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Efavirenz listed in the World Health Organization Prequalification Program: A successful case study of a public private collaboration for technology transfer in pharmaceutical production and quality control in Thailand

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ABSTRACT

Pharmaceutical technology transfer is an important tool for enhancing production development and quality control. The Government Pharmaceutical Organization (GPO) is the state enterprises under the Ministry of Public Health, whose main mission is to produce high quality medicines with reasonable price to increase accessibility to the Thai people. GPO has received the technology transfer from an overseas pharmaceutical company for the successful production of the efavirenz 600 mg tablet that was certified by the WHO Prequalification Program. The research objective was to study how this success has been achieved with the support of technology transference as well as the relevant success factors by investigating the relevant documents and the in-depth interviews with the stakeholders in GPO and the Ministry of Public Health, both in the policy and operational levels, and the transferring team. The results describe the transfer process, the transferred technology, and the collaborative process of the transferrers and transferees. The success comes from several factors including clear and continuous supportive policies at the national and corporate levels, a good relationship with the transferrer and GPO's internal preparative process to be ready for technology transfer. The lessons learned should benefit other local manufacturers to prepare for technology transfer.

Keywords: Efavirenz, pharmaceutical industry, public private collaboration, technology transfer, World Health Organization Prequalification Program

INTRODUCTION

Thailand, one of the best countries with Universal Health Coverage (UHC), has introduced essential health care for all citizens since 2002.[1,2] Although, the free services provided to people include pharmaceutical products, health expenditure is still low comparing with other countries, as a share of gross domestic product in Thailand which was around 3.7% in 2017.[3] One reason is the closed-end payment from the government in terms of capitation basis both for services and medicines. The rising cost of health expenditure comes from substantial proportion of medicines. It was found that those budgets were utilized for pharmaceutical products accounting for nearly half of the budget like other developing countries.[4,5] It was also stated that the top three of leading causes of inefficiency arose from pharmaceuticals including underuse of generic drugs.

The WHO Prequalification Program (WHO PQ) is used as a tool for effectively utilization of international donations including the Global Fund. The pharmaceutical companies who want to sell their medicines under the Global Fund must be listed in the WHO PQ. Global Fund has signed grant agreements for HIV/AIDS, tuberculosis, and malaria programs in Thailand since 2003.[6] The Global Fund's policies are to promote not only access to medicines but also the standard quality products. Therefore, the criteria of using the funding are required to only buy the medicines prequalified by the WHO PQ.[7] At the beginning of implementing UHC, some parts of drug expenditures for tuberculosis, malaria, and HIV/AIDs drugs in Thailand were supported from the Global Fund. To utilize this supportive Global Fund budget, the Thai government needs to purchase such medicines from local pharmaceutical companies with improved standard to achieve the WHO PQ program.

The Government Pharmaceutical Organization (GPO), the government owned pharmaceutical manufacturer in Thailand, supplies the essential medicines used in Thailand including chronic diseases and HIV/AIDS drugs, and also takes the role as drug price stabilizer as well as responsible body for national drug security.[8] To serve the mission, GPO has been well recognized as the champion in producing HIV antiretroviral drugs in Thailand.[9] However, at that time, GPO did not have WHO PQ-compliant drugs, so it was unable to use the Global Fund's budget to purchase the antiretroviral drugs of GPO. In August 2018, as a result of the technology transfer between GPO and Mylan Laboratories Limited, it began to make GPO's efavirenz which is listed in the WHO PQ program.[10]

Technology transfer is one of the crucial methods to improve the capability in pharmaceutical industry, especially for local production to increase the accessibility to medicines.[11] GPO also employs technology transfer from Mylan Laboratories Limited to strengthen the capability to achieve WHO PQ. As per the success in the WHO PQ program registration for the efavirenz 600 mg tablet, there have been several factors influencing that success. Therefore, the objectives of this article were to learn how a local pharmaceutical manufacturer like GPO can develop their potential to achieve WHO PQ from technology transfer. We also explored the factors affecting the achievement and developed the guidelines for other local pharmaceutical companies, especially for the developing countries as an effective pathway toward the international quality standards.

MATERIALS AND METHODS

Study Design

This study is a qualitative research study to take the lessons of collaboration, leading to the WHO PQ program registration, between the GPO and Mylan Laboratories Limited in technology transfer for both production and quality control. We have summarized the lessons in four main points: (1) The roles of key stakeholders in technology transfer, (2) the context, which affected decision to receive the transfer and the tasks to achieve the goals, including both the internal and external factors, (3) the content, related to the details of technology transfer, including the preparative process for receiving the transfer, and the basic infrastructure preparation to meet the WHO PQ standard, and (4) the process from the policy formation until the decision to receive technology transfer, and the implementation of the policy for the WHO PQ program registration.

Sources of Information

Documentary research and in-depth interview were applied. The documents from a variety of sources were studied, namely, reports such as minutes of the Cabinet, GPO's Committee, WHO Inspection Report, related projects, technology transfer contracts, E-mails, websites, and related news in various media. The key informants of the in-depth interviews are policy makers, including politicians, representatives of the Ministry of Public Health, those who involved in the agency that receives technology transfer, the committee and senior managers of the GPO, the operating staff, and the in-charge staff as well as the distributor of the agency that provides technology transfer.

Data Collection

This study used a semi-structured interview, which utilized open-ended questions.

Data Analysis

The content analysis was used to synthesize information obtained from interviews and studied documents. The information was then grouped according to the issues of the given conceptual framework, and the connection between each factor was found.

Ethical Consideration

This research was certified as a research project that could waive the ethical approval with CEO No. 004/2563 on January 29, 2563 BE by the Ethics Committee on Research in Human, Thammasat University. The investigator kept the information obtained from the interviews confidential. All names were anonymous, and the personal information of the interviewees, who gave important information, was not disclosed. Furthermore, the research results have only been presented as an overview.

RESULTS

This study was conducted between September 2019 and May 2020. The 32 informants consisted of one politician, one representatives of the Ministry of Public Health, seven committee and the senior

managers of the GPO, which is the agency that received the transfer, 17 operational staff, four experts of Mylan Laboratories Limited, one Mylan distributor in Thailand, and one Shanghai Desano executive. Many related documents were searched, namely, the minutes of the GPO committee meeting, financial reports, the documents presented to the cabinet to consider budget allocation for GPO, the information from websites, and the relevant news. The thematic analysis of the qualitative data showed two major themes related to our research objectives.

Technology Transfer and the Improvement of GPO Capabilities to Achieve WHO PQ

The results of the study were presented in the order of technology transfer process, starting from policy formulation, decision-making, signing agreement, and implementation.

Policy formulation and decision-making process

The policy was formulated due to the need to have affordable and sustainable supply of high-cost drugs for HIV/AIDS patient treatment in Thai UHC. To increase access to antiretroviral drugs, the government made a policy for the GPO to produce the WHO PQ program registered AIDS antiretroviral drugs so that the Global Fund budget could be used to purchase drugs, which would help reduce the government's budget for drug procurements.[12]

Technology *transfer agreement*

At that time, GPO was already able to produce a fixed-dose combination of antiviral drugs, GPO-VIR S30 tablets (nevirapine 200 mg/lamivudine 150 mg/stavudine 30 mg tablets). Therefore, GPO aimed to make this list of drugs to be registered in the WHO PQ program by performing several tasks:

1. In 2002, technical assistance was sought from the World Health Organization Assessment Team, but the audit results did not meet the WHO GMP requirement. The problems were with the building, tools, quality management system, and the preparation of product dossier that lacked the integrity of the content, especially the information about pharmaceutical development and bioequivalence study
2. The budget for a new factory compliant with the WHO PQ standard was approved by the GPO Committee, with the budget of 900 million baht (approximately 30 baht for 1 US dollar), since it could not pass the WHO quality audit both in 2002 and 2005
3. In 2010, GPO hired the foreign expert team to help GPO prepare documents, review the stand operating procedure, and develop staff capacity to be ready for the audit. Unfortunately, the new factory construction (Rangsit Pharmaceutical Plant 1) was delayed and there was uncertainty about predicted of when it would finish, so the consultant hiring contract was canceled
4. The drug, which was used to registered to the WHO PQ program, was adjusted from GPO-VIR S30 tablets, which is a fixed-dose combination drug, to efavirenz 600 mg tablets, which is a single drug and less complicated to simplify the transfer process.

When analyzing the pitfalls within the organization, it was found that GPO lacked knowledge and skills on many issues to meet the WHO PQ standard. In 2016, GPO finally entered into a technology transfer agreement with the Mylan Laboratories Limited, which was the long-term partner who had supplied raw materials to GPO. The contract specified only one important requirement that GPO had to exclusively purchase efavirenz raw material from Mylan for 3 years, and provided that the raw material prices must not be higher than the international market price by more than 5%, and no other trade restriction was specified.

Implementation according to the technology transfer agreement

In the process of technology transfer, Figure 1 shows the joint working processes during the technology transfer, following the signing of the contract in 2016. Mylan Laboratories Limited has supported GPO in the development and production of efavirenz 600 mg tablets to comply with a rigorous WHO PQ registration

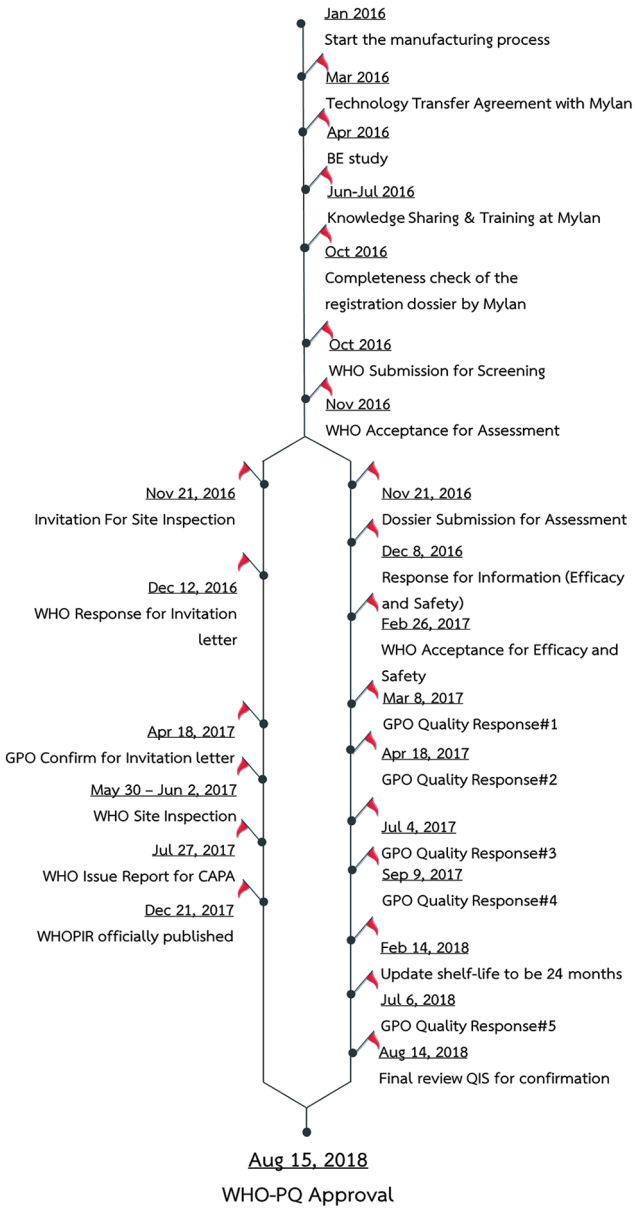

Figure 1: The process of technical technology transfer from Mylan to Government Pharmaceutical Organization

program in terms of registration dossier preparation and manufacturing site inspection at Rangsit Pharmaceutical Plant 1. The World Health Organization granted the approval of the first WHO PQ registration to the HIV antiretroviral drug product, efavirenz 600 mg tablets, of GPO in 2018.

Considering the Mylan technology transfer, GPO was supported in two main areas:

Types of technical support

GPO and Mylan jointly made the project action plan to achieve the detail of the topics of transfer in the technology transfer contract and determine the person in-charge for both parties. Although the contract had not specified the time frame of knowledge transfer, the final outcome of achieving WHO PQ standard was accomplished in a short period (2016–2018). Mylan and GPO collaborated in six key tasks to achieve the WHO PQ standard including: (1) Technology transfer documentation, (2) knowledge of recipes and information on the drug substance, (3) problem-solving during the validation of the production process, (4) quality control and quality assurance processes, (5) bioequivalence study, and (6) the preparation process for registration dossier that complied with the WHO PQ standard.

Workforce capacity building

Mylan supported the following forms of personnel development including sending Mylan specialist personnel to work with the GPO personnel at GPO site, which enabled the personnel from GPO to be trained in the production process and quality management system at Mylan manufacturing site in India, and providing advice by communication and teaching through e-mail and video conference. It was impressive that the personnel in GPO learned well from the Mylan experts who gave advice, monitored the progress, and tirelessly assisted in the manner of teacher that helped students until they succeeded.

Self-preparation and management within GPO to support technology transfer

To make the technology transfer successful, GPO had modified its internal operating model to support technology transfer as follows:

Planning

GPO created a project action plan to achieve the goals. All activities were separately determined on all information topics that must be included in the product dossier submission for WHO PQ program. The persons in-charge within GPO and the required time frame were identified. In addition, the responsibilities of Mylan and GPO in preparing documents for registration were pre-allocated.

Organization

The organization structure was changed, and the number of staff was increased to support the development of GPO production standards. The key action was the management restructuring, which gave one director the authority to supervise both production and quality assurance departments (formerly separated), and to act as a clear and continuous contact person for the audit team [Figure 2].

Assignment and responsibilities

GPO built up a new team to increase efficiency and reduce production costs. The new team recruitment composed of the new personnel recruitment and the appropriate rotation of the old staff to support the expansion of production capacity. In employment contracts, personnel must be able to work on the night shift to keep continuous production cycles for 24 h. In addition, GPO had created a project to increase knowledge of the WHO PQ standard by organizing in-house training.

Budgeting

GPO invested a budget of 21 million baht to develop the production standard. It was used in various expenses, namely, experts' wages for consultation at the beginning of the plant construction, expenses for increasing the number of staff and personnel development, the cost of machinery procurement to remedy shortcoming after the plant audit, audit fees for the WHO PQ's experts, investment in computerized documentation system, the expenses for auditing the raw material production plant and the primary packing plant, and cost of bioequivalence study.

Factors Contributing to the WHO PQ Achievement

The success of the WHO PQ program registration for the efavirenz 600 mg tablets come from contributing factors, both context factors, and process factors, which influenced the efficiency of GPO in receiving technology transfer as follows:

Context factors

There are the contextual factors that drove the development of the GPO's drug production standard by receiving technology transfer including:

1. The international policy, which included the policy of supplying drugs under international subsidy, especially the Global Fund that requires the procurement of medicines which are in WHO PQ list only
2. The national policy, which focused on supporting sustainable operation under the national health security system. The productions of drugs in the country would be able to meet that goal, which would enable people to access essential drugs
3. The enterprise policy was based on the mission of GPO, which is the country's pharmaceutical production unit, the awareness of the mission by the executives, and the opportunity to recognize and see the benefits that acquiring technology transfer would be a way to truly accelerate the capability of GPO. The continuity of the board's policy, the restructuring of work within the organization, and empowering the person in-charge of the project to make decisions were driving forces for promoting various resources to push toward the aimed standard.

Process factors

To receive technology transfer, the following factors in the work process contributed to success according to Distanont *et al*.,[13] which were factors that had affected efficiency of technology transfer in petrochemical industry.

1. Increasing the personnel's absorptive capacity of the new knowledge. Personnel capacity development about the knowledge of GMP, which was the basis for the assessment of standard, and included English language skill for communication with the transferrers and computer

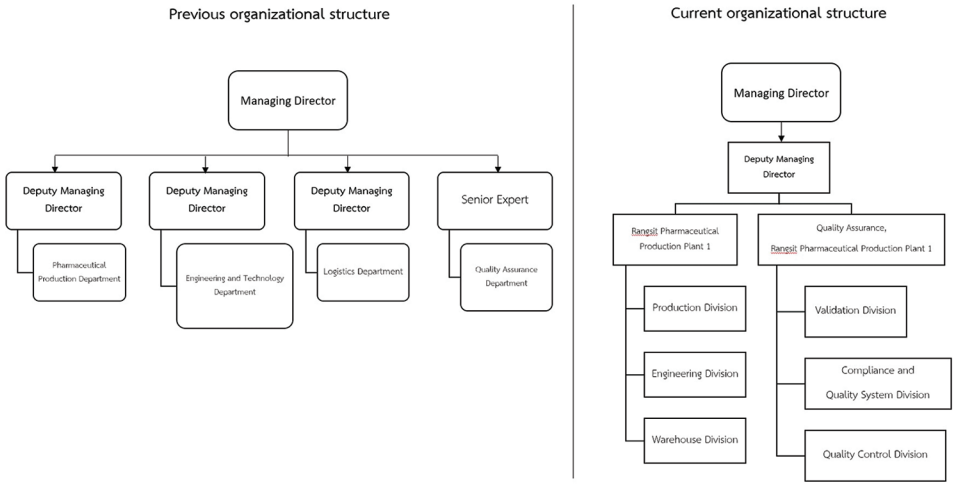

Figure 2: Comparing previous and current Government Pharmaceutical Organization structure

skill for organizing the quality documentation system, which was developed. The communication and teaching from the head to the operator were used to develop the competent next generation of personnel

2. Partner characteristics. The experts from Mylan were the persons with high expertise and dedicated to job teaching. They followed the progress of GPO regularly even though they had no previous experience in transferring technology to other companies. In the part of GPO, there have been several significant operations: Having a supportive policy from the organization board, the authorization of comprehensive decision-making to the person in-charge of the project, support for important resources including budget, workforce increase, and personnel potential development
3. Complexity of technology. A decision had been made to change the drug, planned to be submitted for the WHO PQ Program, from GPO-VIR S30 tablets, which is a fixed-dose combination of three drugs, to efavirenz 600 mg tablets, which is a single drug, because efavirenz 600 mg tablet has less complexity and was in the list of drugs in need, of the Global Fund project that subsidized the drug expenses
4. Interorganizational relationships. The relationship between GPO and Mylan started with a good longstanding relationship since Mylan has been a supplier of raw materials to GPO. That relationship caused confidence and trust of both parties and affected the willingness to transfer technology and absorb knowledge.

DISCUSSION OF STUDY RESULTS

This study presents a lesson in technology transfer from Mylan, India, to GPO in producing efavirenz 600 mg tablets to meet the WHO PQ standard by presenting the formation of the policy, the contracting, and the roles of technology transferrers and transferees. It was found that the drug manufacturers in Thailand in the past obtained the technology transfer through trainings by universities or the instruction manual, provided with the tools, or seller. However, there was a problem that the transferees could not put the obtained knowledge into practice due to the potential and readiness of the Thai pharmaceutical factory, the context differences, and the incomplete technology transfer. As a result, almost all pharmaceutical factories in Thailand had no effective technology transfer.[14] After more than 14 years of efforts, GPO chose Mylan as the technology transferrer because Mylan was formerly a partner in the sale of raw materials of GPO, and be a manufacturer with the WHO PQ registered products. In this case, GPO was able to absorb such technology and then develop itself to create further new technology in accordance with the concept of Kolfer and Meshkati.[15] In addition, if we consider the technology transfer model used, it could be observed that the model corresponded to "A dissemination model," where both sides had a relationship in the manner of teachers (expert transferrers) who educated students (transferees).[16,17]

The essence of the technology transfer contract between Mylan and GPO is different from the contracts of other private pharmaceutical industries. The contract did not specify the form of technology transfer activities, the operational techniques, nor a time for knowledge transfer. Instead, two parties had to define the project action plan without specifying the terms and conditions of commercial restrictions that transferrers tend to oblige the scope of use of technology transfer. It can be observed from this study that the relationship was consistent with the Jussi Heikkilä study,[18] which found that the good relationship and the confidence between two organizations will influence the success of technology transfer. In the case of the relationship between Mylan and GPO, it was found that the trust between each other had an effect on the transfer of tacit knowledge, although there was no clear condition in the contract.[19] In addition, having prior experience in partnerships can be a factor for success in technology transfer.[20]

The factors that made this technology transfer successful were not only the ability to learn technology know-how, but also other necessary factors including: (1) The stable direction-oriented culture of the country and of the supported organizations due to the need for many long-term investments to achieve the goal, (2) restructuring and organizational responsibility to give project administrators full authority to make decisions and directives to communicate clear goals to practitioners, and (3) the capacity of people to assimilate

and to adapt the knowledge learned through technology transfer to be part of the organizational learning culture to achieve sustainability in modifying the acquired technology to generate new technology in the transferee organization.[16,21]

It was also found that the obtained achievement was not only the production of efavirenz 600 mg tablets, which met the WHO PQ standard but also resulted in the knowledge that could be further developed in the production of new drugs in the HIV antiretroviral drug group, for example, GPO-VIR T tablets, which is a fixed-dose combination drug that used efavirenz 600 mg with tenofovir DF 300 mg and emtricitabine 200 mg. Considering the efavirenz 600 mg tablets alone, the government has saved about 860 million baht per year on foreign drug imports since 2017. As for GPO-VIR T tablets, Thailand originally imported 1700 million baht value per year, but could reduce the drug imports by approximately 800 million baht in 2020. Prequalification program of efavirenz helped the government save about 330 million baht on importing drugs from other countries in 2020. Moreover, this success also enhances the confidence of consumers, doctors, pharmacists, and medical personnel in the country in the quality of drugs produced by the GPO. In addition, the successful results laid the foundation for the development of the production system and the quality assurance to meet international standard and created the personnel with knowledge and ability to learn and to extend the plan to the next product, that is, TLD, the combination of tenofovir DF/lamivudine/dolutegravir tablets, with the WHO PQ registration.

CONCLUSIONS

Technology transfer is a vital factor in the development of the pharmaceutical industry in the developing countries to enable the self-development of essential medicines and expand the potential of countries to be self-reliant in medicine. GPO is a state-owned pharmaceutical manufacturer which produces drugs to serve people in Thailand. The more GPO improves its potential by acquiring WHO PQ program registration, the more GPO can save the country's drug expenditure. The success factors to obtain the WHO PQ program registration consisted of the contextual factors, including international, national, and organizational contexts and the process factor. The policy decision that drove GPO to meet the WHO PQ program registration and the decision to choose Mylan as a technology transferrer were the key contextual success factors, while the good relationship between the transferrer and the transferee was one of the critical process factors. The benefits from getting WHO PQ program registration were not only in monetary but also non-monetary terms. This would result in increasing sale in the future and the yield of personnel participating in the registration process with strong potential knowledge and expertise to be able to become a national speaker for the Thai pharmaceutical industry.

Regarding the success of GPO through technology transfer, it is very important that the government provides various measures to promote the transfer of technology from foreign drug manufacturers or from GPO to other local drug manufacturers, without investment factor or the issue of trade competition as obstacles to raise the quality standard level of Thailand's pharmaceutical industry.

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