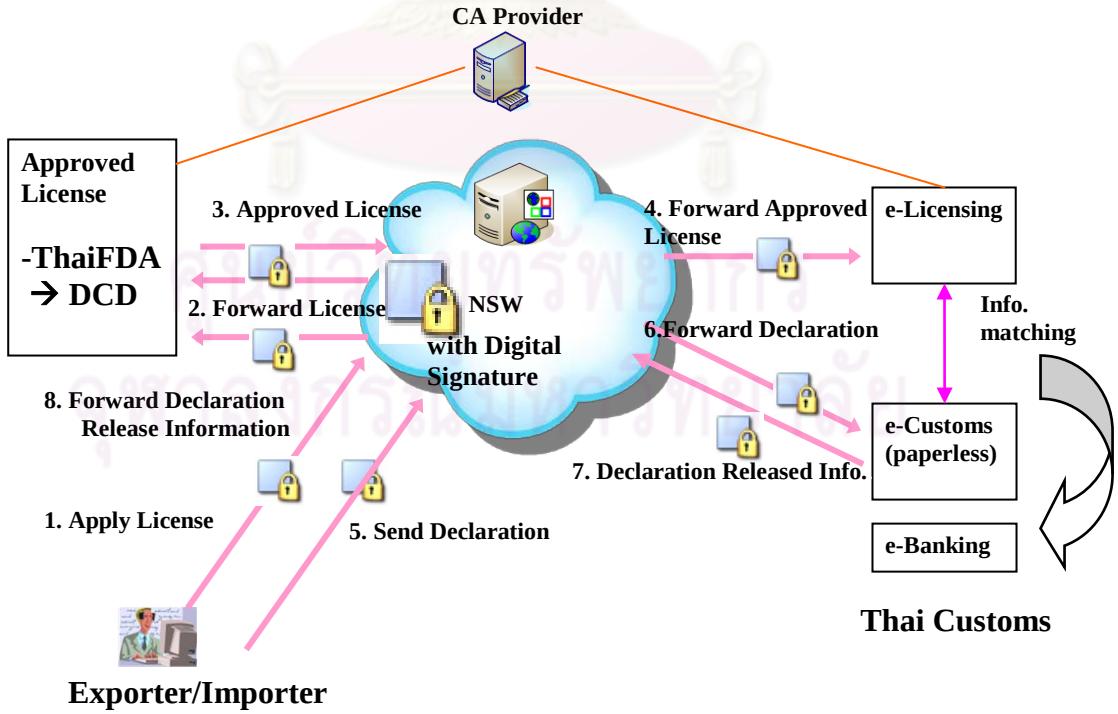

Figure 4.1 The National Single Window (NSW), to develop the control system of the license and certificate through e-logistic system

From key informant interview

The advantage of National Single Window (NSW) is to reduce the steps of logistics, to decrease the investment as well as to finish the approval process in the short time. When the importers plan to import the products into Thailand, they must fill out all relevant data in the webpage of Customs (single window entry) first. After that all data will be shown at the computer of other relevant organization such as at the port of entry of FDA. The officers of those organizations should review all data according to its own laws and requirement, and also the sampling plan if necessary, and then reply the result of consideration to the Customs. That means all relevant organization can do the consideration for importation of the products in advance. In parallel, the recorded data will also be transferred to the e-licensing system to recheck with the database of licensing and certification of each product.

At the day that the products are delivered to the port of the Customs; moreover, the Customs will issue the import entry and invoices through an e-paperless system after data matching with e-licensing system. The tax calculation will be done through an e-banking system. After that the process for releasing of the imported products should be performed by the Customs within 2 minutes. However, the officers of each organization can go to check the imported products in the container or ask the importer to submit the real documents if there are any suspects, and also request the importer or shipping for taking sample according to the sampling plan. If these processes have been requested by other government agencies, the Customs can extend the period of time for releasing the imported products from 2 minutes to 30 minutes.

The Import and Export Inspection Division of FDA is the main organization of FDA to coordinate with the Customs, in order to complete the data network system as NSW. FDA had already tested the NSW system since October 2008. However, the system has not been absolutely operated yet. The database of the health products including the modern medicinal products should be completely reviewed and updated. Now all involved divisions of FDA are in the process of data development.

Furthermore, the modern and high technology have always been applied to use in the routine activities of all organizations, in order to help the officers to finish their works rapidly as well as to decrease the quantity of used paper as the paperless system.

In the present time, there are many channels for communication and publication from the government organization e.g. the FDA, the Customs to the consumer; for example, through the internet, handbill or poster. Nevertheless, using of technology in the incorrect way is usually the problem for consumer protection campaign. The advertisement through the internet of modern medicinal products without the scientific information or safety data support could make the customer believe and then purchase those products for use. That is a risk for consumer to get low-quality of medicinal products or counterfeit one. Besides, more demand of consumer can lead to more supply in the market, through the wrong channel such as by smuggling the medicinal products into Thailand without any inspection at the port of entry.

Result of SWOT analysis

Opportunities (O)

O6) The government provided the policy to establish and use the Logistics & National Single Window (NSW) for import-export promotion campaign purpose, in order to reduce the steps and times for the approval process.

O7) The modern and high technology e.g. e-paperless system have always been applied in the routine activities of all organizations.

O8) There are many channels for communication and publication from the government organization to the consumer e.g. internet, handbill, poster.

Threats (T)

T4) NSW could not be effectively used as the database of health products, including the modern medicinal products has not been reviewed and updated yet.

T5) Using of technology in the incorrect way e.g. advertising of modern medicinal products through the internet without the scientific information or safety data support could be a risk for consumer to get low-quality of medicinal products or counterfeit one.

Table 4.3 Summary table of internal factors, using Host Tor's Theory (1997) and Keidel's Theory (1995)

Item	Elements	Strengths (S)	Weakness (W)
1	**Laws/ Requirements** - Drug Act B.E.2510 - Custom's laws - etc.	S1) Each relevant organization has already established and had full power to implement its laws.	W1) There has no law or measurement in case of the repeated violation. W2) The laws used in the importing system for modern medicinal products could not be promptly implemented or up-to-date e.g. in case of e-paperless service. W3) There has no the specific measurement to adopt by all relevant organizations when the violation detected at the port of entry. W4) The full enforcement of the laws and requirements usually could not be performed e.g. suspension and withdrawal of the license for importation of the modern medicinal product.
2	**Resources** → Budget → Human resources → No. of port of entry	S2) Each organization has been encouraged the fiscal budget to conduct their activities. S3) Each organization has arranged its own officers to do all activities at the port of entry.	W5) The boundary line of Thailand is too long and there has a chance that the importation at the informal port(s) may occur. W6) The number of port of entry of FDA is not sufficient, and not equal to the number of port of entry of the Customs.

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Item	Elements	Strengths (S)	Weakness (W)
		S4) Both the Customs and FDA has already arranged high technology instrument using at the port of entry e.g. mobile scanner of the Customs used for scanning of the container, and RAMAN Spectrophotometer of FDA used for checking the active ingredients without opening the container.	W7) Because of the limitation of FDA's officers, there has no the officers of the IEID of FDA working at some port(s) of entry.
3	**Tasks**		
	3.1 Licensing	S5) License for import of modern medicinal products has required by FDA regarding to the Drug Act B.E. 2510.	W8) Pre-approval inspection has not yet covered some important activities e.g. the cold chain management system for the temperature sensitive medicinal products and vaccines, the traceable inventory system. W9) There has no the requirement to do the on-site inspection before adding other types of medicinal products in existing license for importation of modern medicinal product.
	3.2 Registration	S6) Product registration for each medicinal product has required by FDA regarding to the Drug Act B.E. 2510.	W10) Reviewing of product registration could not be done up to date and spent more times to finish all processes because of the large number of product registration and the limitation of human resource. W11) Sample analysis for some kinds of medicinal product, especially anticancer could not be done since the DMSc's laboratory is not ready in a part of facilities

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Item	Elements	Strengths (S)	Weakness (W)
			and instrument to do the analysis for hazardous medicinal products.
	3.3 Approval process for imported modern medicinal products	S7) The process for the importation approval has been performed following the written procedure(s). The duty and responsibility of each organization has been clearly identified. S8) The additional measurement to clarify the customs tariff of unclearly identified product has been established and operated by the Customs.	W12) After taking sample, FDA must approve the importation of modern medicinal products before the issuing of testing results by DMSc. W13) The import inspection system of the Customs could not be completely performed in some cases e.g. products declared as a sample only, smuggled products by packing with passenger's luggage. W14) Some required documents to consider for importation approval might not be reliable e.g. copy of COA.
	3.4 Sample taking		
	3.4.1 Sampling plan	S9) The annual sampling plan has been defined based on scientific and/or pharmacological information.	W15) FDA could not completely follow the number of sample defined in the annual sampling plan. It depends on the frequency and quantity of importation for the modern medicinal products during a fiscal year by each importer. W16) Annual sampling plan could not define covering all kinds of medicinal product being distributed in the market

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Item	Elements	Strengths (S)	Weakness (W)
			because of the limitation of budget and the high expenses for sample analysis.
	3.4.2 Persons who take sample	S10) The officer responsible for taking sample at the port of entry of FDA were graduated for Bachelor in science, and well-trained following the written procedure.	W17) The officers who work at the port of entry of FDA do not go to the containers or shipment to take sample by themselves because of the limitation of the number of officers.
	3.4.3 Instruments/ Laboratories	S11) The quality control laboratories at the port(s) of entry have been accredited by DMSc.	W18) The number of laboratories and high technology instrument as RAMAN spectrophotometer are still inadequate at the present time.
	3.5 Storage area and condition for keeping the imported medicinal products	S12) Normally the licensee of medicinal product importation always provides the storage area with appropriate condition, to maintain the quality of their imported medicinal products according to its product registration.	W19) There has no the penalty regarding the Drug Act B.E. 2510 in case of transportation and storage the medicinal products under inappropriate condition; therefore, some importers and distributors did not strictly concern about those issues.
	3.6 Post-marketing surveillance system for the imported medicinal products	S13) The officers responsible for conducting the post-marketing surveillance of both the Customs and FDA are well-trained and very skillful in their field.	W20) There has no policy for the abroad on-site GMP inspection at the manufacturers located in the origin countries.

Item	Elements	Strengths (S)	Weakness (W)
		S14) The inspection system and post-audit system for imported products based on a principle of risk management has been established by the Customs to ensure the effectiveness of the customs clearance.	W21) There has no effectively systematic measurement established by both the Customs and FDA to investigate and promptly detect the illegal medicinal products which were not passed through the port of entry of FDA.
	3.7 Prosecution/ Recall/ Rapid Alert	S15) The penalty and prosecution was defined in all relevant laws. Moreover, recall and rapid alert system has been established and strictly followed regarding its procedure.	W22) The measurement to monitor the result of product recall is not effective. W23) Members of the Quality Defect working group do not cover the experts or specialists in several fields of expertise or from other organizations, particularly from DMSc. W24) There has no the specific criteria to distinguish the difference between the quality defect and adverse drug reaction (ADR) issues.
	3.8 Key Performance Indicators (KPIs)	S16) Each organization has defined the KPIs, in order to control and monitor the officers whether they could follow the procedures and do their works effectively. S17) The result of KPIs is usually evaluated and used for improving the previous activities.	W25) Some KPI was not appropriate and could not be the representative of the achievement of the organization.

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Item	Elements	Strengths (S)	Weakness (W)
4	**Technology** → Recording system → Data transfer	S18) Both the Customs and FDA has published the important information through the modern technology and media e.g. website of each organization. S19) The data recording system has already setup for collecting the data concerning the importing system for medicinal products e.g. the data recording system of DCD prepared as database of all licensees and product registrations.	W26) Data record of FDA could not perform as the real time so the evaluation for the current situation of the imported medicinal products could not be done immediately. On the other hand, the Customs can collect and evaluate data of importation and exportation in the real time.
5	**Stakeholders** → FDA - Drug Control Division - The Import and Export Inspection Division - The Legal Affairs Group → Involved organization - Customs - DMSC - Provincial Health Offices → Shipping / agency	S20) Each organization has prepared the procedure for its activities, regarding the laws and other relevant requirements.	W27) Forwarder who was employed by the importer to carry out many kinds of product from the origin countries to Thailand has not been controlled by FDA. Sometimes, the small amount of medicinal products may be overlooked and released without the approval by FDA.

Item	Elements	Strengths (S)	Weakness (W)
6	**Personnel** → Qualification → Training and evaluation → Leadership / Decision Making (Responsibilities, Power, Interpretation of relevant laws)	S21) The officers had been well-trained. They expert in their field as the specialists based on their experiences.	W28) Although there was communication system to provide the necessary knowledge and update laws to the officers working at the port of entry, the interpretation of the laws by each officer still be thoroughly considered. W29) The officers have no more time to improve their own expertise and also develop their own activities because of dramatically increasing of quantity and frequency of the importation resulting from the international agreements.
7	**Structure** → Importing system for modern medicinal products in Thailand. (Cooperation among FDA, Customs, and Ministry of Commerce.)	S22) Each organization has its own clear organization chart and job description of the officers who work concerning the importation approval. S23) The cooperation among relevant organizations has been established in some cases e.g. smuggling of illegal medicinal products.	W30) Work flow for the importation approval of the modern medicinal products requires the shipping/agency to carry out the relevant documents between the Customs' office and the port of entry of FDA. The releasing process of those products may take more times. W31) FDA has supported the budgetary to the Provincial Health Office(s) for conducting the importation approval for health products but FDA does not have the authority to control, standardize and evaluate their works at the port of entry.

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Item	Elements	Strengths (S)	Weakness (W)
8	**Culture** → to know what the relationship among relevant organizations	S24) The officers of each organization perform their work by themselves, regarding to the duty and responsibilities of their organization. S25) Reward system has been established in each organization to motivate their officers. S26) Each organization has the individual authority, the power and responsibility defined in its own laws.	W32) The officers of each organization always work independently and having no closely relation with the others.

Table 4.4 Summary table of external factors, using the PEST Model

Item	Elements	Opportunities (O)	Threats (T)
1.	**Policy**	O1) The top management of each organization encourages any policy to improve and develop the importing system for modern medicinal product. O2) The government always supports the budgetary used for developing of the importation and exportation system. O3) The MOPH has conducted the periodic programme to follow-up the achievement of any health policy or campaign, under responsibility of the Provincial Health Office(s).	T1) The result of agreements used as the non-tariff barrier e.g. FTA, AFTA is that any products from the other countries could be imported into Thailand without tax calculation. Therefore, the quantity and frequency of the importation for health products including modern medicinal products would be dramatically increased, and then it could affect the personal performance and the effectiveness of the consideration for importation approval.
2.	**Economics**	O4) The product owners would improve their capacity and reliability e.g. using more effective logistics' system to reduce a time for transportation and provide the better customer services, to get more market share.	T2) The government notified a policy for limitation of the number of officers in each governmental organization. So the lack of qualified officers in each organization might affect the operation.

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Item	Elements	Opportunities (O)	Threats (T)
3.	**Social/ cultural**	O5) Nowadays, the consumers have more knowledge and always concern about their health.	T3) Attitude on the imported medicinal product of some consumers still presents that medicinal products imported from abroad have more quality and safety than those produced by local manufacturers.
4.	**Technology**	O6) The government provided the policy to establish and use the Logistics & National Single Window (NSW) for import-export promotion campaign purpose, in order to reduce the steps and times for the approval process. O7) The modern and high technology e.g. e-paperless system have always been applied in the routine activities of all organizations. O8) There are many channels for communication and publication from the government organization to the consumer e.g. internet, handbill, poster.	T4) NSW could not be effectively used as the database of health products, including the modern medicinal products has not been reviewed and updated yet. T5) Using of technology in the incorrect way e.g. advertising of modern medicinal products through the internet without the scientific information or safety data support could be a risk for consumer to get low-quality of medicinal products or counterfeit one.

Table 4.5 Summary table to identify the resource of data for each factor

Item	Elements	Content analysis	Key informant interview	Case study
	Host Tor's Theory			
1	**Laws/ Requirements**	S1	W1, W2, W3, W4	S1, W1
2	**Resources**	S2	S3, S4, W5, W6, W7	-
3	**Tasks**			
	3.1 Licensing	S5	W8, W9	-
	3.2 Registration	S6	W10, W11	-
	3.3 Approval process for imported modern medicinal products	S7	S8, W12, W13, W14	-
	3.4 Sample taking			
	3.4.1 Sampling plan	S9	W15, W16	-
	3.4.2 Persons who take sample	S10	W17	-
	3.4.3 Instruments/ Laboratories	S11	W18	-
	3.5 Storage area and condition for keeping the imported medicinal products	S12	W19	-
	3.6 Post-marketing surveillance system for the imported medicinal products	S13, S14	W20, W21	-
	3.7 Prosecution/ Recall/ Rapid Alert	S15	W22, W23, W24	S15, W22
	3.8 Key Performance Indicators (KPIs)	S16, S17	W25	-

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Table 4.5 Summary table to identify the resource of data for each factor (cont'd)

Item	Elements	Content analysis	Key informant interview	Case study
	Host Tor's Theory (cont'd)			
4	**Technology**	S18, S19	W26	-
5	**Stakeholders**	S20	W27	-
6	**Personnel**	-	S21, W28, W29	-
7	**Structure**	-	S22, S23, W30, W31	-
8	**Culture**	-	S24, S25, S26, W32	-
	PEST Model (identify "environment" of Host Tor's Theory)			
1	**Policy**	O1, O2, O3	T1	-
2	**Economics**	-	O4, T2	-
3	**Social/ cultural**	-	O5, T3	-
4	**Technology**	O6, O7	O8, T4, T5	-

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4.2 Results of Step II : Synthesize strategies

After finishing of step I, all elements of the main theory, the Host Tor's Theory (1997) were analyzed. The next processes were composed of 2 processes, prioritizing and proposing the strategies to improve the system performance.

4.2.1 Prioritize strategies

The SWOT derived from step I were selected based on key informants' opinion. These selected were proposed for the expert review to prioritize. The prioritization was conducted using weighing and rating for each selected factor.

In this process, all selected SWOT was separated into 2 tables including the table of Internal Factor Analysis Summary (IFAS) as Table 4.6 and the table of External Factor Analysis Summary (EFAS) as Table 4.8. The internal factors consisted of the strengths (S) and weaknesses (W) must be identified by using IFAS, and the external factor consisted of the Opportunities (O) and threats (T) must be shown in EFAS respectively. Both IFAS and EFAS must define the weight and rating for each selected factor. Besides, the summary table to compare between the selected internal factors and elements of Host Tor's Theory was shown as Table 4.7, while the summary table to compare between the selected external factors and elements of PEST Model was presented as Table 4.9.

The weight stands for the feasibility of success of each factor. The factor that could be performed easier and had the possibility to reach a goal faster than another factor must be weighed with higher number. Total weight of each table, IFAS and EFAS must be 100 absolutely. However, the total weight of S must be 50 and total weight of W must be 50 in the table of IFAS. It was the same for factor O and T in the table of EFAS.

For the rating, the expert must consider for the importance of selected factor and then prioritize by using the number 1 to 5. The no.1 means that the factor was the least important factor affecting the importing system of modern medicinal products and the no.5 means that the factor was the most important factor that could mainly affect the performance of the importing system.

Furthermore, the current situation of the importing system of modern medicinal products could be identified by using the result of totally weight scored of SWOT. The cut point between the total weight scored of internal factors and those of

external factors in one of the four quadrants of the SWOT matrix was used for assuming the current importing system. It was shown in Table 4.10.

In addition, the experts who reviewed and prioritized the selected factors consisted of the expert from each organization concerning the importing system of modern medicinal products as the DCD and the Import and Export Inspection Division of FDA, and the Customs.

4.2.2 Propose strategies

From IFAS and EFAS, SWOT with the rating of 5 and 4 were selected. However, some SWOT with the rating of 3 was selected under the decision making by the focus group.

The components of the focus group included

- 5 key personnel from the Import and Export Inspection Division
- The Chief of the Inspectorate Unit, DCD of FDA
- 1 expert from the Customs

In addition, the summary table of selected factors was shown as Table 4.11. After that all selected SWOT were analyzed through the Strategic Factor Analysis Summary (SFAS) as presented in Table 4.12. Summary table to compare between the selected factors and elements of theory used in the study was shown as Table 4.13. In the table of SFAS, the rating of each selected factor should be the same as mentioned in IFAS and EFAS. Moreover, the duration as the expected time to reach the achievement was identified as S = short time, M = medium time, and L = long time.

From SFAS, the SWOT matrix (Confrontation matrix) was used as a tool for developing the strategies for improving the importing system for modern medicinal products. Those strategies were separated into four strategies as followed;

1) SO strategy: Use the internal strengths (S) and the external opportunities (O) to develop the advantage

2) ST strategy: Use the internal strengths (S) to avoid the external threats (T)

3) WO strategy: Use the external opportunities (O) to conquer the internal weaknesses (W)

4) WT strategy: attempt to reduce the internal weaknesses (W) and also to avoid the external threats (T)

The members of focus group had widely discussed and then considered for the feasible specific strategies as presented in Table 4.14 that would be used to improve the system performance of the importing system of modern medicinal products.

Table 4.6 Internal Factor Analysis Summary (IFAS)

Internal Strategic Factors	Weight	Rating	Weighted Score	Comments
Strengths (S)				
S1) Each relevant organization has already established and had full power to implement its laws.	7	5	35	
S5) License for import of modern medicinal products has required by FDA regarding to the Drug Act B.E. 2510.	6	5	30	
S6) Product registration for each medicinal product has required by FDA regarding to the Drug Act B.E. 2510.	6	5	30	
S8) The additional measurement to clarify the customs tariff of unclearly identified product has been established and operated by the Customs.	3	3	9	
S9) The annual sampling plan has been defined based on scientific and/or pharmacological information.	4	3	12	
S14) The inspection system and post-audit system for imported products based on a principle of risk management has been established by the Customs to ensure the effectiveness of the customs clearance.	5	4	20	
S18) Both the Customs and FDA has published the important information through the modern technology and media e.g. website of each organization.	3	4	12	
S19) The data recording system has already setup for collecting the data concerning the importing system for medicinal products e.g. the data recording system of DCD prepared as database of all licensees and product registrations.	3	4	12	

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Internal Strategic Factors	Weight	Rating	Weighted Score	Comments
Strengths (S)				
S21) The officers had been well-trained. They expert in their field as the specialists based on their experiences.	7	4	28	
S25) Reward system has been established in each organization to motivate their officers.	6	4	24	
Total (S)	50		212	

Weakness (W)				
W1) There has no law or measurement in case of the repeated violation.	3	3	9	
W2) The laws used in the importing system for modern medicinal products could not be promptly implemented or up-to-date e.g. in case of e-paperless service.	3	3	9	
W3) There has no the specific measurement to adopt by all relevant organizations when the violation detected at the port of entry.	3	3	9	
W4) The full enforcement of the laws and requirements usually could not be performed e.g. suspension and withdrawal of the license for importation of the modern medicinal product	3	3	9	
W5) The boundary line of Thailand is too long and there has a chance that the importation at the informal port(s) may occur.	3	2	6	
W6) The number of port of entry of FDA is not sufficient, and not equal to the number of port of entry of the Customs.	5	4	20	
W7) Because of the limitation of FDA's officers, there has no the officers of the IEID of FDA working at some port(s) of entry.	3	3	9	
W12) After taking sample, FDA must approve the importation of modern medicinal products before the issuing of testing results by DMSc.	3	3	9	

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Internal Strategic Factors	Weight	Rating	Weighted Score	Comments
Weakness (W)				
W14) Some required documents to consider for importation approval might not be reliable e.g. copy of COA.	3	3	9	
W17) The officers who work at the port of entry of FDA do not go to the containers or shipment to take sample by themselves because of the limitation of the number of officers.	3	3	9	
W18) The number of laboratories and high technology instrument as RAMAN spectrophotometer are still inadequate at the present time.	5	4	20	
W20) There has no policy for the abroad on-site GMP inspection at the manufacturers located in the origin countries.	3	3	9	
W22) The measurement to monitor the result of product recall is not effective.	3	3	9	
W29) The officers have no more time to improve their own expertise and also develop their own activities because of dramatically increasing of quantity and frequency of the importation resulting from the international agreements.	4	4	16	
W31) FDA has supported the budgetary to the Provincial Health Office(s) for conducting the importation approval for health products but FDA does not have the authority to control, standardize and evaluate their works at the port of entry.	3	3	9	
Total (W)	50		161	
Total (S + W)	100		212+161 = 373	

Table 4.7 Summary table to compare between the selected internal factors and elements of Host Tor's Theory

Element no.	Strengths (S)	Weighted Score	Weaknesses (W)	Weighted Score
1	S1	35	W1, W2, W3, W4	9 + 9 + 9 +9 = 36
2	-	-	W5, W6, W7	6 + 20 + 9 = 35
3.1	S5	30	-	-
3.2	S6	30	-	-
3.3	S8	9	W12, W14	9 +9 = 18
3.4.1	S9	12	-	-
3.4.2	-	-	W17	9
3.4.3	-	-	W18	20
3.6	S14	20	W20	9
3.7	-	-	W22	9
4	S18, S19	24	-	-
6	S21	28	W29	16
7	-	-	W31	9
8	S25	24	-	-
Total	**10**	**212**	**15**	**161**

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Table 4.8 External Factor Analysis Summary (EFAS)

External Strategic Factors	Weight	Rating	Weighted Score	Comments
Opportunities (O)				
O1) The top management of each organization encourages any policy to improve and develop the importing system for modern medicinal product.	10	5	50	
O2) The government always supports the budgetary used for developing of the importation and exportation system.	9	4	36	
O3) The MOPH has conducted the periodic programme to follow-up the achievement of any health policy or campaign, under responsibility of the Provincial Health Office(s).	7	3	21	
O6) The government provided the policy to establish and use the Logistics & National Single Window (NSW) for import-export promotion campaign purpose, in order to reduce the steps and times for the approval process.	9	4	36	
O7) The modern and high technology e.g. e-paperless system have always been applied in the routine activities of all organizations.	7	3	21	
O8) There are many channels for communication and publication from the government organization to the consumer e.g. internet, handbill, poster.	8	3	24	
Total (O)	50		188	

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External Strategic Factors	Weight	Rating	Weighted Score	Comments
Threats (T)				
T1) The result of agreements used as the non-tariff barrier e.g. FTA, AFTA is that any products from the other countries could be imported into Thailand without tax calculation. Therefore, the quantity and frequency of the importation for health products including modern medicinal products would be dramatically increased, and then it could affect the personal performance and the effectiveness of the consideration for importation approval.	12	4	48	
T2) The government notified a policy for limitation of the number of officers in each governmental organization. So the lack of qualified officers in each organization might affect the operation.	11	3	33	
T3) Attitude on the imported medicinal product of some consumers still presents that medicinal products imported from abroad have more quality and safety than those produced by local manufacturers.	8	3	24	
T4) NSW could not be effectively used as the database of health products, including the modern medicinal products has not been reviewed and updated yet.	10	4	40	
T5) Using of technology in the incorrect way e.g. advertising of modern medicinal products through the internet without the scientific information or safety data support could be a risk for consumer to get low-quality of medicinal products or counterfeit one.	9	3	27	
Total (T)	50		172	
Total (O + T)	100		188+172 = 360	

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Table 4.9 Summary table to compare between the selected external factors and elements of PEST model

Element no.	Opportunities (P)	Weighted Score	Weaknesses (W)	Weighted Score
Policy	O1, O2, O3	50 + 36 + 21 = 107	T1	48
Economics	-	-	T2	33
Social/ cultural	-	-	T3	24
Technology	O6, O7, O8	36 + 21 + 24 = 81	T4, T5	40 + 27 = 67
Total	**6**	**188**	**5**	**172**

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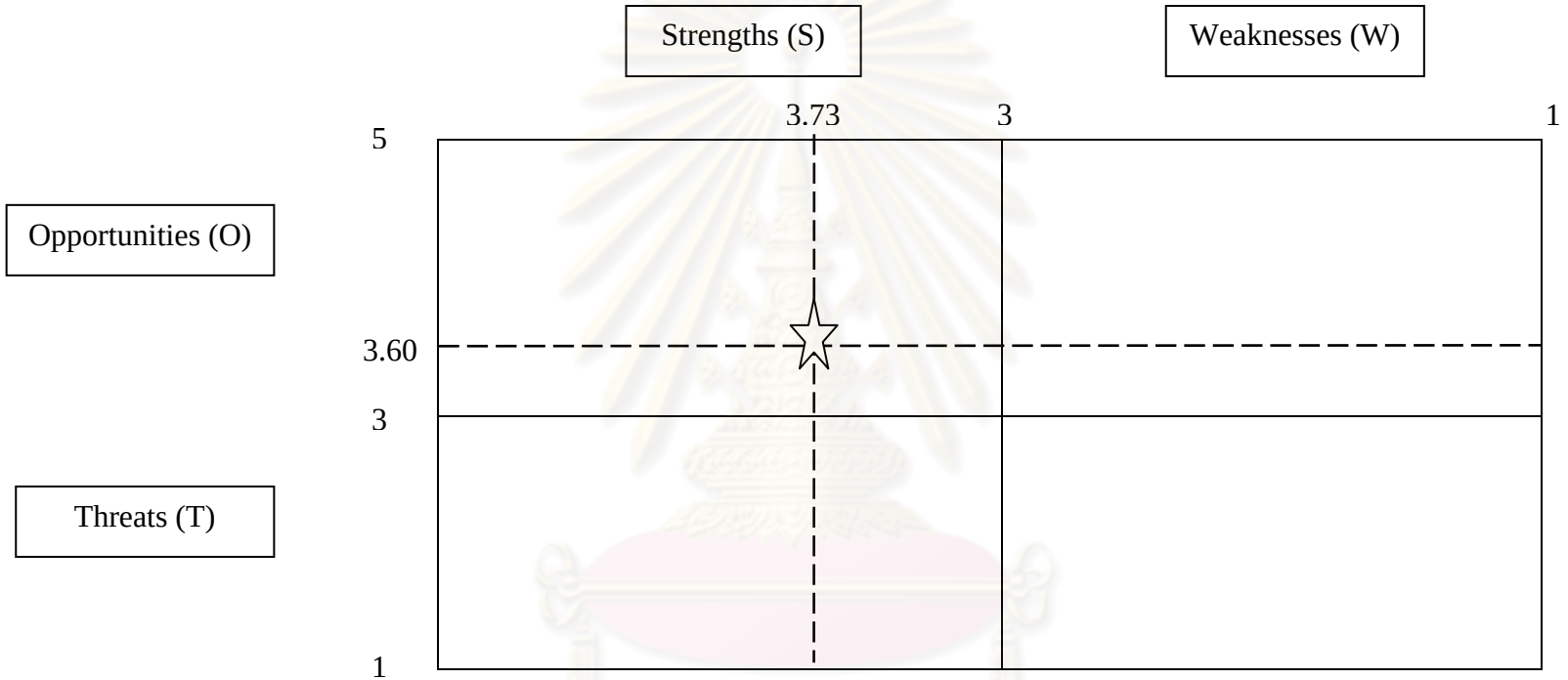
Table 4.10 SWOT matrix used for assuming the current importing system



Strengths (S)	Weaknesses (W)	S + W	(S + W)/100
212	161	373	3.73

Opportunities (O)	Threats (T)	O + T	(O + T)/100
188	172	360	3.60

Remark: The current situation of the importing system for modern medicinal products

Internal situation = strengths (S) > weakness (W)

External situation = Opportunities (O) > Threats (T)

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From IFAS and EFAS, SWOT with the rating of 5 and 4 were selected to be analyzed through the Strategic Factor Analysis Summary (SFAS). However, some SWOT with the rating of 3 was selected under the decision making by the focus group. Moreover, the duration as the expected time to reach the achievement was also identified as S = short time, M = medium time, and L = long time. Finally, the total selected factors were shown in the Table 4.11 and Table 4.12.

Table 4.11 Summary table of selected factors

SWOT analysis		**Total factors**	**Selected factors (for IFAS & EFAS)**	**Selected factors (for SFAS)**
Internal factors	**Strengths (S)**	26	10	6
	Weaknesses (W)	32	15	8
External factors	**Opportunities (O)**	8	6	4
	Threats (T)	5	5	3

Table 4.12 Strategic Factor Analysis Summary (SFAS)

Key Strategic Factors	Weight	Rating	Weighted Score	Duration			Comments
				S	M	L	
Strengths (S)							
S1) Each relevant organization has already established and had full power to implement its laws.	5	5	25	/			
S21) The officers had been well-trained. They expert in their field as the specialists based on their experiences.	5	4	20	/			
S14) The inspection system and post-audit system for imported products based on a principle of risk management has been established by the Customs to ensure the effectiveness of the customs clearance.	3	4	12		/		
S25) Reward system has been established in each organization to motivate their officers.	3	4	12	/			
S18) Both the Customs and FDA has published the important information through the modern technology and media e.g. website of each organization.	5	4	20	/			
S19) The data recording system has already setup for collecting the data concerning the importing system for medicinal products e.g. the data recording system of DCD prepared as database of all licensees and product registrations.	3	4	12		/		

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Table 4.12 Strategic Factor Analysis Summary (SFAS) (cont'd)

Key Strategic Factors	Weight	Rating	Weighted Score	Duration			Comments
				S	M	L	
Weaknesses (W)							
W29) The officers have no more time to improve their own expertise and also develop their own activities because of dramatically increasing of quantity and frequency of the importation resulting from the international agreements.	4	4	16		/		
W18) The number of laboratories and high technology instrument as RAMAN spectrophotometer are still inadequate at the present time.	6	4	24	/			
W12) After taking sample, FDA must approve the importation of modern medicinal products before the issuing of testing results by DMSc.	3	3	9			/	
W31) FDA has supported the budgetary to the Provincial Health Office(s) for conducting the importation approval for health products but FDA does not have the authority to control, standardize and evaluate their works at the port of entry.	3	3	9			/	
W1) There has no law or measurement in case of the repeated violation.	3	3	9			/	
W6) The number of port of entry of FDA is not sufficient, and not equal to the number of port of entry of the Customs.	5	4	20		/		

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Table 4.12 Strategic Factor Analysis Summary (SFAS) (cont'd)

Key Strategic Factors	Weight	Rating	Weighted Score	Duration			Comments
				S	M	L	
W3) There has no the specific measurement to adopt by all relevant organizations when the violation detected at the port of entry.	5	3	15		/		
W4) The full enforcement of the laws and requirements usually could not be performed e.g. suspension and withdrawal of the license for importation of the modern medicinal product.	4	3	12			/	
Opportunities (O)							
O1) The top management of each organization encourages any policy to improve and develop the importing system for modern medicinal product.	9	5	45	/			
O2) The government always supports the budgetary used for developing of the importation and exportation system.	6	4	24	/			
O6) The government provided the policy to establish and use the Logistics & National Single Window (NSW) for import-export promotion campaign purpose, in order to reduce the steps and times for the approval process.	8	4	32		/		
O3) The MOPH has conducted the periodic program to follow-up the achievement of any health policy or campaign, under responsibility of Provincial Health Office(s).	7	3	21		/		

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Table 4.12 Strategic Factor Analysis Summary (SFAS) (cont'd)

Key Strategic Factors	Weight	Rating	Weighted Score	Duration			Comments
				S	M	L	
Threats (T)							
T1) The result of agreements used as the non-tariff barrier e.g. FTA, AFTA is that any products from the other countries could be imported into Thailand without tax calculation. Therefore, the quantity and frequency of the importation for health products including modern medicinal products would be dramatically increased, and then it could affect the personal performance and the effectiveness of the consideration for importation approval.	4	4	16			/	
T4) NSW could not be effectively used as the database of health products, including the modern medicinal products has not been reviewed and updated yet.	5	4	20	/			
T2) The government notified a policy for limitation of the number of officers in each governmental organization. So the lack of qualified officers in each organization might affect the operation.	4	3	12		/		
Total (S + W + O + T)	100		385				

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Table 4.13 Summary table to compare between the selected factors and elements of theory used in the study

Theory	Element no.	Strengths (S)	Weighted Score	Weaknesses (W)	Weighted Score
Host Tor's					
	1	S1	25	W1, W3, W4	9 + 15 + 12 = 36
	2	-	-	W6	20
	3.3	-	-	W12	9
	3.4.3	-	-	W18	24
	3.6	S14	12	-	-
	4	S18, S19	20 + 12= 32	-	-
	6	S21	20	W29	16
	7	-	-	W31	9
	8	S25	12	-	-
PEST Model	P	O1, O2, O3	45 + 24 + 21 = 90	T1	16
	E	-	-	T2	12
	S	-	-	-	-
	T	O6	32	T4	20
	Total	**10**	**212**	**15**	**161**

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4.2.2.1 Strategies synthesized from SWOT matrix

From SFAS, the ***SWOT matrix (Confrontation matrix)*** was used as a tool for developing the strategies for improving the importing system for modern medicinal products. The members of focus group had widely discussed and then considered for the feasible specific strategies as followed;

1) SO strategy: Use the internal strengths (S) and the external opportunities (O) to develop the advantage

This could be used as the offensive strategy and should be performed first.

2) ST strategy: Use the internal strengths (S) to avoid the external threats (T)

The aim of this strategy is to maintain, improve and develop the existing strengths, in order to ensure that there have no any threats make the system failed.

3) WO strategy: Use the external opportunities (O) to conquer the internal weaknesses (W)

This could be used as the defensive strategy by using the opportunities to support or set up the measurement to reduce the weaknesses as much as possible.

4) WT strategy: attempt to reduce the internal weaknesses (W) and also to avoid the external threats (T)

The aim of this strategy is to manage the existing weaknesses and the threats, in order to prevent the effect of those on the system.

All strategies considered depending on SWOT matrix was presented in the Table 4.14.

Table 4.14 Strategies based on SWOT matrix

External factors / **Internal factors**	**Opportunities (O)** **O1) O2) O3) O6)**	**Threats (T)** **T1) T2) T4)**
Strengths (S)	**SO strategies**	**ST strategies**
S1) S14) S18) S19) S21) S25)	S18 S19 S21, O6O1O2) To speed up the establishment of National Single Window (NSW) in order to increase the effectiveness of the importing system for modern medicinal products S25, O1O2) To manage the human resources and budgetary through the reward system	S1 S14 S21, T1) To establish more effective post-marketing surveillance system S18S21, T2) To increase communication channels by setting up the information center and promote inter- and intra-organizational communication S19S21, T4) To complete database of modern medicinal products and link all data into NSW
Weaknesses (W)	**WO strategies**	**WT strategies**
W1) W3) W4) W6) W12) W18) W29) W31)	W29, O6O1O2) To improve the competency of the officers and other persons involving in the importing system for modern medicinal products	W6, T1) To develop the operation procedure manual for officers working at port of entry

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Table 4.14 Strategies based on SWOT matrix (cont'd)

Internal factors **External factors**	**Opportunities (O)** **O1) O2) O3) O6)**	**Threats (T)** **T1) T2) T4)**
Weaknesses (W)	**WO strategies**	**WT strategies**
W1) W3) W4) W6) W12) W18) W29) W31)	W3, O1O2) To establish the task force among organizations for achieving the specific purposes, particularly the detection of smuggling of illegal medicinal product at the port of entry W31, O3O1) To identify factors related to the improvement of importing system as key performance indicators W6, O1O2) and W18, O1O2) To increase the number of ports of entry of FDA and the number of instruments for quality control W1W12, O1) and W4, O1) To revise all relevant laws and regulations to carry higher penalty for illegal medicinal products	

SO strategies

1) S18 S19 S21, O6O1O2

To speed up the establishment of National Single Window (NSW) in order to increase the effectiveness of the importing system for modern medicinal products

Since the government provides the policy and supports the budgetary for all organizations concerning the importation and exportation to establish and use the Logistics & National Single Window (NSW) as one of the export promotion campaign, in order to reduce the steps and times for the importation approval process. In this regard, all stakeholders involving in the importing system for modern medicinal products must also establish the NSW in order to facilitate the importation and also control the imported medicinal products according to the relevant laws such as the Drug Act B.E.2510. Moreover, the Customs has been appointed to act as the focal point. The Thai FDA, the authorized organization for issuing the license and product registration for modern medicinal products being imported and distributed into the market should prepare all database of the licensees and product registration of modern medicinal products through the existing data recording system. However, it also should be re-checked about the compatibility between the recording system of FDA and the Customs. Besides, this project will be continuously worked out because the officers of both the Customs and FDA are well-trained and expert in their field.

As the achievement of this policy is that NSW should be effectively established and performed within B.E.2558, the top management of each organization involved in the importing system for modern medicinal products has strongly encouraged the projects regarding this policy. Therefore, the annual action plan should be defined, and the success of NSW should be one of the key performance indicators (KPIs) of the top management as well.

2) S25, O1O2

To manage the human resources and budgetary through the reward system

Reward system is very useful for each organization to manage the human resource effectively. This system can be used for motivating all officers to perform their work to get more effective. The top management should support the

establishment of reward system in its organization, and the budgetary for this activity should be arranged as well.

For example;

2.1) In case of investigation and capture the violator who infringes the Drug's laws, both during the process of importation and post-marketing surveillance, the officers should receive the rewards that had already proportional calculated based on a value of the seized illegal medicinal products.

2.2) In case of the Provincial Health Office(s) that responsible for inspection of the imported medicinal products instead of the officers of FDA, they should be rewarded if they can completely follow the procedure regarding the importing system for modern medicinal products and achieve a goal of KPIs as required.

ST strategies

3) S1 S14 S21, T1

To establish more effective post-marketing surveillance system

Since the international agreements e.g. the Free Trade Agreement (FTA), ASEAN Free Trade Area (AFTA) are one of the causes of increasing of quantity and frequency of the importation for health products including modern medicinal products into Thailand. That might affect the effectiveness of the importation approval by the officers of the Customs and the FDA, especially at the port of entry.

However, each organization in the importing system for modern medicinal products consisting of the Customs and the FDA has already had full power to implement the laws on their behalf. Therefore, the specific measurement should be developed to ensure that all medicinal products being imported into Thailand will be checked following the Drug's law and the Custom's law as well as maintained its quality according to the specification defined in its product registration.

Nowadays, the Customs has already established the inspection system based on a risk management as well as the post-audit system to ensuring the effectiveness of the customs clearance and the releasing process for the imported products.

In this regard, Thai FDA should consider for reviewing the existing system and then establishing the new post-marketing system which should consider for adapting

from the post-audit system of the Customs. The new post-marketing system should include;

3.1) Thai FDA should learn and cooperate with the Customs in case of doing the post-marketing surveillance following the post-audit system of the Customs. All data from both organizations such as a quantity and value of importation of modern medicinal products, history of licensee(s) should be pooled and used for setting up the action plan of the post-marketing surveillance for imported modern medicinal products. Moreover, the inspectors from both the Customs and FDA should do the post-audit together based on risk management for modern medicinal products being imported in the market.

3.2) Thai FDA should set up the annual inspection plan to inspect the licensee for importation of modern medicinal product and also other relevant organization or agencies involving in the supply chain e.g. distributor, logistics company. This annual inspection plan should be defined base on a principle of Good Distribution Practice (GDP) and Good Storage Practice (GSP), the collected data about the quality defect of medicinal products and history of a law violation.

4) S18S21, T2

To increase communication channels by setting up the information center and promote inter- and intra-organizational communication

Since the government notified a policy for limitation of the number of officers in each governmental organization, a lack of qualified officers is still a problem of all organization involving in the importing system for modern medicinal products. The alternative system should be thoroughly considered.

The information centre used as a route for communication among all stakeholders should be established. Nowadays, both the Customs and FDA has published the information to the consumer through modern technology and media as a website of each organization. It will be useful for achieving a goal of the information centre because both the Customs and FDA can share the information and also transfer the important information to the customer through their website. Moreover, the officers of the Customs and FDA much expert in their field as the specialists based on

their experiences. So the information being communicated must be prepared by those qualified officers.

The objective of establishment of this information centre is not only keeping the communication with the customer but also data sharing between the Customs and FDA about the importation of modern medicinal products. The information center consists of

4.1) The public awareness can be performed through this information centre. The Customs and FDA should appoint the key persons to responsible for preparing and updating the information through the website. Moreover, it will be a route for communication among the customer, licensees and relevant organization involving in the importing system for modern medicinal products.

4.2) The intranet system used for data linking between the Customs and FDA should be established. The database about the importation of modern medicinal products must be prepared by both the Customs and FDA. This database emphasizes on a history of each company licensed by FDA, including any violation of the Drug Act B.E.2510, in order to be used as the basic information for the officers of the Customs and FDA. The database should be categorized the level of observation to let the officers of the Customs and FDA knows which licensee must be monitored and paid more attention. The criteria for making decision and the appropriate measurement should be thoroughly considered together by the Customs and FDA.

5) S19S21, T4

To complete database of modern medicinal products and link all data into NSW

The National Single Window (NSW) will be effectively used based on the completion of database of the license and product registration of health products, including the modern medicinal products. In the present time, database of modern medicinal products prepared by the Drug Control Division (DCD) of Thai FDA has not been reviewed and updated yet. Moreover, there has a problem about the compatibility between the data recording system of the DCD and those of the Customs. So it may take more times to solve this problem.

However, the officers who work for collecting all data and preparing the database are well-trained and expert in their field. Therefore, the database from DCD may be finished following the timeframe for completion of database defined in the action plan of Thai FDA. And then the data network between the Customs and FDA under the NSW system should be performed in timely manner.

That means this strategy should be used for encouraging the achievement of the NSW system that would be applied for the importing system of modern medicinal product in the near future.

WO strategies

6) W29, O6O1O2

To improve the competency of the officers and other persons involving in the importing system for modern medicinal products

Since the international agreements could be a cause of dramatically increasing of quantity and frequency of the importation for health products including modern medicinal products into Thailand, the officers have no more time to improve their own expertise and also develop their own activities. Therefore, the training programme should be thoroughly considered, particularly in the issues related to the importing system for modern medicinal products.

The top management of each organization should provide all supports for the training programme for its own officers. The instructors should come from both the Customs and FDA, in order to share the information with another when the training has been arranged. In addition, the importer or product owner may participate in the training programme for some important issues. The topic that should be trained such as how to do when the National Single Window (NSW) has been established, how to identify the modern medicinal products according to its product registration, and what the process of customs clearance is.

7) W3, O1O2

To establish the task force among organizations for achieving the specific purposes, particularly the detection of smuggling of illegal medicinal product at the port of entry

Nowadays, each organization concerning the importing system for modern medicinal products will take action when the violation was detected at the port of entry. However, there has no the specific measurement with the cooperation among all relevant organization for this situation.

The special team including the representatives of each organization concerning the importing system for modern medicinal products such as the Customs, FDA, and product owners should be formally and systematically established, in order to work together for special purposes e.g. the smuggling of illegal medicinal products. Moreover, the key persons who will be a focal point of each organization should be identified, and always closely coordinate with another.

To be successful, the top management of each organization should promote all activities and also support the budgetary to perform this special team.

For example;

7.1) The team-building between the Customs and FDA for consideration of the customs tariff of each health product, including the modern medicinal products should be established. Since it is possible that some medicinal products may not be identified in any existing group of customs tariff, those must be thoroughly considered by the working group which its members consists of the experts from both the Customs and FDA.

7.2) The team-building between the Customs and FDA for special purposes should be established. The main objective of this special team is to take action when the violation of the relevant laws occurred, particular the smuggling of illegal medicinal products. Furthermore, the product owners should be invited to cooperate in this activity, in order to collect and then inform any useful data to the Customs and FDA team.

8) W31, O3O1

To identify factors related to the improvement of importing system as key performance indicators

To get the success of handling on inspecting and controlling the import and export of health products, including modern medicinal products, the agreement between the Customs and Thai FDA should be prepared and signed by the top

management of each organization, and then the cooperation of both organizations would be strictly concerned.

The Customs should also thoroughly consider for adding the issue about the achievement of importing system of modern medicinal product as one of the key performance indicators (KPIs), in order to evaluate the effectiveness of the operation of the officers.

The Ministry of Public Health has established the periodic programme to follow up the achievement of any health policy or campaign, under responsibility of the Provincial Health Office(s). This activity will be performed through the annual supervision conducted by the health expert team of the ministry. Therefore, all major activities about the importation approval of modern medicinal products should be identified as one of KPIs of the consumer protection policy of the ministry. If it is possible, the Provincial Health Offices(s) may be willing to follow the procedure prepared by Thai FDA. The standardization and evaluation by Thai FDA for the operating of the officers of the Provincial Health Office(s) at the port of entry may be effectively performed.

9) W6, O1O2 and W18, O1O2

To increase the number of ports of entry of FDA and the number of instruments for quality control

9.1) W6, O1O2

Since the number of port of entry of FDA is not sufficient, and not equal to the number of port of entry of the Customs, some modern medicinal product are imported into Thailand without the monitoring and approving by FDA. The construction of the new ports of entry and also the renovation of 26 existing ports should be thoroughly considered, and finished as soon as possible (maybe within 5 years).

Moreover, the limitation of the number of port of entry that permits to import the modern medicinal products should be defined.

9.2) W18, O1O2

Furthermore, the basic testing of quality control for health products, including modern medicinal products should be performed at the port of entry but this

activity must be done in the short time as possible since it may affect the time period for releasing of imported products defined by the Customs. Therefore, the laboratories and high technology instrument as RAMAN spectrophotometer should be procured and established at the port of entry of FDA.

These above projects will be successful if the top management of the Ministry of Public Health and Thai FDA provide a strong support. Moreover, the budgetary for some projects to develop the importing system for modern medicinal product e.g. project to establish the new ports of entry and purchase high technology instrument has already been approved by the Committee of Ministry of Public Health.

10) W1W12, O1 and W4, O1

To revise all relevant laws and regulations to carry higher penalty for illegal medicinal products

10.1) W1W12, O1

In case of the importer who infringes the law repeatedly, there has no any law or measurement to adopt for this case. The penalty according to the Customs Act B.E. 2543 and Drug Act B.E. 2510 could be performed case by case only. Therefore, the reviewing and revising the relevant laws should be considered. However, the additional measurement should be thoroughly considered and performed in parallel.

In addition, the approval for importation of modern medicinal products has to be done before the issuing of testing results by DMSc. If the testing result presents as out-of-specification while those failed medicinal products had already distributed in the market for a long time before issuing the conclusion of testing results, that means there has a risk for the consumer or patients who access those medicinal products at that time. So the measurement for product recall should be strengthened. Moreover, the alternative methods to ensuring the quality of imported medicinal products before releasing at the port of entry should be provided, particularly through some changes of the process or required documents for making a decision of the importation approval.

For these activities, the top management should encourage and present it as one of policies of Thai FDA that the licensees must follow strictly.

10.2) W4, O1

Since the FDA could not now fully endorse some contents defined in the Drug's laws and requirement concerning the importing system for modern medicinal products particularly in case of suspension and withdrawal of the license(s), the specific measurement and also criteria for those cases should be developed and implemented as soon as possible.

Furthermore, the top management of Thai FDA should support these activities as the suitable process for monitoring and controlling the licensee(s) following the Drug Act B.E.2510.

The alternative measurement that should be used in order to improve those above activities concerning the importing system for modern medicinal products consists of

1) The measurement to improve the process of consideration for product registration

Since Thai FDA had already applied for the PIC/S membership since 2005 as well as the new Ministerial Notification of GMP for modern medicinal products which is equivalent to the PIC/S GMP Guide will be notified in the year of 2010, the changing of the process of consideration for product registration of the modern medicinal products being imported from abroad should be thoroughly concerned. It can be separated into three groups as followed;

1.1) If the origin manufacturer has been passed the GMP assessment conducted by the National Regulatory Authority (NRA) of that country which is one of the PIC/S members and also implement the PIC/S GMP Guide as the law, the required documents include

- GMP Certificate with clearly defined the PIC/S GMP Guide as the reference for conducting the assessment
- GMP inspection report which its format must be adopted from the format of PIC/S GMP inspection report
- Certificate of analysis (COA)
- Certificate of Pharmaceutical Products (CPP)
- Others e.g. process validation, analytical method validation, stability study data, etc.

1.2) If the origin manufacturer has been passed the GMP assessment conducted by the National Regulatory Authority (NRA) of that country which has implemented the code of GMP in equivalence with PIC/S GMP Guide as the law e.g. WHO GMP and EU GMP, the required documents include

- GMP Certificate with clearly defined the reference for conducting the assessment
- GMP inspection report which must be certified by NRA of the origin country
- Certificate of analysis (COA)
- Certificate of Pharmaceutical Products (CPP)
- Others e.g. process validation, analytical method validation, stability study data, etc.

1.3) If the origin manufacturer has been passed the GMP assessment conducted by the National Regulatory Authority (NRA) of that country which has implemented other GMP requirements as the law e.g. China where endorsed its own GMP code as a law, the required documents include

- Pre-approval inspection (on-site GMP inspection) must be performed by the FDA as required
- Site Master File (SMF) presented the overview of all systems established in the origin manufacturer
- Quality manual and relevant documents to show the quality system and quality risk management of the origin manufacturer
- GMP Certificate with clearly defined the reference for conducting the assessment
- GMP inspection report which must be certified by NRA of the origin country
- Certificate of analysis (COA)
- Certificate of Pharmaceutical Products (CPP)
- Others e.g. process validation, analytical method validation, stability study data, etc.

Besides, the list of oversea manufacturers where passed the pre-approval inspection (on-site GMP inspection) done by the GMP inspectors of Thai

FDA should be prepared and then used as the basic information when the consideration for product registration is performed in the next time.

Although the oversea manufacturers which have been audited by the National Regulatory Authority (NRA) and found to conform to PIC/S GMP standards or other GMP guide equivalent to PIC/S GMP e.g. WHO and EU GMP need not be audited by the GMP inspectors of Thai FDA if the submitted evidence is found to be acceptable. The on-site GMP inspection of those manufacturers should be performed as well, in order to identify their name in the list of approved oversea manufacturers.

Nevertheless, if the dosage form of the medicinal product which the licensee would like to apply for product registration differs from the previous one and/or the production has been performed in the new plant, the Thai FDA may conduct the on-site GMP inspection prior to consider for the approval of product registration.

2) The measurement for the repeated failure of testing result

Thai FDA has already established “Procedure of consideration for the testing result analyzed by DMSc”. The penalty according to the Drug Act B.E. 2510 could be performed case by case only. Nowadays, there has no measurement to be adopted in case of the repeated violation such as the repeated failure on testing results of the sample taken by FDA. Therefore, the alternative measurement should be thoroughly considered, in order to solve these problems as followed;

2.1) First step: collecting data through the sample taking

All data about the modern medicinal products with quality defect problem should be collected and informed the Import and Export Inspection Division, in order to do the monitoring and controlling more at the port of entry. Moreover, those data should be used for setting the annual sampling plan for each kind of modern medicinal product, and also the criteria should be provided as

2.1.1) If the frequency of importation is consistent e.g. 5-6 times per year, the sample taking should be performed three consecutive importation

2.1.2) If the frequency of importation is rare e.g. 1-2 times per year, the sample taking should be performed at each time of importation

Remark: The licensee for importation of modern medicinal products could not distribute its own products before the issuing of testing results by DMSc.

2.2) Second step: take more action when the repeated failure found

If the testing results are passed according to its own product registration, it should be recorded as a history of those medicinal products and the product owners. However, if the testing results are failed, the specific measurement should be implemented as followed;

For example, in case of sub-standard medicinal products, category no.2 (Ex: Testing results presented the out-of-specification in any item stated in its finished product specification e.g. weight variation, disintegration, dissolution, pH, etc.)

2.2.1) For the 1st time : the licensee(s) should follow the "Procedure of consideration for the testing result analyzed by DMSc". They must be warned and should follow the procedure for product recall. In addition, all details of its quality defect and the progressive activities should be published through the FDA's website on the topic of "Safety Alert".

Moreover, the licensee(s) should be punished according to the penalty defined in the Drug Act B.E.2510 although it is the first violation.

2.2.2) For the 2nd time : if testing results are failed in the same issue(s), the licensee(s) should follow the "Procedure of consideration for the testing result analyzed by DMSc" defined that the licensee must be prosecuted according to the content in the Drug Act B.E.2510. Besides, the licensee will be ordered by FDA to recall the product from the market, and follow the process of product recall respectively.

Furthermore, all details of its quality defect and the progressive activities should be published through the FDA's website on the topic of "Safety Alert".

Moreover, the additional measurement should be operated respectively;

- Reviewing of product registration should be thoroughly considered and performed by the Drug Control Division of Thai FDA

- Details of the quality defect of this product and all activities already done should be recorded in the intranet system for data linking between the Customs and FDA (defines in the strategy of S18S21, T3T2) in order to be used as the database for monitoring and controlling of the importation of that licensee(s) as well as for decision making of releasing the imported medicinal product in the next time.

2.2.3) For the 3rd time : the licensee(s) should be prosecuted according to the content in the Drug Act B.E.2510. Product recall must be performed as well. Moreover, the public awareness should be done through the "Safety Alert" on the FDA's website.

Besides, the additional measurement should be implemented as followed;

- Reviewing of product registration should be thoroughly considered and performed by the Drug Control Division of Thai FDA.

- Recording as the history of those licensee(s) and modern medicinal products into the intranet system of the Customs and FDA must be required.

- Listing of the licensee(s) who infringe the Drug Act B.E.2510 repeatedly, especially in case of the quality defect of their own products should be prepared by the Import and Export Inspection Division and the Drug Control Division as the database. This database must be reviewed and considered when the licensee(s) stated in the list apply for new product registration.

- Proposing the Drug Committee to consider for suspension or withdrawal of the license for importation of modern medicinal product of those licensee(s) who violate the Drug Act B.E.2510 repeatedly should be performed respectively.

Remark: If the testing results of several items of medicinal products imported by the same licensee are failed, the proposing to consider for suspension or withdrawal of the license and/or product registration should be performed immediately.

3) The measurement in the process of importation approval, including the required documents

3.1) Process for importation approval for modern medicinal products

3.1.1) The Customs' officers should check all relevant documents for importation requesting. Moreover, the history of licensee(s) for importation of modern medicinal products recorded in the intranet system of the Customs and FDA should be completely reviewed, and the level of observation should be defined. And then those documents are transferred to the port of entry of FDA respectively.

3.1.2) The FDA's officers at the port of entry should re-check the details of medicinal products being imported and also the level of observation as the Customs defined. In case of the licensee whose imported medicinal products were failed in the three consecutive sample taking, additional activities must be performed as followed;

3.1.2.1) The sample taking should be done by the FDA's officers at the container which the modern medicinal products being imported contains

3.1.2.2) Inform the Customs' officers that they can release all of those medicinal products, with some conditions as

- During the sample analysis done by DMSc, all of those imported medicinal products should be kept in the warehouse of the licensee, and the documents to identify a status of "holding" should be written by the FDA's officers to ensure that those medicinal products must not be distributed into the market before the issuing of its testing results.

- If the testing results are passed, those imported medicinal products will be approved by Thai FDA to be distributed into the market finally.

3.2) Documents required for importation approval for modern medicinal products

All relevant documents used to consider for importation approval for modern medicinal products consists of

- License for importation of modern medicinal product
- Product registration, including finished product specification
- Commercial invoice

- Packing list
- Certificate of analysis (issued by the manufacturer)
- GMP Certificate

In the present time, some important documents could not be reliable and then must be thoroughly considered such as

3.2.1) Certificate of analysis (COA)

Since the COA that was required to present to the FDA's officers at the port of entry is the copy one only. Moreover, the format of each COA is too different although coming from the same country e.g. COA from the manufacturers of China. The difference always found is the pattern in a part of approval for COA including both QA manager's signature and stamp of company's logo.

The format of COA issued by the manufacturer from origin country should defined as

- Name and address of the manufacturer
- Name, lot/batch no., manufacturing date and expiry date of the imported medicinal product
- Testing results according to its product registration issued by the Thai FDA
- Date of analysis and release
- Signature with the name, surname and the position of QA manager, the authorized person who responsible for releasing the finished product

Remark:

(1) The formal letter to confirm that QA manager named in the COA had already been authorized by the manufacturer should be required. Moreover, the name of that QA manager should defined in the list of authorized persons to release the finished products which was certified by the National Regulatory Authority (NRA) of the origin country.

(2) In the future, the harmonization on the issuing of COA should be encouraged by the NRA of each country.

(2.1) All local manufacturers are required to inform the name of authorized persons who responsible for releasing the finished products to the NRA

(2.2) Format of COA should be the same pattern in all manufacturers

3.2.2) Certificate of Pharmaceutical Products (CPP)

Nowadays, these documents are not required at the port of entry of FDA. These documents can be used for ensuring that the imported medicinal products are registered and distributed in the origin country. In some country, some medicinal products are allowed to be produced for export only. It should be thoroughly concerned about the quality and safety of those medicinal products. So these documents should be additionally required documents to consider for importation approval for modern medicinal products.

4) The measurement to improve the effectiveness of the monitoring for product recall

Since the product recall is one of measurement that the licensee(s) who infringe the Drug Act B.E.2510 should perform, particularly resulting from the quality defect of its own products, the effectiveness of the recall process must be concerned to ensure that the defective medicinal products being distributed in the market are absolutely eradicated. Therefore, the appropriate measurement to improve the effectiveness of product recall should be thoroughly considered and performed.

The existing system for product recall defined that the monitoring for product recall should be done by the FDA's officers. Contact by phone is the method used for communication between the licensee(s) and the FDA's officers. It is too difficult to monitor the real result of product recall.

The alternative measurement should be considered as followed;

4.1) Before reaching the time as required, the inspector of the Inspectorate Unit of the Drug Control Division should monitor at the site of licensee(s), in order to stimulate the licensee(s) to finish the process of product recall in timely manner. Moreover, the appropriateness of the recall process done by the licensee(s) should be thoroughly considered and discussed.

4.2) After reaching the time as required, the Thai FDA should prepared and sent the warning letter to the licensee(s) and other additional measurement should be performed as followed;

4.2.1) Prohibit the importation of those licensees' medicinal products (in case of importer) or prohibit the production of those licensees' medicinal products (in case of local manufacturer)

4.2.2) Proposing the Drug Committee to consider for suspension or withdrawal of the license

WO strategies

11) W6, T1

To develop the operation procedure manual for officers working at port of entry

The quantity and frequency of the importation for health products including modern medicinal products into Thailand would be dramatically increased because of the result of international agreements. That could affect the personal performance and the effectiveness of the consideration for importation approval by the officers of the Customs and the FDA, especially at the port of entry.

Furthermore, there has no the port of entry of FDA in some area, and the officers of the Customs must be responsible for checking and approving the importation of health products, including modern medicinal products instead of FDA. The Customs' officers may not be expert in a field of health products, particularly modern medicinal products.

Therefore, the Customs should cooperate with FDA to establish the alternative measurement to facilitate their own officers. The specific manual to inform all about the importing system for health products, including modern medicinal products should be prepared. The details in this manual may consist of

- All relevant laws and requirement (both the Customs' and FDA's)
- Steps for importation approval of health products, including modern medicinal products
- How to do or take action when the violation of FDA's and the Customs' laws occurred at the port of entry
- Principle and criteria for decision making about unidentified customs tariff
- How to observe and identify the illegal health products, especially the illegal medicinal products
- Other if necessary

CHAPTER V
DISCUSSIONS

The results of study were discussed in this chapter. It was separated into 2 mainly issues as (1) discussion based on strategies and (2) discussion based on main theory, Host Tor's Theory.

5.1 Discussion based on strategies

All strategies proposed in chapter IV were considered through the feasibility to succeed and duration to reach an achievement of each factor. It was separated into 1) SO strategies 2) ST strategies 3) WO strategies 4) WT strategies, respectively.

From the SWOT analysis, some strategies could be proposed for the performance improvement of the importing system. These strategies were divided into short-term and long-term strategies as followed. The main elements which were considered for the specific strategies to improve the performance of the importing system for modern medicinal product consist of 1) Laws/ Requirements 2) Resources 3) Technology and 4) Personnel.

Nonetheless, the strategies concerning laws/requirements and resources always need more time to improve and develop. It should be prepared the long-term action plan, including timeframe clearly. On the other hands, the strategies concerning technology and personnel could be completely done and successful in the short time.

Short-term strategies

1) To speed up the establishment of National Single Window (NSW) in order to increase the effectiveness of the importing system for modern medicinal products

2) To increase communication channels by setting up the information center and promote inter- and intra-organizational communication

3) To complete database of modern medicinal products and link all data into NSW

4) To manage the human resources and budgetary through the reward system

5) To improve the competency of the officers and other persons involving in the importing system for modern medicinal products

Long-term strategies

1) To increase the number of ports of entry of FDA and the number of instruments for quality control

2) To establish the task force among organizations for achieving the specific purposes, particularly the detection of smuggling of illegal medicinal product at the port of entry

3) To identify factors related to the improvement of importing system as key performance indicators

4) To establish more effective post-marketing surveillance system

5) To develop the operation procedure manual for officers working at port of entry

6) To revise all relevant laws and regulations to carry higher penalty for illegal medicinal products

Nonetheless, the timeframe for short-term strategies and long-term strategies should be defined by among involved organizations, in order to achieve the objectives of each strategy and the performance of importing system for modern medicinal product must be improved soon.

5.2 Discussion based on Host Tor's Theory and PEST Model

The proposed strategies compared with the elements of Host Tor's Theory and PEST Model (to identify "environment" of Host Tor's Theory) could be concluded as the table 5.1.

Table 5.1 Comparison between proposed strategies and elements of theory

Strategy no.	Host Tor's Theory	PEST Model
1	Element 4, 6	Element 1
2	Element 8	Element 1
3	Element 1, 3.6, 6	Element 1
4	Element 4, 6	Element 1

Table 5.1 Comparison between proposed strategies and elements of theory (cont'd)

Strategy no.	Host Tor's Theory	PEST Model
5	Element 4, 6	Element 1
6	Element 6	Element 1, 4
7	Element 1	Element 1
8	Element 7	Element 1
9	Element 2, 3.4.3	Element 1
10	Element 1, 3.3	Element 1
11	Element 2	Element 1

Remark

Host Tor's Theory

Element 1: Laws/ Requirements

Element 2: Resources

Element 3: Tasks

3.3: Approval process for imported modern medicinal products

3.4.3: Instruments/ Laboratories

3.6: Post-marketing surveillance system for the imported medicinal products

Element 4: Technology

Element 6: Personnel

Element 6: Structure

Element 8: Culture

PEST Model

Element 1: Policy

Element 4: Technology

From the above summary table, the main elements which were considered for the specific strategies to improve the performance of the importing system for modern medicinal product consist of 1) Laws/ Requirements 2) Resources 3) Technology and 4) Personnel.

For the angle of laws/requirements and resources, the proposed strategies could be performed in the future because those issues always need more time to improve and develop. Therefore, the strategies concerning laws/requirements and resources should be prepared the long-term action plan, including timeframe clearly.

According to technology and personnel issue, the strategies could be completely done and successful in the short time. The existing system has already adapted any technology, in order to facilitate all works to reach a goal rapidly. Moreover, the strategies to improve the competency of personnel could be performed and assessed first. Therefore, the strategies concerning technology and personnel should be done following the short-term action plan.

5.3 Other issues for discussion

In addition, some issues should be discussed, in order to add more suggestions for this study as followed;

5.3.1 Develop additional strategies for any remaining "blind spots" in SWOT matrix

The result of study as the strategies to improve performance of the importing system for modern medicinal products had been synthesized through the SWOT matrix including SO, ST, WO and WT strategy.

Nevertheless, all data from SFAS and SWOT analysis should be used as basic information for setting other strategies. Some remaining "blind spots" in SWOT matrix i.e. SW and OT strategy should be also thoroughly considered as followed;

1) SW strategy

This strategy is synthesized by using the internal strengths (S) to conquer the internal weaknesses (W). Some appropriate strategies could be developed and implemented within the shorter time. However, the cooperation among all stakeholders will be the main factor to achieve a goal to eradicate the weakness and then improve the importing system for modern medicinal products.

The example of the strategies developed from SW strategy will be presented as

1.1) S21, W29

To improve the capabilities of the Customs' officers working at the port of entry without the FDA

Before the announcement by FDA about the limitation of the number of port of entry that modern medicinal products could be imported will be performed and effectively implemented, the Customs' officers who work at the port of entry where having no the port of entry of FDA should be trained by the experts from FDA, in a field of health products particularly the modern medicinal products. The well-trained officers of FDA should have a chance to share and discuss with the Customs' officers who expert in their field, in order to improve their own capacities and to ensure that all products including medicinal products being imported into Thailand will be carefully scanned and checked prior to be approved to distribute in the market.

1.2) S23, W21

To establish the systematic measurement to combating the illegal medicinal products in advance

Before the team-building between the Customs and FDA would be effectively performed according to strategy no. 4) W3, O1O2 (To establish the cooperation team among all stakeholders to take action together for achieving the specific purposes), the systemic measurement to promptly detect the illegal medicinal products which were smuggled and distributed in the market, without passing through the port of entry of FDA should be discussed and then prepared in advance.

Since the cooperation among relevant organizations concerning the importing system for modern medicinal product e.g. the Customs and FDA has been routinely done in case of the most important and very urgent issues such as the smuggling of illegal medicinal products, the officers who act as the focal point of each organization should do the round-table conference, to discuss and exchange the information and then conclude the specific measurements for each case. Finally those measurements should be proposed to the top management of each organization and also added in the content of MOU which would be signed by the top management of the Customs and FDA respectively.

For instance,

- To prepare the active measurement, all relevant organizations should discuss together what the root cause of the problem of smuggling of illegal medicinal product and the route of transportation of those products. Besides, the Inspectorate Unit of Thai FDA, the organizations responsible for drug post-marketing surveillance should share the information with the Import and Export Inspection Division of FDA and the Customs which are the organizations responsible to detect and thoroughly filter the illegal medicinal products prior to be imported into Thailand, in order to understand about the current situation of illegal medicinal product distributed in the market. And then the suspicious persons or companies should be closely watched when they travel in and out of Thailand or import and export their products. The Customs should inform the FDA and also the policemen about the history of journey or the history of import and export, in order to monitor and pursue their behaviors. If there are sufficient testimonies, the operation to seize the accused among the FDA, the Customs, and the policemen should be performed immediately. These procedures should be defined as the systematic measurement for combating the illegal medicinal product being imported and distributed in the market of Thailand.

- To prevent the smuggling of illegal medicinal products through the baggage carried by passenger or parcel post that is not required to pass through the port(s) of entry of FDA, the government should request the Customs and other relevant organizations of origin country to strictly control and check the passenger's baggage and parcel post being exported, in order to ensure that there has no the illegal medicinal products were smuggled and distributed into Thailand.

2) OT strategy

The external opportunities (O) will be used to avoid the external threats (T) in this strategy. Although the developed strategies may be succeeded in the long period of time, those can be proposed as one of the additional measurement which can be used in parallel to decrease the effects of any external threats.

The example of the strategies developed from OT strategy will be presented as

2.1) O5O8, T5

To transfer the correct information to the customers through the existing channels

Since using the technology in the correct way such as advertising of the modern medicinal products through the internet without the scientific information or safety data support is a cause of the increasing of smuggling of illegal medicinal products or low-quality of medicinal products, the relevant organization concerning the importing system for modern medicinal product, particularly the FDA should always transfer only correct and updated information of health products including medicinal products to the consumers through the existing channels for communication and publication e.g. FDA's website, handbill, poster, and also any social networks such as facebook and twitter.

Furthermore, the consumers now concern more about their health. Therefore, the quality, safety and efficacy of the medicinal products which is a kind of high risk health products are the main issues that the consumers consider.

2.2) O6O1O2, T1

To push the National Single Window (NSW) effectively in timely manner following the defined action plan

Since the quantity and frequency of the importation for health products including modern medicinal products into Thailand would be dramatically increased resulting from the international agreements mentioned that any products from the other countries could be imported into Thailand without tax calculation, the National Single Window (NSW) should be used for reducing the steps and times of the importation approval process since all involved organizations can check relevant data of each product on their behalf from the same page and consider in advance for importation approval respectively.

Under the encourage by the government and top management of each organization concerning the importing system for modern medicinal product, the NSW would be the useful and effective system of our country to maintain the main objectives of the importing system as to facilitate the importation as well as to control and monitor the quality of imported products.

Although the NSW has not been completely developed in the present time, especially in a part of medicinal products, it would be finished in timely manner since the achievement of the NSW has been defined in the action plan of each organization concerning the importing system for modern medicinal product, and then the evaluation of those action plan must be strictly performed.

5.3.2 Use the existing Key Performance Indicators (KPIs) as a tool for the importing system development

All organizations concerning the importing system for modern medicinal products have already established its own key performance indicators (KPIs) as a tool for controlling all involved persons to perform their own activities effectively and for achieving a goal of the organization related to the importing system for modern medicinal products.

The Customs has defined the KPIs to ensure that the taxation system for import and export as well as the measurement to detect the violation of copyright, patent and trademark are more effective.

The Food and Drug Administration (FDA), particularly the division concerning the importing system for modern medicinal products as the Drug Control Division and the Import and Export Inspection Division has already defined the KPIs as well. However, there had no the evaluation of some KPIs and then use those results to improve the importing system for medicinal products. Therefore, the Thai FDA should thoroughly consider for the result of KPIs, in order to develop the appropriate measurement to improve the performance of importing system for modern medicinal product.

For instance,

The Pre-marketing Control Unit of the Drug Control Division

KPI 1: The application for issuing the license that was considered and approved in timely manner should not be less than 92%

KPI 2: The application for issuing the product registration that was considered and approved in timely manner should not be less than 91%

The result of KPI 1 and KPI 2 had been collected only the number of application for issuing the license and product registration which was approved in timely manner. Those numbers should be used to evaluate the current situation. For example, the significant increasing of the number of approved license or the product registration for the imported medicinal products should be considered and evaluated (1) what the cause of those increasing number is, (2) which country that always be the origin of imported medicinal products, with low quality as sub-standard, (3) what the affectation on the local market of modern medicinal product, and (4) how to forecast the tendency of the importation of modern medicinal product. And then the appropriate policy to encourage or improve the current situation of the modern medicinal product being distributed in the market should be thoroughly considered and established if possible.

The Import and Export Inspection Division

KPI 3: The imported health products that were sampled for inspection having more quality regarding its specification should not be less than 95%

The KPI 3 defined by the Import and Export Inspection Division was not suitable and reasonable. Since the officers might take a sample of imported health products including the medicinal products from the reliable importer whose imported medicinal products always passed the testing done by the DMSc and also had no the history of violation of the FDA's law such as the Drug act B.E. 2510, the sample taken at the port of entry following the sampling plan would not come from the several importers and not be the representative of all imported medicinal products. That means the result of this KPI could not be evaluated the real situation of the quality of health products including the modern medicinal product being imported into the market.

Therefore, this KPI should be changed and the new version of KPIs related to the effectiveness of the importing system for modern medicinal product should be established respectively as followed;

(1) The number of medicinal products being imported into the market that were taken sample should not be less than 85%

(2) The number of detection and prosecution for the violation of the FDA's law occurred at the port of entry should not less than 90%

5.3.3 Adapt from the control system of modern medicinal products of Health Sciences Authority (HSA), Singapore

Thailand should thoroughly consider for adapting the Singapore importing system for modern medicinal products to improve the existing system as followed;

1) The Wholesale Dealer's license for medicinal products should be really established and implemented following the content defined in the Drug Act B.E.2510.

Although the existing Drug's law mentioned on all kinds of license that can be issued by the licensing authority as Thai FDA, there has no the issuing of the Wholesale Dealer's license before. Nowadays, the most of wholesale dealers has been licensed as the licensee for sale of modern medicinal product only.

For the granting of the Wholesale Dealer's license, it should be considered when the company has been audited and found to comply with GDP standard. Moreover, the licensed wholesale dealers can only deal in registered medicinal products, including the imported medicinal products.

2) The products authorized for importation should be listed in the license.

Nowadays, the license for importation of modern medicinal product would not define the products authorized for importation. That will be useful for controlling and monitoring the local importers when they import the licensed products on their behalf.

3) The license for distribution of modern medicinal product should be defined.

In the present time, there are some logistic companies acting as the distributor to transport and distribute any products, including modern medicinal product. Therefore, Thai FDA should consider for issuing another license as the license for distribution of modern medicinal product, and then inform those logistic companies to apply for license respectively.

4) The Good Distribution Practice (GDP) should be required as regulation.

In the present time, GDP has not been developed as the main criteria for approval of issuing the licenses, in order to ensure that the quality of the products will be maintained during storage and distribution.

Besides, the draft of GDP prepared by the Drug Control Division of Thai FDA should be thoroughly considered to be implemented as soon as possible. And it should be notified as the basic requirement that the on-site audit should be performed according to GDP standard, prior to issue the license for importation and wholesale.

5) GMP conformity assessment of oversea manufacturers of medicinal product

Since the oversea manufacturers of modern medicinal product have not been audited by the pharmaceutical GMP inspector of Thai FDA, the imported medicinal products has been required only its certificate of analysis (COA) and GMP certification. Moreover, Thai FDA is in the process of applying for PIC/S member and also the PIC/S GMP standard would be required as the national regulation.

Therefore, the on-site GMP inspection at the oversea manufacturer to assess the compliance to the PIC/S GMP standard should be performed by the GMP inspectors of Thai FDA, if necessary.

Nevertheless, the manufacturers which have been previously audited by the National Regulatory Authority (NRA) and found to conform to PIC/S GMP standards or other GMP guide equivalent to PIC/S GMP e.g. WHO and EU GMP need not be audited by the GMP inspectors of Thai FDA if the submitted evidence is found to be acceptable.

5.3.4 Promote the Good Importer Practices (GIP) into the importing system for modern medicinal products

The Good Importer Practices (GIP) guidance is the important measurement adapted to use in the importing system for modern medicinal product, in order to guide all involved organizations to improve their own operations and encourage the importing system development respectively.

Nowadays, GIP guidance developed by U.S. Food and Drug Administration (US FDA) should be thoroughly considered. Although this GIP guidance has not been formally notified by US FDA, the principles and recommendations stated in this guidance should be thoroughly adapted for using as “best practices” in the importing system of modern medicinal product of our country.

CHAPTER VI
CONCLUSIONS AND RECOMMENDATIONS

This chapter provided the conclusions and the recommendations for the study on system analysis and strategic development for medicinal product importation. The details were described as followed;

6.1 Conclusions

The results of study were concluded that the strategies which would be proposed to improve the performance of the importing system for modern medicinal product came from 2 main steps with different study designs as followed;

<u>Step I</u> : to analyze the current importing system for modern medicinal products (Situation analysis)

This step was done to identify all factors affecting the effectiveness of current importing system for modern medicinal products by using the combination of three theories including Host Tor's Theory (1997) as the main theory and Keidel's Theory (1995) and PEST Model as the supplementary theory. All relevant data were collected through the process of content analysis, key informant interview, and case study.

After that all collected data following each element of Host Tor's Theory (1997) should be identified by using SWOT analysis. This process could conclude what the strengths (S), weaknesses (W), Opportunities (O), and threats (T) of the current importing system for modern medicinal products. Furthermore, the internal factors included the strengths (S) and weaknesses (W), and the external factors consisted of the Opportunities (O) and threats (T).

<u>Step II</u> : purpose to synthesize strategies to improve performance of the importing system for modern medicinal products

The next processes were composed of 2 processes, prioritizing and proposing the strategies to improve the system performance.

1) Prioritize strategies

The SWOT derived from step I were selected based on key informants' opinion. These selected were proposed for the *expert review* to prioritize. The prioritization was conducted using weighing and rating for each selected factor.

In this process, all selected SWOT was separated into 2 tables including the table of Internal Factor Analysis Summary (IFAS) and the table of External Factor Analysis Summary (EFAS). Both IFAS and EFAS must define the weight and rating for each selected factor.

The weight stands for the feasibility of success of each factor. The factor that could be performed easier and had the possibility to reach a goal faster than another factor must be weighed with higher number.

For the rating, the expert must consider for the importance of selected factor and then prioritize by using the number 1 to 5. The no.1 means that the factor was the least important factor and no.5 means that the factor was the most important factor that could mainly affect the performance of the importing system.

2) Propose strategies

From IFAS and EFAS, SWOT with the rating of 5 and 4 were selected and analyzed through the Strategic Factor Analysis Summary (SFAS). However, some SWOT with the rating of 3 was selected under the decision making by the focus group. The focus group included 1) 5 key personnel from the Import and Export Inspection Division 2) the chief of the Inspectorate Unit, DCD of FDA and 3) an expert from the Customs. Moreover, the duration as the expected time to reach the achievement was also identified.

Finally, SWOT matrix (Confrontation matrix) was used as a tool for developing the strategies for improving the importing system for modern medicinal products.

All strategies that were the result of this study consist of 11 strategies. The strategies that were possible to succeed in short time included 5 strategies as followed;

Short-term strategies

1) Strategy no.1: S18 S19 S21, O6O1O2

To speed up the establishment of National Single Window (NSW) in order to increase the effectiveness of the importing system for modern medicinal products

2) Strategy no.4: S18S21, T2

To increase communication channels by setting up the information center and promote inter- and intra-organizational communication

3) Strategy no.5: S19S21, T4

To complete database of modern medicinal products and link all data into NSW

4) Strategy no.2: S25, O1O2

To manage the human resources and budgetary through the reward system

5) Strategy no.6: W29, O6O1O2

To improve the competency of the officers and other persons involving in the importing system for modern medicinal products

For 6 remaining strategies, it had a chance to perform in parallel or in the future as followed;

Long-term strategies

1) Strategy no.9: W6, O1O2 and W18, O1O2

To increase the number of ports of entry of FDA and the number of instruments for quality control

2) Strategy no.7: W3, O1O2

To establish the task force among organizations for achieving the specific purposes, particularly the detection of smuggling of illegal medicinal product at the port of entry

3) Strategy no.8: W31, O3O1

To identify factors related to the improvement of importing system as key performance indicators

4) Strategy no.3: S1 S14 S21, T1

To establish more effective post-marketing surveillance system

5) Strategy no.11: W6, T1

To develop the operation procedure manual for officers working at port of entry

6) Strategy no.10: W1W12, O1 and W4, O1

To revise all relevant laws and regulations to carry higher penalty for illegal medicinal products

The main elements which were considered for the specific strategies to improve the performance of the importing system for modern medicinal product consist of 1) Laws/ Requirements 2) Resources 3) Technology and 4) Personnel.

Nonetheless, the strategies concerning laws/requirements and resources always need more time to improve and develop. It should be prepared the long-term action plan, including timeframe clearly. On the other hands, the strategies concerning technology and personnel could be completely done and successful in the short time.

6.2 Recommendations

The result of this study is the identified current situation of importing system for modern medicinal product as well as the synthesized strategies to improve the performance of those importing system. All organizations concerning the importing system for modern medicinal product could apply the results as the politic proposal and basic information to consider for reviewing, revising and improving of the existing system.

Nevertheless, all developed strategies would be much more useful for improving the medicinal product importation if the cooperation among all organizations involved in the importing system for modern medicinal product has already established. The top management of each organization should sincerely encourage the cooperation among other organizations. Furthermore, the bilateral agreement between the Customs and the FDA should be prepared as soon as possible, in order to support the applying for the measurements which were proposed by the researcher. Both the Customs and FDA; however, should thoroughly consider together for selecting the appropriate proposed measurements and the feasibility to operate those selected measurements.

In addition, the strategies which were proposed in this study and selected to be used in the real practice should be carefully considered to implement and monitor. To get the achievement of implementation of those strategies; moreover, the specific team which consists of the authorized representatives from both the Customs and the FDA as the members should be established and strictly performed to control and monitor the success of defined strategies.

The appropriate steps to implement and monitor all strategies should be identified and followed. Firstly, the action plan and key performance indicators (KPIs) for each strategy should be developed. Secondly, the responsibilities, key personnel or focal point and the required budgets for each strategy should be also clearly identified. Thirdly, the monitoring process should be performed, in order to control and ensure that all involved persons working for each organization concerning the importing system for modern medicinal product would follow the procedures and achieve a goal of each KPIs. Finally, the established specific team should review the whole processes of the new importing system for modern medicinal product, in order to evaluate and then conclude whether the defined strategies were successful or not.

Furthermore, the suggestion for further study is that to follow up the implementation of each selected strategy done by all organizations involved in the importing system for modern medicinal product. Some interventions e.g. the team-building between the Customs and Thai FDA to take action together for some specific cases such as detecting and prosecuting the violator who always import low-quality of medicinal products, should be put in the importing system of modern medicinal product, and then the evaluation for the effectiveness of the new version of the importing system should be performed.

Moreover, the involved persons who would be interviewed by the researcher in the step of key informant interview should be thoroughly selected from all stakeholders, expanding from the Customs and Thai FDA to the private sectors, particularly the importer, distributor and logistic company. Then the satisfaction of all stakeholders including both the government and private agency should be assessed, in order to know more which strategy is appropriate for them all, which strategy must be improved and which strategy should be maintained.

In addition, some issues which were identified as the current situation of importing system for modern medicinal product in this study could be repeatedly reviewed and considered as the database to synthesize other strategies, if appropriate and feasible.

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APPENDICES

APPENDIX A

คำชี้แจง
เอกสารข้อมูลคำอธิบาย/ คำชี้แจงสำหรับอาสาสมัครที่เข้าร่วมการวิจัย
(Patient or Participant Information Sheet)

คำชี้แจง:	*ภายใต้หัวข้อใหญ่ทุกข้อ ได้อธิบายให้ทราบถึงละเอียดที่ผู้วิจัย และ/หรือผู้เสนอขอรับการพิจารณาฯ ต้องกรอกข้อมูลอย่างไรบ้าง จึงขอความกรุณาผู้วิจัย และ/หรือ ผู้เสนอโครงการวิจัย กรุณาอ่านรายละเอียดคำชี้แจงก่อน แล้วกรอกรายละเอียดในเอกสารข้อมูลคำอธิบาย/ คำชี้แจงสำหรับอาสาสมัครที่เข้าร่วมการวิจัย (ตามแบบฟอร์มที่กำหนด)* ***ให้ครบถ้วนทุกข้อ***

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หน่วยงานที่ทำการศึกษาวิจัย	หลักสูตรวิทยาศาสตร์มหาบัณฑิต สาขาวิชาเภสัชศาสตร์สังคมและบริหาร (นานาชาติ) คณะเภสัชศาสตร์ จุฬาลงกรณ์มหาวิทยาลัย
โทรศัพท์ (สามารถติดต่อได้ 24 ชั่วโมง)	081-3744884

ท่านได้รับเชิญให้เข้าร่วมการศึกษาวิจัยเรื่อง “การวิเคราะห์และพัฒนายุทธศาสตร์ของระบบการนำเข้ายา (SYSTEM ANALYSIS AND STRATEGIC DEVELOPMENT FOR MEDICINAL PRODUCT IMPORTATION)” ก่อนที่ท่านจะตัดสินใจให้ความยินยอมเข้าร่วมการศึกษาวิจัยนี้ ผู้วิจัยใคร่ขอชี้แจงรายละเอียดของโครงการวิจัยให้ท่านทราบ และขอให้ท่านทำความเข้าใจขั้นตอนที่ผู้วิจัยจะขอให้ท่านปฏิบัติ ขั้นตอนนี้เป็น **“กระบวนการให้คำยินยอม”**

กรุณาอ่านข้อมูลต่อไปนี้ด้วยความรอบคอบ และสอบถามถึงข้อสงสัยต่างๆ โดยไม่ลังเล

1. บทนำ

ยาแผนปัจจุบัน เป็นสิ่งที่ผู้ป่วยต้องใช้ในการรักษาโรค จึงจำเป็นต้องมีคุณภาพ ความปลอดภัย และประสิทธิผลในการรักษาเพียงพอ โดย สำนักงานคณะกรรมการอาหารและยา เป็นหน่วยงานที่รับผิดชอบในการกำกับดูแลผลิตภัณฑ์ยาที่มีการผลิต ขาย และนำหรือสั่งเข้ามาในราชอาณาจักร

อย่างไรก็ตาม จากข้อมูลเปรียบเทียบมูลค่าการนำเข้าและมูลค่าการผลิตยาแผนปัจจุบันระหว่างช่วงปีพ.ศ. 2544 – 2550 พบว่ามูลค่าการนำเข้ายามีแนวโน้มสูงกว่ามูลค่าการผลิต ซึ่งแสดงให้เห็นว่ามีปริมาณการใช้ยาแผนปัจจุบันที่นำเข้าจากต่างประเทศสูงมากขึ้นและค่าใช้จ่ายในการรักษาของผู้ป่วยก็จะสูงขึ้นด้วยเช่นกัน

นอกจากนี้ ข้อมูลการเฝ้าระวังความปลอดภัยของผลิตภัณฑ์สุขภาพ (Safety Alert) ที่สำนักงานคณะกรรมการอาหารและยา เผยแพร่แก่ผู้บริโภคผ่านทางเว็ปไซต์ www.fda.moph.go.th แสดงให้เห็นว่าผลการวิเคราะห์คุณภาพของยาที่นำเข้าจากต่างประเทศหลายรายการที่ตกมาตรฐานและจะต้องดำเนินการเรียกเก็บคืนจากท้องตลาด

อนึ่ง ปัจจุบันยังพบมีปัญหาการลักลอบนำเข้ายาที่ผิดกฎหมายเช่น ยาปลอม ยาที่มิได้ขึ้นทะเบียนตำรับ เป็นต้น ซึ่งมาตรการในการตรวจสอบ ติดตาม เฝ้าระวังปัญหาดังกล่าวควรมุ่งเน้นที่การสร้างความเข้มแข็งของระบบการนำเข้ายาเพื่อให้สามารถตรวจสอบและป้องกันปัญหาดังกล่าวได้ก่อนที่จะกระจายออกสู่ท้องตลาด

ดังนั้น จะเห็นได้ว่าระบบการนำเข้ายาแผนปัจจุบันของประเทศไทยจำเป็นจะต้องมีประสิทธิภาพเพียงพอที่จะสร้างความมั่นใจให้แก่ผู้บริโภคได้ว่ายาที่นำเข้าจากต่างประเทศเหล่านั้นมีคุณภาพ ความปลอดภัย และประสิทธิผลในการรักษา จึงเป็นที่มาของการวิจัยในหัวข้อ “การวิเคราะห์และพัฒนายุทธศาสตร์ของระบบการนำเข้ายา (SYSTEM ANALYSIS AND STRATEGIC DEVELOPMENT FOR MEDICINAL PRODUCT IMPORTATION)”

2. วัตถุประสงค์ของการวิจัย

1. เพื่อวิเคราะห์ปัจจัยที่มีผลกระทบต่อระบบการนำเข้ายาแผนปัจจุบันของประเทศไทย
2. เพื่อพัฒนายุทธศาสตร์ในการทำให้ระบบการนำเข้ายาแผนปัจจุบันมีประสิทธิภาพมากยิ่งขึ้น

3. วิธีการศึกษาวิจัย

การวิจัยนี้ ประกอบด้วยการศึกษาข้อมูลจากเอกสารต่างๆ ที่เกี่ยวข้อง (Content analysis) และการสัมภาษณ์หรือสอบถามข้อมูลจากผู้เชี่ยวชาญและ/หรือผู้ปฏิบัติงานที่เกี่ยวข้อง (Key informant interview) โดยผู้เข้าร่วมการวิจัยประกอบด้วยผู้เชี่ยวชาญ เช่น ผู้อำนวยการกองงานด่านอาหารและยา และผู้อำนวยการกองควบคุมยา เป็นต้น และผู้ปฏิบัติงานเช่น เจ้าหน้าที่ของกองงานด่านอาหารและยา ณ ด่านอาหารและยาบางแห่ง (ท่าอากาศยานสุวรรณภูมิ ท่าเรือคลองเตย และลาดกระบัง) และเจ้าหน้าที่ของกรมศุลกากร (เจ้าหน้าที่ประจำด่าน) ซึ่งคำถามที่ใช้ในการสัมภาษณ์มีรายละเอียดตามแบบสัมภาษณ์ที่แนบท้าย

นอกจากนี้ จะทำการศึกษาในลักษณะของ Case study โดยพิจารณาคัดเลือกผลิตภัณฑ์ยาที่สนใจจากข้อมูลการเฝ้าระวังความปลอดภัยของผลิตภัณฑ์สุขภาพ (Safety Alert) เป็นหลัก จากนั้นทำการวิเคราะห์กระบวนการและมาตรการต่างๆ ตามระบบการนำเข้าสำหรับผลิตภัณฑ์ยานั้น รวมถึงค้นคว้าข้อมูลเกี่ยวกับรูปแบบของระบบการนำเข้ายาของประเทศอื่นร่วมด้วย

ภายหลังการเก็บข้อมูลดังกล่าวข้างต้นเสร็จสิ้นแล้ว ผู้วิจัยจะนำข้อมูลที่ได้มาทำการวิเคราะห์ตามหลักการของ SWOT analysis เพื่อวิเคราะห์หาจุดแข็ง (Strengths) จุดอ่อน (Weaknesses) โอกาส (Opportunities) และอุปสรรค (Threats) ของระบบการนำเข้ายา จากนั้นจึงนำข้อมูลการวิเคราะห์ที่ได้เสนอให้ผู้เชี่ยวชาญพิจารณา (Expert review) เพื่อคัดกรองและเรียงลำดับความสำคัญของข้อมูลที่ผู้วิจัยควรจะนำไปพิจารณากำหนดยุทธศาสตร์ในการพัฒนาต่อไป

ผู้วิจัยกำหนดยุทธศาสตร์สำหรับการพัฒนาระบบการนำเข้ายา โดยใช้ SWOT matrix เป็นเครื่องมือในการวิเคราะห์และกำหนดยุทธศาสตร์ จากนั้น จึงนำยุทธศาสตร์ที่กำหนดไว้เสนอต่อที่ประชุม (Focus group) ซึ่งมีผู้แทนจากทุกส่วนที่เกี่ยวข้องเข้าร่วมเช่น ผู้อำนวยการกองงานด่านอาหารและยา ผู้อำนวยการกองควบคุมยา ผู้แทนจากกรมศุลกากร เป็นต้น เพื่อรับทราบผลการวิจัยในเบื้องต้นและร่วมกันพิจารณาหรือแสดงความคิดเห็นเพื่อปรับปรุงแก้ไขยุทธศาสตร์สำหรับการพัฒนาระบบการนำเข้ายาที่ผู้วิจัยเสนอ ให้มีความเหมาะสมและสามารถนำไปปรับใช้ได้อย่างมีประสิทธิภาพต่อไป

อนึ่ง หน่วยงานอื่นๆ ที่เกี่ยวข้องในระบบการนำเข้ายากล่าวคือ กลุ่มกฎหมายอาหารและยาของสำนักงานคณะกรรมการอาหารและยา กรมวิทยาศาสตร์การแพทย์ และกรมการค้าต่างประเทศ กระทรวงพาณิชย์ ในการวิจัยนี้ ไม่นับเป็นกลุ่มผู้เข้าร่วมการวิจัย เนื่องจากจะไม่มีการสัมภาษณ์หรือสอบถามข้อมูลจากเจ้าหน้าที่ของหน่วยงานดังกล่าว แต่จะศึกษาจากข้อมูลที่มีการรวบรวมและเผยแพร่ผ่านสื่อต่างๆ เช่น เอกสารเผยแพร่ของหน่วยงาน เว็ปไซต์ เป็นต้น

4. ความเสี่ยง ความไม่สบาย และผลข้างเคียงที่อาจเกิดขึ้น

การวิจัยนี้เป็นการสัมภาษณ์ผู้ที่ปฏิบัติงานเกี่ยวข้องกับระบบการนำเข้ายาของประเทศไทยเท่านั้น จึงมีความเสี่ยงเพียงเล็กน้อย เช่น ผู้เข้าร่วมการวิจัยอาจไม่สบายใจในการตอบบางคำถาม หรืออาจเสียเวลาในการตอบคำถาม เป็นต้น

5. ผลประโยชน์ที่อาจจะได้รับ

ผู้เข้าร่วมการวิจัยจะได้รับประโยชน์จากการวิจัยนี้ กล่าวคือ เมื่อระบบการนำเข้ายาได้รับการพัฒนาอย่างเหมาะสมและมีประสิทธิภาพแล้ว จะทำให้ท่านสามารถปฏิบัติงานในหน้าที่ความรับผิดชอบของตนได้อย่างเป็นระบบ สะดวก รวดเร็ว และมีประสิทธิภาพมากยิ่งขึ้น

นอกจากนี้ ผลของการวิจัยนี้จะเป็นประโยชน์ต่อการพัฒนาระบบการนำเข้ายาของประเทศไทย เนื่องจากมีวัตถุประสงค์เพื่อวิเคราะห์ปัจจัยที่มีผลกระทบต่อระบบการนำเข้ายาแผนปัจจุบันของประเทศไทย และนำข้อมูลที่เก็บรวบรวมได้มาพัฒนายุทธศาสตร์ของระบบการนำเข้ายาให้มีประสิทธิภาพมากยิ่งขึ้น ดังนั้น ผู้วิจัยจึงคาดหวังว่าผลของการวิจัยนี้ จะได้รับการยอมรับและมีการนำไปปรับใช้โดยทุกหน่วยงานที่เกี่ยวข้อง เพื่อพัฒนาระบบการนำเข้ายาของประเทศไทยต่อไปตามลำดับ

6. ทางเลือกอื่นในการรักษา

ไม่มี

7. ค่าใช้จ่ายและค่าชดเชย

ไม่มี

8. เงินชดเชยสำหรับการบาดเจ็บหรืออันตรายที่อาจเกิดขึ้น

การวิจัยนี้ ไม่ก่อให้เกิดการบาดเจ็บหรืออันตรายใดๆ แก่ผู้เข้าร่วมการวิจัย เนื่องจากเป็นการสัมภาษณ์ผู้เข้าร่วมการวิจัยเฉพาะในส่วนที่มีความเกี่ยวข้องเท่านั้น รวมทั้งไม่ก่อให้เกิดความเสียหายต่อชื่อเสียงและหน้าที่การงานของผู้เข้าร่วมการวิจัยแต่อย่างใด

9. สิทธิในการถอนตัวออกจากการศึกษาวิจัย

ท่านมีสิทธิ์ในการถอนตัวออกจากการเข้าร่วมโครงการวิจัยนี้เมื่อใดก็ได้ โดยไม่มีผลกระทบใดๆ ทั้งสิ้น

10. การรักษาความลับของบันทึกทางการแพทย์ และข้อมูลการศึกษาวิจัย

ผู้วิจัยจะเก็บข้อมูลของผู้เข้าร่วมการวิจัยไว้เป็นความลับ ไม่มีการเปิดเผยรายชื่อของผู้เข้าร่วมการวิจัยให้ผู้อื่นทราบแต่อย่างใด รวมถึงผู้บังคับบัญชาของผู้เข้าร่วมการวิจัยด้วย โดยจะเปิดเผยเฉพาะข้อมูลที่ได้รับในรูปของสรุปผลการวิจัย โดยผู้มีสิทธิ์เข้าถึงข้อมูลประกอบด้วยผู้วิจัย และอาจารย์ที่ปรึกษาเท่านั้น

11. การเปิดเผยข้อมูลการศึกษาวิจัย

การเปิดเผยข้อมูลจะเป็นในรูปของสรุปผลการวิจัยเท่านั้น โดยผู้มีสิทธิ์เข้าถึงข้อมูลการศึกษาวิจัยมีเพียงผู้วิจัยและอาจารย์ที่ปรึกษาเท่านั้น

12. การสอบถามข้อสงสัย

หากมีข้อสงสัยประการใด สามารถติดต่อได้ที่

12.1) ผู้วิจัย : นางสาวพัชรีวรรณ ฝังนิล

กลุ่มกำกับดูแลยาหลังออกสู่ตลาด กองควบคุมยา สำนักงานคณะกรรมการอาหารและยา กระทรวงสาธารณสุข

เบอร์โทรศัพท์: 081-3744884 และ 0-2590-7315

12.2) อาจารย์ที่ปรึกษา : ผศ.ภญ.ดร.รุ่งเพ็ชร สกุลบำรุงศิลป์

ภาควิชาเภสัชศาสตร์สังคมและบริหาร คณะเภสัชศาสตร์ จุฬาลงกรณ์มหาวิทยาลัย

เบอร์โทรศัพท์: 081-4244808 และ 0-2218-8386

ทั้งนี้ หากผู้วิจัยไม่ปฏิบัติตามที่ชี้แจงในเอกสารข้อมูลคำอธิบาย ท่านสามารถร้องเรียนมายังคณะกรรมการพิจารณาจริยธรรมการศึกษาวิจัยในมนุษย์ ฝ่ายวิจัย คณะเภสัชศาสตร์ จุฬาลงกรณ์มหาวิทยาลัย โทร.02-218-8256

APPENDIX B

การวิเคราะห์และพัฒนายุทธศาสตร์ของระบบการนำเข้ายา

SYSTEM ANALYSIS AND STRATEGIC DEVELOPMENT

FOR MEDICINAL PRODUCT IMPORTATION

คำถามหรือข้อความที่จะใช้ในการสัมภาษณ์หรือสอบถามข้อมูลจากผู้เกี่ยวข้อง จัดแบ่งตามบทบาทหน้าที่ความรับผิดชอบของแต่ละหน่วยงานและ/หรือบุคคล โดยมีรายละเอียดดังนี้

สำนักงานคณะกรรมการอาหารและยา

<u>กองงานด่านอาหารและยา</u>

1) ผู้อำนวยการกอง

1. หน่วยงานของท่านมีบทบาทอย่างไรในระบบการนำเข้ายาของประเทศไทย
2. ในมุมมองของท่าน สถานการณ์ปัจจุบันของระบบการนำเข้ายาเป็นอย่างไร และมีประสิทธิภาพมากน้อยเพียงใด
3. หน่วยงานของท่านมีการจัดรูปแบบองค์กรอย่างไรทั้งในส่วนกลางและส่วนภูมิภาค และแต่ละหน่วยงานมีหน้าที่ความรับผิดชอบเกี่ยวกับระบบการนำเข้ายาอย่างไร
4. ด่านอย.ที่มีทั้งหมดในปัจจุบัน มีจำนวนเท่าไรและเพียงพอหรือไม่
5. ตัวชี้วัดที่เกี่ยวข้องกับระบบการกำกับดูแลการนำเข้ายามีการกำหนดไว้หรือไม่ อย่างไร และหากมีการกำหนดไว้ ผลการดำเนินการที่ผ่านมาสอดคล้องตามตัวชี้วัดหรือไม่ อย่างไร
6. การประสานความร่วมมือกับหน่วยงานอื่นที่เกี่ยวข้องเป็นอย่างไร และต้องการให้มีการเปลี่ยนแปลงหรือพัฒนาหรือไม่ อย่างไร
7. NSW (National Single Window) คืออะไร มีวัตถุประสงค์อย่างไร มีข้อดีและ/หรือข้อเสียอย่างไร และต้องดำเนินการอย่างไรจึงจะประสบความสำเร็จตามวัตถุประสงค์
8. ปัญหาและอุปสรรคที่พบบ่อยครั้งในการควบคุมการนำเข้าผลิตภัณฑ์ยาคืออะไร
9. มีกฎหมายหรือกฎเกณฑ์ที่ใช้ในการควบคุมการนำเข้าอย่างไรบ้าง
10. หากพบมีการละเมิดกฎหมายหรือกฎเกณฑ์ที่กำหนดไว้ มีมาตรการอย่างไรในการดำเนินการ เช่น กรณีผลการวิเคราะห์ของยานำเข้าที่สุ่มตัวอย่างเพื่อส่งวิเคราะห์คุณภาพที่กรมวิทยาศาสตร์การแพทย์ พบว่าตกมาตรฐาน จะทำอย่างไร
11. การคัดเลือกบุคลากรเพื่อปฏิบัติงานในตำแหน่งต่างๆ พิจารณาอย่างไร

(เช่น หัวหน้าด่านอย.แต่ละด่าน เจ้าหน้าที่ประจำด่านอย. เจ้าหน้าที่บันทึกข้อมูล เป็นต้น)

12. บุคลากรจำเป็นต้องมีคุณสมบัติพื้นฐานอย่างไร เช่น วุฒิการศึกษา ประวัติการฝึกอบรม สุขภาพร่างกายและจิตใจ เป็นต้น
13. หลักสูตรการฝึกอบรมที่จำเป็นสำหรับเจ้าหน้าที่ในหน่วยงานของท่านมีอะไรบ้าง ความถี่ในการอบรมและวิธีการประเมินผลเป็นอย่างไร
14. ต้องการการสนับสนุนในด้านใดเพิ่มเติมหรือไม่ (เช่น งบประมาณ บุคลากร เครื่องมือ/อุปกรณ์ต่างๆ เป็นต้น) อย่างไร
15. นโยบายระดับประเทศและ/หรือข้อตกลงทางการค้าระหว่างประเทศอาทิเช่น AFTA, ASEAN Harmonization, MRA ส่งผลกระทบต่อการปฏิบัติงานหรือไม่ อย่างไร
16. มีข้อเสนอแนะในการพัฒนาหรือปรับปรุงระบบการนำเข้ายาหรือไม่ อย่างไร

2) หัวหน้ากลุ่มงานในส่วนกลาง

1. หน่วยงานของท่านมีบทบาทและหน้าที่ความรับผิดชอบอย่างไร
2. ในมุมมองของท่าน สถานการณ์ปัจจุบันของระบบการนำเข้ายาเป็นอย่างไร และมีประสิทธิภาพมากน้อยเพียงใด
3. ตัวชี้วัดที่เกี่ยวข้องกับระบบการกำกับดูแลการนำเข้ายามีการกำหนดไว้หรือไม่ อย่างไร และหากมีการกำหนดไว้ ผลการดำเนินการที่ผ่านมาสอดคล้องตามตัวชี้วัดหรือไม่ อย่างไร
4. การประสานความร่วมมือกับหน่วยงานอื่นที่เกี่ยวข้องเป็นอย่างไร และต้องการให้มีการเปลี่ยนแปลงหรือพัฒนาหรือไม่ อย่างไร
5. ในปัจจุบัน ระบบการส่งต่อข้อมูลเป็นอย่างไร มีประสิทธิภาพมากน้อยเพียงใด และจำเป็นต้องมีการปรับปรุงหรือพัฒนาเพิ่มเติมหรือไม่ อย่างไร
6. ปัญหาและอุปสรรคที่พบบ่อยครั้งในการปฏิบัติงานคืออะไร
7. บุคลากรจำเป็นต้องมีคุณสมบัติพื้นฐานอย่างไร เช่น วุฒิการศึกษา ประวัติการฝึกอบรม สุขภาพร่างกายและจิตใจ เป็นต้น
8. หลักสูตรการฝึกอบรมที่จำเป็นสำหรับเจ้าหน้าที่ในหน่วยงานของท่านมีอะไรบ้าง ความถี่ในการอบรมและวิธีการประเมินผลเป็นอย่างไร
9. ต้องการการสนับสนุนในด้านใดเพิ่มเติมหรือไม่ (เช่น งบประมาณ บุคลากร เครื่องมือ/อุปกรณ์ต่างๆ เป็นต้น) อย่างไร

10. นโยบายระดับประเทศและ/หรือข้อตกลงทางการค้าระหว่างประเทศอาทิเช่น AFTA, ASEAN Harmonization, MRA ส่งผลกระทบต่อการปฏิบัติงานหรือไม่ อย่างไร
11. มีข้อเสนอแนะในการพัฒนาหรือปรับปรุงระบบการนำเข้ายาหรือไม่ อย่างไร

3) หัวหน้าและเจ้าหน้าที่ด่านอาหารและยา

(ด่านท่าเรือกรุงเทพฯ และด่านท่าอากาศยานสุวรรณภูมิ (ด่านคลังสินค้า))

1. กรณีที่มีการนำเข้าผลิตภัณฑ์ยาเข้ามาในประเทศ มีขั้นตอนการพิจารณาอนุมัติตรวจปล่อยอย่างไร
2. กำหนดให้มีการสุ่มตรวจผลิตภัณฑ์ยาที่นำเข้าหรือไม่ อย่างไร
3. ตัวชี้วัดที่เกี่ยวข้องกับระบบการกำกับดูแลการนำเข้ายามีการกำหนดไว้หรือไม่ อย่างไร และหากมีการกำหนดไว้ ผลการดำเนินการที่ผ่านมาสอดคล้องตามตัวชี้วัดหรือไม่ อย่างไร
4. ในปัจจุบัน ระบบการส่งต่อข้อมูลเป็นอย่างไร มีประสิทธิภาพมากน้อยเพียงใด และจำเป็นต้องมีการปรับปรุงหรือพัฒนาเพิ่มเติมหรือไม่ อย่างไร
5. NSW (National Single Window) คืออะไร มีวัตถุประสงค์อย่างไร มีข้อดีและ/หรือข้อเสียอย่างไร และต้องดำเนินการอย่างไรจึงจะประสบความสำเร็จตามวัตถุประสงค์
6. การประสานความร่วมมือกับหน่วยงานอื่นที่เกี่ยวข้องเป็นอย่างไร และต้องการให้มีการเปลี่ยนแปลงหรือพัฒนาหรือไม่ อย่างไร
7. ปัญหาและอุปสรรคที่พบบ่อยครั้งในการตรวจปล่อยสินค้า (เช่น การสำแดงเท็จ ความไม่สอดคล้องกับพิกัดศุลกากร ความไม่ชัดเจนของประเภทผลิตภัณฑ์ (ผลิตภัณฑ์คาบเกี่ยว))
8. มีกฎหมายหรือกฎเกณฑ์ที่ใช้ในการควบคุมการนำเข้าผลิตภัณฑ์ยาอย่างไรบ้าง
9. หากพบมีการละเมิดกฎหมายหรือกฎเกณฑ์ที่กำหนดไว้ มีมาตรการอย่างไรในการดำเนินการ
10. หน้าที่ความรับผิดชอบและอำนาจในการตัดสินใจของบุคลากรแต่ละคนแตกต่างกันหรือไม่ อย่างไร
11. การคัดเลือกบุคลากรเพื่อปฏิบัติงานในตำแหน่งต่างๆ พิจารณาอย่างไร

    (เช่น เจ้าหน้าที่ผู้มีอำนาจในการตรวจปล่อยสินค้า เจ้าหน้าที่บันทึกข้อมูล เจ้าหน้าที่ที่ทำหน้าที่สุ่มตัวอย่างและตรวจวิเคราะห์เบื้องต้นที่ด่านอย.)
12. บุคลากรจำเป็นต้องมีคุณสมบัติพื้นฐานอย่างไร เช่น วุฒิการศึกษา ประวัติการฝึกอบรม สุขภาพร่างกายและจิตใจ เป็นต้น

13. หลักสูตรการฝึกอบรมที่จำเป็นสำหรับเจ้าหน้าที่ในหน่วยงานของท่านมีอะไรบ้าง ความถี่ในการอบรมและวิธีการประเมินผลเป็นอย่างไร
14. ต้องการการสนับสนุนในด้านใดเพิ่มเติมหรือไม่ (เช่น งบประมาณ บุคลากร เครื่องมือ/อุปกรณ์ต่างๆ เป็นต้น) อย่างไร
15. นโยบายระดับประเทศและ/หรือข้อตกลงทางการค้าระหว่างประเทศอาทิเช่น AFTA, ASEAN Harmonization, MRA ส่งผลกระทบต่อการปฏิบัติงานหรือไม่ อย่างไร
16. มีข้อเสนอแนะในการพัฒนาหรือปรับปรุงระบบการนำเข้ายาหรือไม่ อย่างไร

<u>กองควบคุมยา</u>

1) ผู้อำนวยการกอง

1. หน่วยงานของท่านมีบทบาทอย่างไรในระบบการนำเข้ายาของประเทศไทย
2. หน่วยงานของท่านมีการจัดรูปแบบองค์กรอย่างไร และแต่ละหน่วยงานมีหน้าที่ความรับผิดชอบเกี่ยวกับระบบการนำเข้ายาอย่างไร
3. ในมุมมองของท่าน สถานการณ์ปัจจุบันของระบบการนำเข้ายาเป็นอย่างไร และมีประสิทธิภาพมากน้อยเพียงใด
4. ตัวชี้วัดที่เกี่ยวข้องกับระบบการกำกับดูแลการนำเข้ายามีการกำหนดไว้หรือไม่ อย่างไร และหากมีการกำหนดไว้ ผลการดำเนินการที่ผ่านมาสอดคล้องตามตัวชี้วัดหรือไม่ อย่างไร
5. การประสานความร่วมมือกับหน่วยงานอื่นที่เกี่ยวข้องเป็นอย่างไร และต้องการให้มีการเปลี่ยนแปลงหรือพัฒนาหรือไม่ อย่างไร
6. NSW (National Single Window) คืออะไร มีวัตถุประสงค์อย่างไร มีข้อดีและ/หรือข้อเสียอย่างไร และต้องดำเนินการอย่างไรจึงจะประสบความสำเร็จตามวัตถุประสงค์
7. ปัญหาและอุปสรรคที่พบบ่อยครั้งในการควบคุมการนำเข้าผลิตภัณฑ์ยาคืออะไร
8. มีกฎหมายหรือกฎเกณฑ์ที่ใช้ในการควบคุมการนำเข้าอย่างไรบ้าง
9. หากพบมีการละเมิดกฎหมายหรือกฎเกณฑ์ที่กำหนดไว้ มีมาตรการอย่างไรในการดำเนินการ เช่น กรณีผลการวิเคราะห์ของยานำเข้าที่สุ่มตัวอย่างเพื่อส่งวิเคราะห์คุณภาพที่กรมวิทยาศาสตร์การแพทย์ พบว่าตกมาตรฐาน จะทำอย่างไร
10. บุคลากรจำเป็นต้องมีคุณสมบัติพื้นฐานอย่างไร เช่น วุฒิการศึกษา ประวัติการฝึกอบรม สุขภาพร่างกายและจิตใจ เป็นต้น

11. หลักสูตรการฝึกอบรมที่จำเป็นสำหรับเจ้าหน้าที่ในหน่วยงานของท่านมีอะไรบ้าง ความถี่ในการอบรมและวิธีการประเมินผลเป็นอย่างไร
12. ต้องการการสนับสนุนในด้านใดเพิ่มเติมหรือไม่ (เช่น งบประมาณ บุคลากร เครื่องมือ/อุปกรณ์ต่างๆ เป็นต้น) อย่างไร
13. นโยบายระดับประเทศและ/หรือข้อตกลงทางการค้าระหว่างประเทศอาทิเช่น AFTA, ASEAN Harmonization, MRA ส่งผลกระทบต่อการปฏิบัติงานหรือไม่ อย่างไร
14. มีข้อเสนอแนะในการพัฒนาหรือปรับปรุงระบบการนำเข้ายาหรือไม่ อย่างไร

2) หัวหน้ากลุ่มงาน (Pre-marketing and Post-marketing)

1. หน่วยงานของท่านมีบทบาทและหน้าที่ความรับผิดชอบอย่างไรในระบบการนำเข้ายาของประเทศไทย
2. ในมุมมองของท่าน สถานการณ์ปัจจุบันของระบบการนำเข้ายาเป็นอย่างไร และมีประสิทธิภาพมากน้อยเพียงใด
3. การประสานความร่วมมือกับหน่วยงานอื่นที่เกี่ยวข้องเป็นอย่างไร และต้องการให้มีการเปลี่ยนแปลงหรือพัฒนาหรือไม่ อย่างไร
4. ปัญหาและอุปสรรคที่พบบ่อยครั้งในการปฏิบัติงานคืออะไร
5. กฎหมายหรือกฎเกณฑ์ที่ใช้ในการปฏิบัติงานมีอะไรบ้าง
6. หากพบมีการละเมิดกฎหมายหรือกฎเกณฑ์ที่กำหนดไว้ มีมาตรการอย่างไรในการดำเนินการ เช่น กรณีมีข้อมูลผลการวิเคราะห์ยานำเข้าจากกรมวิทยาศาสตร์การแพทย์พบว่าตกมาตรฐาน จะทำอย่างไร
7. ต้องการการสนับสนุนในด้านใดเพิ่มเติมหรือไม่ (เช่น งบประมาณ บุคลากร เครื่องมือ/อุปกรณ์ต่างๆ เป็นต้น) อย่างไร
8. นโยบายระดับประเทศและ/หรือข้อตกลงทางการค้าระหว่างประเทศอาทิเช่น AFTA, ASEAN Harmonization, MRA ส่งผลกระทบต่อการปฏิบัติงานหรือไม่ อย่างไร
9. มีข้อเสนอแนะในการพัฒนาหรือปรับปรุงระบบการนำเข้ายาหรือไม่ อย่างไร

กรมศุลกากร

1) หัวหน้าด่านศุลกากร หรือเจ้าหน้าที่ผู้เชี่ยวชาญของกรมศุลกากร

1. กรณีที่มีการนำเข้าผลิตภัณฑ์ยาเข้ามาในประเทศ มีขั้นตอนการพิจารณาอนุมัติตรวจปล่อยอย่างไร
2. กำหนดให้มีการสุ่มตรวจสินค้าที่นำเข้าหรือไม่ อย่างไร
3. ด่านศุลกากรที่มีทั้งหมดในปัจจุบัน มีจำนวนเท่าไรและเพียงพอหรือไม่
4. ตัวชี้วัดที่หน่วยงานกำหนดไว้ประกอบด้วยอะไรบ้าง และผลการดำเนินการที่ผ่านมาสอดคล้องตามตัวชี้วัดหรือไม่ อย่างไร
5. การส่งต่อสินค้าที่มีการนำเข้าให้หน่วยงานอื่นๆ ที่เกี่ยวข้อง มีหลักเกณฑ์และขั้นตอนในการพิจารณาอย่างไร
6. ในปัจจุบัน ระบบการส่งต่อข้อมูลระหว่างหน่วยงานเป็นอย่างไร มีประสิทธิภาพมากน้อยเพียงใด และจำเป็นต้องมีการปรับปรุงหรือพัฒนาเพิ่มเติมหรือไม่ อย่างไร
7. NSW (National Single Window) คืออะไร มีวัตถุประสงค์อย่างไร มีข้อดีและ/หรือข้อเสียอย่างไร และต้องดำเนินการอย่างไรจึงจะประสบความสำเร็จตามวัตถุประสงค์
8. การประสานความร่วมมือกับหน่วยงานอื่นที่เกี่ยวข้องเป็นอย่างไร และต้องการให้มีการเปลี่ยนแปลงหรือพัฒนาหรือไม่ อย่างไร
9. ปัญหาและอุปสรรคที่พบบ่อยครั้งในการตรวจปล่อยสินค้า (เช่น การสำแดงเท็จ ผลิตภัณฑ์ยาที่นำเข้าไม่สอดคล้องกับพิกัดศุลกากร)
10. มีกฎหมายหรือกฎเกณฑ์ที่ใช้ในการควบคุมการนำเข้าอย่างไรบ้าง
11. หากพบมีการละเมิดกฎหมายหรือกฎเกณฑ์ที่กำหนดไว้ มีมาตรการอย่างไรในการดำเนินการ
12. หน่วยงานของท่านมีการจัดรูปแบบองค์กรอย่างไร และหน่วยงานใดที่รับผิดชอบหรือมีความเกี่ยวข้องกับระบบกำกับดูแลการนำเข้ายา
13. หน้าที่ความรับผิดชอบและอำนาจในการตัดสินใจของบุคลากรแต่ละคนแตกต่างกันหรือไม่ อย่างไร
14. การคัดเลือกบุคลากรเพื่อปฏิบัติงานในตำแหน่งต่างๆ พิจารณาอย่างไร

    (เช่น เจ้าหน้าที่ที่ทำหน้าที่ตรวจสอบสินค้าหรือสัมภาระ เจ้าหน้าที่ที่ทำหน้าที่ตรวจสอบบุคคลเช่น ผู้โดยสารขาเข้าที่ท่าอากาศยานสุวรรณภูมิ)
15. บุคลากรจำเป็นต้องมีคุณสมบัติพื้นฐานอย่างไร เช่น วุฒิการศึกษา ประวัติการฝึกอบรม สุขภาพร่างกายและจิตใจ เป็นต้น

16. หลักสูตรการฝึกอบรมที่จำเป็นสำหรับเจ้าหน้าที่ในหน่วยงานของท่านมีอะไรบ้าง ความถี่ในการอบรมและวิธีการประเมินผลเป็นอย่างไร
17. ต้องการการสนับสนุนในด้านใดเพิ่มเติมหรือไม่ (เช่น งบประมาณ บุคลากร เครื่องมือ/อุปกรณ์ต่างๆ เป็นต้น) อย่างไร
18. นโยบายระดับประเทศและ/หรือข้อตกลงทางการค้าระหว่างประเทศอาทิเช่น AFTA, ASEAN Harmonization, MRA ส่งผลกระทบต่อการปฏิบัติงานหรือไม่ อย่างไร
19. มีข้อเสนอแนะในการพัฒนาหรือปรับปรุงระบบการนำเข้ายาหรือไม่ อย่างไร

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