

Current Situation of the Modern Pharmaceutical Manufacturing Industry in Thailand

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Abstract The modern pharmaceutical manufacturing industry in Thailand remains a downstream industry. In 2019, there were 142 GMP certified modern pharmaceutical manufacturing facilities, most of which are manufacturers of finished products containing pharmaceutical chemicals. The manufacturing industry in 2018 was worth 77 billion baht, an increase of 5% from the previous year with a net profit of about 8 %. Although the export of pharmaceutical products has increased, competition is high and the competitive advantages have decreased compared to the potential of import trade. In 2015, the ratio of production value to import value was approximately 35:65. Businesses were more interested in research and development, mostly focusing on the development of generic drugs and new generic drugs in conventional dosage forms. The motivation for production came from the Thai Innovation List policy. Since 2009, documents for drug registration application must comply with the format specified by ASEAN. In addition, drugs approved for registration previously had no expiration date; however, now, the Drug Act, B.E. 2562 (2019) stipulates that registered drugs are valid for 7 years from the date of issue. In 2003, the Ministry of Public Health adopted the World Health Organization guide to Good Manufacturing Practices (GMP), and in 2011, this was superseded by the Pharmaceutical Inspection Co-operation Scheme (PIC/S) GMP. Nevertheless, issues that still need to be addressed include the creation of standardized product code management and traceability systems. It is also recommended that government agencies should have more cooperation with businesses to advance the pharmaceutical industry as well as support the use of locally produced drugs.

Keywords: modern pharmaceutical manufacturing industry; modern drugs; good manufacturing practice (GMP)

Introduction

The modern pharmaceutical manufacturing industry is one of the most important industries in Thailand since medicine costs are a major expense

borne by the public health system. Moreover, the pharmaceutical industry is one of the target industries that must be transformed into an industry of the future, according to the National Strategic Master Plan (2018-

2037).⁽¹⁻²⁾ Similar to other industries in Thailand, the Thai pharmaceutical industry has focused on production to substitute imported drugs and to export these drugs. The industry focuses on promoting the development of production efficiency and raising production standards with the goal to allow people to access effective and safe pharmaceutical products at reasonable prices. In addition, according to the 20-year national strategy, the National Drug System Development Committee has resolved to accelerate the drug system development strategy to support public health system reform. One important strategy is focusing on increasing the potential of the pharmaceutical manufacturing industry in Thailand. This article is aimed at presenting a review of the current situation of the modern pharmaceutical manufacturing Industry in Thailand and providing recommendations for the direction of the pharmaceutical manufacturing industry in the future for all stakeholders involved in the pharmaceutical industry, public health personnel, or those with an interest to learn more.

Overview: Current Situation of the Modern Pharmaceutical Manufacturing Industry

The current Thai modern pharmaceutical manufacturing industry is still a downstream industry. Most manufacturers import active pharmaceutical ingredients from foreign countries to mix with excipients and produce finished products in the desired dosage forms using pharmaceutical processes and technology. As of October 2018, there were 194 modern pharmaceutical manufacturing facilities in Thailand, 85 from this number located in Bangkok.⁽³⁾ As of June 2019, there were 142 GMP certified modern pharmaceutical manufacturing facilities in Thailand.⁽⁴⁾ In fact, the

number of operating facilities was slightly more since some facilities were in the process of improving their manufacturing standards. From 142 the GMP ones, there were 91 pharmaceutical manufacturing facilities producing finished products for humans, 8 for animals, 36 for humans and animals, 4 facilities for manufacturing pharmaceutical chemicals, and 3 facilities for manufacturing both pharmaceutical chemicals and finished products.

Most of the facilities that manufacture finished products specialized in chemical drugs, and there were only 7 biopharmaceutical manufacturing facilities. Classified by ownership, 9 facilities were government-owned or stock-based pharmaceutical manufacturing facilities. The remaining facilities were privately-owned, mostly by Thais, with foreigners owning or holding the major shares of 9 facilities.⁽⁵⁾

In 2018, the modern pharmaceutical manufacturing industry in Thailand was worth approximately 76.9 billion baht (Table 1) with revenue from human pharmaceutical drug sales of approximately 66.4 billion baht (86% of total revenue) and revenue from animal pharmaceutical drug sales of approximately 10.5 billion baht (14% of total revenue). The expansion of revenue in 2016, 2017, and 2018 were 7.1%, 5.6%, and 4.8%, respectively, indicating stagnation of growth. The modest growth is likely a result of illnesses in a growing population as well as an aging population, improved access to treatment channels under the National Health Security System, and a medical tourism industry that is likely to expand.⁽⁶⁾ The Government Pharmaceutical Organization in Thailand is the organization with the highest income; in 2018, revenue from its drug sales was 6,784 million baht, accounting for 8.8% of the

Table 1 Business Operations and Income of Modern Pharmaceutical Manufacturing Companies in Thailand

Item	2015	2016	2017	2018
Human drug sales (million baht)	56,200	60,100	63,200	66,400
Veterinary drug sales (million baht)	8,700	9,400	10,200	10,500
Total sales (million baht)	64,900	69,500	73,400	76,900
Sales expansion (%)	N/A	7.1	5.6	4.8
Total net profit (million baht)	5,600	6,300	6,830	N/A
Net return (%)	8.6	9.0	9.3	N/A

Note: Data source: Department of Business Development, Ministry of Commerce⁽⁵⁾

industry's total revenue.⁽⁷⁾ If the income distribution of only companies that produce human drugs was considered, 75% of industry-wide revenue came from manufacturers with the top 30 sales.

Although the manufactured drugs were mainly produced for domestic consumption, exports had increased. In 2018, drug exports were valued at 17.9 billion baht, an increase of 3.41% from 2017 and almost double from 2009.⁽⁸⁾ The top ten exporting countries in descending order were Myanmar, Vietnam, Cambodia, Japan, Philippines, Hong Kong, Malaysia, Belgium, Laos and Singapore.

Research and Development

While research and development (R&D) is an important step in obtaining new products, over ten years ago, most pharmaceutical manufacturers did not give much importance to R&D.⁽⁹⁾ Most of their operations focused on the development of drug formulas to improve drug properties, while the R&D budget comprised less than 1% of total budget. Drugs were manufactured and distributed without using advanced technology or equipment, and in terms of R&D of new drugs (i.e. new chemical entity),

Thailand did not have the capacity for investing in technology and personnel. However, the circumstances of pharmaceutical R&D in Thailand has changed dramatically in the last ten years. Many pharmaceutical companies have set up R&D departments with increased budgets. Technology has been used to develop pharmaceutical products in a wider variety of dosage forms. The types of R&D of pharmaceutical products were summarized as follows:

1) Research and development of generic drugs in conventional dosage forms

Almost all product development of modern pharmaceutical manufacturers in Thailand focuses on the development of generic drug formulas. In Thailand, generic drugs are classified according to the definition and information used for registration and fall into 2 types: generic drugs and new generic drugs. Research and development of both types of generic drugs contain the same main steps. The key difference is that new generic drugs are required to undergo a bio-equivalence study to prove equivalent drug levels in the body. Such levels directly relate to the effectiveness of drug treatment.⁽¹⁰⁾ These procedures are in accordance with the guidelines and international require-

ments of the Association of Southeast Asian Nations (ASEAN) harmonization of standards⁽¹¹⁻¹³⁾, US Food and Drug Administration, European Medicines Agency (EMA), and International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), which require clear presentation of quality information at every step. The average duration of research is about 2-5 years, and the cost of developing a formula varies depending on the type of product and type of drug. Costs can range from 1 million to 10 million baht or higher if the active ingredients are expensive; in particular, when new drug molecules are applied. For the development of new generic drugs, the cost of the bioequivalence study must also be included. As the average period for a bioequivalence study is between 6-12 months, the cost of a study is generally between 2-5 million baht or higher if the study has specific factors or the drug being studied has a high fluctuation in drug levels in the blood. For this reason, not many companies have the capacity to develop new generic drugs in the market.

2) Research and development of generic drugs using a high technology platform

Certain drugs require high-level technology to formulate or produce, such as modified-release drug products, sterile lyophilized products, inhalers, nasal sprays, etc. Currently, some pharmaceutical manufacturers in Thailand focus on the development of this group of drugs by investing heavily in technology and personnel. The production of drugs using advanced technologies helps reduce the need to import drugs from foreign countries and increases accessibility to those drugs. The advantage for manufacturers using high technology platforms in production is that there

are fewer competitors in the market.

3) Research and development of new drugs

Currently, a very small number of new drug formulations have been developed and approved in Thailand. Examples include new fixed dose combination drugs, GPO-VIR (anti-retroviral medication), or drugs developed from herbs such as little ironweed. This may be due to many reasons, for example, unpreparedness of the industrial sector or relevant stakeholders, as well as a lack of clear guidelines for the registration of new drugs produced in Thailand. As a result, even though new research had been conducted by universities, research agencies, and domestic pharmaceutical manufacturers, these studies had not been led to new drug registrations. Nevertheless, at present, circumstances have started to change for the better due to an increase in newly-formed supporting agencies as well as clearer policies, guidelines, and procedures prescribed by government regulators.

In recent years, the government has collaborated with the private sector to carry out activities or projects that support R&D in the pharmaceutical industry as follows:

a) Establishment of agencies providing services to conduct bioequivalence studies: currently, there are 8 agencies that have the capacity to provide these services. These organizations have been certified by the Bureau of Laboratory Quality Standards, Department of Medical Sciences, confirming that these agencies have operational standards that comply with the OECD (Organization for Economic Co-operation and Development) Good Laboratory Practice (GLP) principles or the ISO (International Organization for Standardization) 17025 standards for drug levels in

blood tests.

b) Establishment of organizations to support the development of new drugs that are not new molecules and to improve the quality of generic drugs, e.g. Chulalongkorn Drug Discovery and Drug Development Research Center (Chula4DR) and Chulalongkorn University's Drug and Health Products Innovation and Promotion Center (CU-D-HIP).

c) Implementation of Thailand Center of Excellence for Life Sciences (TCELS), such as formation of an international network to search for new active ingredients and develop new drugs under activities of natural product drug discovery (NPDD); conception of a project for the development of drugs, vaccines, and biologics; and creation of the Excellence Center for Drug Discovery (ECDD).

d) Support from the Technology Management Center (TMC) under the National Science and Technology Development Agency (NSTDA), such as the Innovation Technology Assistance Program (ITAP), Private Sector R&D Promotion Program (RDP).

e) Imposition of new regulations by the Thai Food and Drug Administration (FDA) on the development and registration of generic drugs. The FDA also imposed clear policies, guidelines, and procedures for promoting the development of new drugs in Thailand. Additionally, the FDA announced the criteria for registration of new drugs developed from existing drugs and set up a specialized working group to advise on and be responsible for the registration of drugs in this group.

These agencies and government policies have contributed to the support and promotion of research and development, which has significantly increased over the past decade. Accordingly, the approval of

new generic drug registrations during the last 5 years has increased. This reflects the stronger research and development capabilities of organizations in Thailand.

Drug Registration

Pharmaceutical products that are manufactured or imported for the market in Thailand must be registered with the FDA to confirm effectiveness and safety. During the registration process, the registrant must submit supporting documents and academic evidence as required to experts for consideration. In 2009, an agreed upon common format for the preparation of a well-structured Common Technical Dossier, which was determined by ASEAN countries, was required for drug product registration; namely, the ASEAN Common Technical Dossier (ACTD). The ACTD requires more academic evidence, making drug registration more difficult than before.

In 2012, a document on "Guidelines for registration of drug formulas appearing in the Minister's notified pharmacopoeia, using pharmacopoeia standard requirements and methods for analyzing active pharmaceutical ingredients and finished products" was published in order to accelerate and increase efficiency of the consideration process for the registration of drug formulas listed in a pharmacopoeia notified by the Minister or in newer versions. Later, in 2013, there was a notification on "Prescribing documents or evidence of registered modern drug variation" in order to ensure that variations in registered modern drugs are in accordance with academic principles and the ASEAN Variation Guidelines (AVG). In this notification, the terms and conditions for submitting a variation request and required documents are defined. However, the variations listed in the ASEAN Agree-

ment are not comprehensive; therefore, in 2018, the FDA notified an additional list of variations (Non-AVG) absent from the ASEAN Agreement.

A newly launched Drug Act (Issue 6) B.E. 2562 (2019)⁽¹⁴⁾ directly affects drug registration. In this Act, drug registration is valid for only 7 years from the date of issue as specified in the registration certificate. The manufacturers must renew the registration before the registration certificate expires. In addition, when filing for registration, it is required to show documents on the number of patents or petty patent applications that have been published under the Patent Act. In the case that there is a research study to support the drug formula registration, especially in human research, the research must comply with the specified criteria, procedures, and conditions. The provisions of this Act cause manufacturers to be more careful when selecting drug formulas to be registered.

The accumulation of many pending drug formula registrations is currently a significant issue. The issue occurs because of operating procedures and insufficient human resources of the government sector as well as the lack of technical knowledge of industry representatives responsible for the registration. These challenges are recognized by various relevant sectors, which are currently improving the registration process to be more efficient. In addition to improving the operating procedures of the Bureau of Drug Administration, the FDA has also set up a One Stop Service and Consultation Center to facilitate and provide advice to businesses. In addition, both public and private agencies, such as the National Science Technology and Innovation Policy Office, Thai Industrial Pharmacist Association, Regulatory Affairs Pharmacy Association (Thailand), Pharmaceutical Research and

Manufacturers Association, Thai Self-Medication Industry Association, Thai Pharmaceutical Manufacturers Association, and the Faculty of Pharmacy of various universities collaborate in trainings or creation of curricula on Good Registration Management (GRM) to increase knowledge for personnel engaged in drug registration.

Pharmaceutical Manufacturing

The incident that has had the highest impact on the domestic pharmaceutical industry in the past ten years was when the Ministry of Public Health passed the Good Manufacturing Practice (GMP) into law for pharmaceutical manufacturers. This was to raise the standards of pharmaceutical manufacturing in the country to international levels. In 2003, the Ministry of Public Health issued a public health regulation, “Prescribing the criteria, procedures, and conditions for modern drug manufacture B.E. 2546 (2003)”⁽¹⁵⁾, and a notification of the Ministry of Public Health, “Prescribing the details regarding the criteria and procedures for the manufacture of modern drugs under the Drug Law B.E. 2546 (2003)”⁽¹⁶⁾, with reference to the GMP regulations of the World Health Organization version 1992. Subsequently, several GMP inspector units worldwide, including Thailand, sought to become members of the Pharmaceutical Inspection Co-operation Scheme (PIC/S) to raise their pharmaceutical manufacturing standards for international trade benefits. Moreover, Thailand had signed the ASEAN Sectoral Mutual Recognition Arrangement for Good Manufacturing Practice Inspection of Medicinal Products (ASEAN MRA on GMP Inspection)⁽¹⁷⁾ on 10 April 2009. This agreement was made to achieve mutual acceptance of the results of the GMP assessment

of ASEAN member states with the condition that member states must use the GMP of PIC/S guidelines or equivalent criteria for inspection. For these reasons, in 2011, the Ministry of Public Health issued a new notification of the Ministry of Public Health, “Prescribing the details regarding the criteria and procedures for the manufacturing of modern drugs under the Drug Law B.E. 2554 (2011)”, based on the PIC/S GMP version 2009. This notification also applies to the manufacturing of traditional medicines.

PIC/S GMP regulations that focus on prevention of contamination, cross-contamination, and other process errors, cause many businesses to invest in renovations of their production sites and purchases of new machinery. If it is not possible to improve existing production sites, then it is necessary to construct new ones. As a result, the investment value may reach 200 million – 1 billion baht, depending on the risk or rigor associated with the drug being produced. At the same time, the capacity of personnel working in the pharmaceutical system must be developed and recruiting personnel in various professions, such as pharmacists, engineers, and scientists, are required.

These requirements led to collaboration between public and private sectors, such as the FDA, Thai Pharmaceutical Manufacturers Association (TPMA), Thai Industrial Pharmacist Association (TIPA), International Society for Pharmaceutical Engineering (ISPE) Thailand Affiliate, and the Faculty of Pharmacy of various universities, to organize activities or projects to develop the capacity of personnel in the industry. One of the most important projects was a project requesting support from the FTA fund. Under this project, the TPMA requested for financial support from the Ministry of Commerce, and the Faculty of

Pharmacy, Srinakharinwirot University acted as a consultant for project implementation. The activities of this project included creation of working instructions and self-assessment forms, pilot evaluation of the selected pharmaceutical manufacturers by international experts, and organization of training workshops for personnel in the pharmaceutical industry.

In addition, since 2006, the Board of Investment (BOI) has promoted the manufacture of pharmaceutical products and active pharmaceutical substances to facilitate businesses in the Thai pharmaceutical industry to adjust their operations to PIC/S GMP standards, under the condition that pharmaceutical manufacturers applying for tax benefits must receive PIC/S GMP certification within 2 years from operation start date. The benefits received include exemptions for corporate tax, machinery tax, and export duty on raw materials.

The abovementioned activities and projects have greatly contributed to the development of pharmaceutical industry standards in Thailand. Most of the businesses were able to develop their standards to receive PIC/S GMP certification; however, some small businesses were unable to upgrade their manufacturing standards due to insufficient investment and personnel challenges. Moreover, some business owners chose to cease operations rather than invest in meeting industry standards, while others are still in the process of making a decision. For this reason, the number of modern drug manufacturing sites in the country has steadily decreased over the past ten years.

Logistics of the Pharmaceutical Industry

Logistics management refers to the process of planning, delivering effective and efficient flow control, goods storage, services, and related

processes from the starting point of production to the end point of consumers. Logistics management is one part of supply chain management that needs to be efficient and effective⁽¹⁸⁾. Currently, logistics management in the pharmaceutical industry takes 2 forms: First, the manufacturers or product owners operate their own logistics. Second, the manufacturers or product owners hire a third party logistics company.

In the past, domestic manufacturers and small importers often chose to manage logistics themselves, while large importers, especially multinational pharmaceutical companies, often outsourced to third parties. However, at present, there is a tendency for domestic manufacturers and small importers to use third party services as well in order to reduce administrative costs. The delivery of pharmaceutical products to hospitals must comply with the Good Distribution Practice (GDP), which requires sufficient delivery records for product traceability. In addition, in Thailand, drug deterioration has occurred due to incorrect storage or inappropriate temperature control in storage locations. Therefore, it is necessary to pay attention to the Good Storage Practice (GSP) as well.

A current challenge found in Thailand's drug distribution system is limited traceability. Problems with data traceability often occur, and these problems become more complicated when the drugs are distributed to clinics and drugstores that use wholesale distributors as intermediaries. While online orders have become more popular, and computer systems have made data recording more convenient, limitations in tools, information technology, and product codes persist; as such effective data tracing up to the original point of manufacture remains a challenge. The

issue is more pronounced for imported drugs that require many more steps to trace the data back to foreign manufacturers, as well as through the delivery process by either plane, boat, train, or car and include cargo stops at airports, harbors, or railways. In some cases, regional distribution centers are used, which do not directly import drugs from foreign manufacturers. The complexity of the drug distribution chain leads to ineffective data traceability, and often, this shortcoming permits the spread of counterfeit drugs.

Data traceability requires the use of a product code; currently, many organizations designate pharmaceutical product codes for different purposes:

- 1) Hospitals and service units have their own drug codes for internal use.
- 2) The FDA uses assigned drug registration numbers when issuing drug formula registration certificates.
- 3) The Thai Health Coding Center and the Bureau of Health Administration are the main organizations that develop 24-digit drug codes for use in hospitals to link data across the country⁽¹⁹⁾.
- 4) The Thai Health Information Standards Development Center (THIS) develops Thai Medicines Terminology (TMT) and data maintenance mechanisms.⁽²⁰⁾

Developing health data codes is important and should be included in the plan to be implemented at the national level so that the country will have an efficient and integrated health information system. International drug codes are essential for monitoring efficacy, safety and rational use of drugs. At present, many countries have established measures to prevent counterfeit drugs, to track drugs, and to trace data by

using different tools and technologies. A tracking and data tracing system, using globally accepted system such as serialization, which is commonly used in the European Union and the United States, should be considered in Thailand. In addition, supporting systems must be developed throughout the country. Implementation may start between hospitals and government regulators, which are organizations responsible for the country's main drug distribution chain. When strengthened, the system can then be rolled out to clinics and drugstores, which are the last points of distribution before reaching the patient.

Drug Market

The domestic drug market has high competition since the number of importers and distributors, which are the main competitors of domestic manufacturers, have increased significantly. Up until 2018, the FDA issued licenses to import or order modern drugs to a total of 811 companies. Most of the licenses were issued to companies that order generic drugs manufactured in foreign countries to sell domestically. As a result, the number of imported drug formula registrations has increased considerably.⁽²¹⁾ In 2015, the proportion of import value to production value was 65:35, whereas, before 2002, production value was higher than import value. For example, in 1995, the ratio of import value to production value was 35:65.⁽²²⁾ The data suggests that the competitiveness of pharmaceutical manufacturers in the country has decreased compared to importers. Import value is higher due to the increased import of biologics, anti-cancer drugs, and other prototypes of patented high-price drugs. In addition, there have been imports of low-price generic drugs from India and China too.

In 2017, Thailand had a total drug market value of approximately 180 billion baht, the second largest market size in Southeast Asia after Indonesia. The market growth rate has been about 5–6% per year, and the value of drugs sold through public hospitals accounts for about 60% of the total drug market value.

As for government procurement, the Government Procurement and Supplies Management Act. B.E. 2560 (2017) was issued to replace the Regulations of the Prime Minister's Office on Procurement B.E. 2535 (1992); but entitlements are still given to the government pharmaceutical manufacturing unit by compelling government agencies to purchase drugs listed on the National List of Essential Medicines by a specific method from the Government Pharmaceutical Organization (GPO) or the Thai Red Cross Society (unless they are unable to produce and sell drugs on time according to the government agency's annual plan)⁽²³⁾. However, the new Government Procurement and Supplies Management Act provides government agencies with the ability to buy drugs that are in the Thai innovation list by a specific method. The government agencies have to purchase generic drugs in the Thai innovation list to a total value of no less than 30% of the demand plan. This guideline helps motivate private pharmaceutical manufacturers in the country to find opportunities for the development of new generics to compete drugs for which their patents are about to expire.

Recommendations for the Development of the Modern Drug Manufacturing Industry

1) Government agencies must have clear measures to support the domestic pharmaceutical industry by

cooperating with more businesses. For example, the GPO should research and develop drugs and then share the information to private manufacturers. The GPO and private manufacturers should not develop the same new generic drugs. The GPO should establish stability of pharmaceutical raw materials, produce orphan drugs and some essential drugs that the private sector does not produce, create a mechanism for price balance, support the manufacture of target drugs and drugs in the Thai innovation list on a continual basis, and promote the expansion to overseas markets.

2) Upgrade drug logistics by developing Good Distribution Practice (GDP) and Good Storage Practice (GSP) guidelines, and developing drug codes and health information systems in the country to monitor drug quality problems and increase drug safety efficiently.

3) Review the National List of Essential Medicines and the list of non-prescription drugs and update it to be suitable with changes in technology. This will align research and development of domestic drug manufacture with the Ministry of Public Health's policies, namely, the primary medical policy and the policy on development for reducing overcrowding in hospitals.

4) Promote the manufacture of new generic drugs and the use of technology to develop pharmaceutical products in a variety of dosage forms in line with patient needs and public health policies. Set up measures to ensure that the private manufacturers can sell the drugs at appropriate median prices to the public. In addition, there should be a clear policy to support the use of drugs produced in the country, especially drugs that are formulated from pharmaceutical ingredients produced in Thailand, and to enable the public and private sectors to procure raw materials conjoint-

ly. Also, there should be a policy on the synthesis or manufacture of various standard substances.

References

1. Central Office of Industrial Economics. 10 Target Industries: Economic Driving Mechanisms for the Future. Bangkok: Office of Industrial Economics; 2017.
2. Notification of the Prime Minister's Office on the National Strategic Master Plan (2018 - 2037). Royal Thai Government Gazette Volume 136, Section 51 A (dated 18 April B.E. 2562).
3. Food and Drug Administration. Statistics of drug business licenses in the year 2018 [Internet]. [cited 2019 Jun 15]. Available from: <http://www.fda.moph.go.th/sites/drug/SitePages/Statistic.aspx>
4. Food and Drug Administration. List of modern medicine GMP compliance manufacturers [Internet]. [cited 2019 Jun 15]. Available from: http://www.fda.moph.go.th/sites/drug/Post/Shared%20Documents/Modern_GMP_THAI.pdf
5. Department of Business Development. DBD DataWarehouse [Internet]. [cited 2019 Apr 10]. Available from: <https://datawarehouse.dbd.go.th>
6. Tunpaiboon N. Business trend/industry 2018-2020: pharmaceutical industry. Krungsri Research [Internet]. [cited 2019 Apr 18]. Available from: https://www.krungsri.com/bank/getmedia/2aaa5a05-86b2-4c9d-9314-5d59735da733/IO_Pharmaceutical_2018_EN.aspx
7. Government Pharmaceutical Organization. Annual report 2018 (draft) [Internet]. [cited 2019 Jun 15]. Available from: <https://www.gpo.or.th/Default.aspx?tabid=96>
8. Information and Communication Technology Center, Office of the Permanent Secretary Ministry of Commerce. Export value of pharmaceutical products [Internet]. [cited 2019 Apr 20]. Available from: <http://tradereport.moc.go.th/Report/Default.aspx?Report=MenucomTo-pNRecode&Option=3&Lang=Th&ImExType=1&com-code=332000000>

9. Committee on Modern Medicine Industry Analysis. Modern Medicine Industry. In: Suwit Wibulpolprasert, Editor. Thai drug system. Bangkok: Agricultural Co-operative Federation Thailand Printing; 2002. p. 451-96.
10. Food and Drug Administration. Guideline for the conduct of drug bioavailability and bioequivalence studies [Internet]. [cited 2019 Jun 15]. Available from: <http://elib.fda.moph.go.th/fulltext2/word/16378/1.pdf>
11. Food and Drug Administration. Guideline/regulations for generic drug formula registration based on ASEAN Harmonization. Bangkok: War Veterans Organization of Thailand Printing; 2013.
12. Food and Drug Administration. Guideline/regulations for new generic drug formula registration based on ASEAN harmonization. Bangkok: War Veterans Organization of Thailand Printing; 2013.
13. Food and Drug Administration. Guideline/regulations for new drug formula registration based on ASEAN harmonization. Bangkok: War Veterans Organization of Thailand Printing; 2013.
14. Drug Act (No. 6) B.E. 2562. Royal Thai Government Gazette Volume 136, Section 50 A (dated 16 April B.E. 2562).
15. Food and Drug Administration. Public Health Ministerial Regulation on “Prescribing the criteria, procedures, and conditions of modern drug manufacture 2003” [Internet]. [cited 2019 Jun 15]. Available from: <http://www.fda.moph.go.th/sites/drug/Shared%20Documents/Law02-Ministerial-regulations/Principles-medicine-manufacture2546.pdf>
16. Food and Drug Administration. Notification of the Ministry of Public Health on “Prescribing the details regarding the criteria and procedures for the manufacture of modern drugs under the Drug Law 2003” [Internet]. [cited 2019 Jun 15]. Available from: <http://www.fda.moph.go.th/sites/drug/Shared%20Documents/Law03-TheMinistryOfHealth/Law03-23-01.pdf>
17. Amatamahatthana P. Development of modern medicine GMP in Thailand. Thai Industrial Pharmacist Association Journal 2014;2(2):40-5.
18. Saenchaiyathon K. Logistics and supply chain management. Bangkok: Chulalongkorn University Press; 2015.
19. Thai Health Coding Center. 24-digit national drug code [Internet]. [cited 2019 Aug 5]. Available from: <http://thcc.or.th/homemedicin.php>
20. Thai Health Information Standards Development Center. Development of Thai medicines terminology [Internet]. [cited 2019 Aug 5]. Available from: <http://www.this.or.th/index2.php>
21. Food and Drug Administration. Statistics of drug formula registration number [Internet]. [cited 2019 Apr 15]. Available from: <http://www.fda.moph.go.th/sites/drug/SitePages/Statistic.aspx>
22. Food and Drug Administration. Value of modern drug manufacture and import into the kingdom [Internet]. [cited 2019 Apr 20]. Available from: <http://www.fda.moph.go.th/sites/drug/SitePages/Statistic.aspx>
23. The Government Gazette. Ministerial regulations on prescribing materials that the government needs to promote or support, and prescribing the procedures of procurement by selective and specific methods B.E. 2560. Royal Thai Government Gazette Volume 134, Section 86 A (dated 23 August B.E. 2560).

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อุตสาหกรรมการผลิตยาแผนปัจจุบันของไทยยังคงเป็นอุตสาหกรรมระดับปลายน้ำ ในปี พ.ศ.2562 มีสถานที่ผลิตที่ยังดำเนินการและผ่านการรับรอง GMP จำนวน 142 แห่ง ส่วนใหญ่เป็นการผลิตยาสำเร็จรูปประเภทยาเคมี การผลิตในปี พ.ศ.2561 มีมูลค่าประมาณ 77,000 ล้านบาท โดยขยายตัวเพิ่มขึ้นประมาณร้อยละ 5 จากปีก่อนหน้า กำไรสุทธิประมาณร้อยละ 8 การส่งออกมีแนวโน้มสูงขึ้น การแข่งขันภายในประเทศรุนแรงมากขึ้นโดยศักยภาพในการแข่งขันของผู้ผลิตลดลงเมื่อเทียบกับผู้นำเข้า ในปี พ.ศ.2558 สัดส่วนมูลค่าการผลิตต่อการนำเข้าอยู่ที่ประมาณ 35:65 ผู้ประกอบการให้ความสนใจกับการวิจัยและพัฒนามากขึ้น แต่ส่วนใหญ่เป็นการพัฒนายาสามัญและยาสามัญใหม่รูปแบบทั่วไป โดยแรงจูงใจสำคัญคือนโยบายชั่งน้ำหนักนวัตกรรมไทย การขึ้นทะเบียนยาต้องใช้รูปแบบเอกสารตามที่อาเซียนกำหนดตั้งแต่ปี.ศ. 2552 และ พ.ร.บ.ยา (ฉบับที่ 6) พ.ศ. 2562 กำหนดให้ทะเบียนยาที่มีอายุ 7 ปี จากเดิมที่ไม่มีกำหนดวันหมดอายุ กระทรวงสาธารณสุขได้ประกาศใช้หลักเกณฑ์และวิธีการในการผลิตยา (Good Manufacturing Practice; GMP) ตามแนวทางขององค์การอนามัยโลก (WHO GMP) เป็นกฎกระทรวงตั้งแต่ พ.ศ. 2546 และเปลี่ยนเป็นหลักเกณฑ์ GMP ของ PIC/S (Pharmaceutical Inspection Co-operation Scheme) ในปี พ.ศ.2554 ด้านโลจิสติกส์มีประเด็นที่ยังต้องพัฒนาคือการสร้างระบบจัดการรหัสผลิตภัณฑ์ที่ได้มาตรฐานและการตรวจสอบย้อนกลับ ข้อเสนอแนะที่สำคัญของผู้ประกอบการคือ หน่วยงานภาครัฐควรมีความร่วมมือกับผู้ประกอบการมากขึ้นในการพัฒนาอุตสาหกรรมการผลิตยารวมถึงสนับสนุนการใช้ยาที่ผลิตในประเทศ

คำสำคัญ: อุตสาหกรรมการผลิตยาแผนปัจจุบัน; ยาแผนปัจจุบัน; หลักเกณฑ์วิธีการที่ดีในการผลิตยา