

CENTRAL BARGAINING AND **PROCUREMENT**

FOR ACCESSIBILITY OF ESSENTIAL MEDICAL SUPPLIES AND EFFICIENT USE OF RESOURCE



GLOSSARY

MEDICAL SUPPLIES

This term is used broadly in this paper and covers medicinal and non-medicinal products¹ including medicines, clinical materials and various types of medical devices that are used to prevent, treat, and maintain health and life of persons with various ailments/conditions according to the ministerial announcement on Ethical Criteria for Procurement and Promotion of Medicinal and Non-Medicinal Products of the Ministry of Public Health in 2021.² Medical supplies are categorized according to their characteristics as follows: (1) Medicinal products refer to drugs under the Pharmaceuticals Act, narcotics under the Narcotics Act, and psychotropic substances under the Psychotropic Substances Act; and (2) Non-medicinal products refer to clinical materials, dental materials, medical science materials, X-ray materials, other medical materials such as medical devices used for specific patients, etc.

INACCESSIBLE ESSENTIAL MEDICAL SUPPLIES³

This refers to medicinal and non-medicinal products that are necessary for prevention and treatment, and have been included in the national essential drugs list. These supplies have specific characteristics that require central mechanisms for administering them and making them accessible to the public such as the following: (1) It is a drug that is very expensive or has a significant impact on the affordability of society and patients; (2) It is an orphan drug in the antidote and anti-serum groups that requires minimum purchase insurance⁴; (3) It is a drug that requires knowledge, expertise, and specific systems to manage; or it is a drug that must be supplied, stored, and distributed through a standardized cold chain to maintain quality, and efficiency, and reduce wastage of limited supply⁵; or (4) It is a non-medicinal product, such as medical devices and prosthetic organs that are expensive but necessary for the treatment process and which have problem of accessibility.

CENTRAL BARGAINING AND PROCUREMENT

Central bargaining and procurement is one of the strategies for effective management of limited resources in order to obtain quality, essential medical supplies in an appropriate and timely fashion. These supplies are distributed to various service units across the country.⁶ Since 2007, the National Health Security Office (NHSO) has worked with partners and working groups from all sectors to develop a 'National Bargaining and Purchasing Mechanism' to manage certain essential medical supplies. These supplies have characteristics that affect accessibility. The procurement mechanism encompasses three main processes: Selection, bargaining/procurement, stock supply, and distribution.

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1 INTRODUCTION

"Medical Supplies" refers to both medicinal and nonmedicinal products¹, i.e., drugs, materials, and various types of medical devices used to prevent, treat, and maintain the health and life of people from various ailments/conditions. Medical supplies are fundamental components of a health service system.⁷ Without some essential medical supplies, providing effective health services to achieve various public health goals would not be possible.

Therefore, the provision of essential medical supplies to meet the needs of the people -- both quantitatively and qualitatively – and, in particular, medical supplies for specific groups of diseases with specific characteristics, require a central mechanism for procurement. These special products include vaccines, anti-retroviral (ARV) drugs, orphan drugs, anti-toxins, etc. There is a need to provide universal and equal access to those medical supplies for patients. It is a mission that is of paramount importance to the lives of patients. It is also a management challenge that requires knowledge, experience, mobilization, and specialized expertise.⁸

The National Health Security Office (NHSO) is a representative of the people who are entitled to health insurance and patient groups. NHSO's main mission is to drive public health services that meet the needs of the people.⁹ The 'National Bargaining and Purchasing Mechanism' was developed in 2007⁸ as a central mechanism for management of certain essential medical supplies with specific characteristics that affect public access. This mechanism covers the main processes of selection, procurement (bargaining and purchasing), stock, and distribution.

The mechanism for bargaining and purchasing at the national level is in accordance with the good governance principle of participation.^{10, a} Thus, the central implementation process is a collaboration between the NHSO and network members of various working groups. This collaboration starts in the planning stage, and continues through reporting and evaluation, as well as analysis of problems of each type of medical product with different characteristics across such dimensions as costeffectiveness, budget burden, legal framework, and regulatory framework as they affect procurement. The result of this collaboration has led to a model for managing special procurement under the national health insurance program that can sustainably increase people's access to medicines in a way that is economical, costeffective, transparent, and auditable at every step.⁷

^a Thailand, led by the MOPH, has developed ethical standards and relevant policy guidelines to strengthen the good governance of the medical supply system of MOPH services, which has six main components: Rule of Law, Ethics, Transparency, Accountability, Value for Money, and Participation.

2 WHY IS THERE A NEED FOR A CENTRAL MEDICAL SUPPLY MANAGEMENT MECHANISM?

Since 2002, the NHSO has aimed to enable every Thai citizen to receive universal health coverage with confidence.⁹ The NHSO developed a universal health insurance (UHC) system through the use of empirical evidence and constructive participation from all sectors.¹¹ The vision was a system which provides equal access to quality services and medicines to the public as needed, and to protect people from bankruptcy due to serious and chronic diseases or conditions whose treatment costs are too high for the average citizen to bear. Those costly illnesses put patients and families at risk of bankruptcy, catastrophic health expenditure, and health impoverishment.¹²

Despite the successful establishment of the Universal Coverage Scheme (i.e., UCS or Gold Card) to provide the majority of Thais with health insurance, in the initial stage of the policy implementation, it was found that patients with certain diseases or conditions were still having trouble accessing the requisite medical supplies that can be referred to as 'Essential medical supplies with accessibility problems.'³ That is, these were medicinal and/or non-medicinal product that are necessary for prevention and treatment. Such medical supplies are characterized by the need for a central mechanism to manage and make them accessible to the public.

Therefore, a mechanism for bargaining and purchasing at the national level was developed to solve the problem of people's access to costly health services in the spirit of universal access to needed health care (i.e., the National Health Security Act under the Constitution of the Kingdom of Thailand, No. 2540, Section 52, which states that "Thais have an equal right to standard health care services, and the poor have the right to free medical care from public health facilities as provided by law").^b

^b In 2006, the coverage of the new text was revised. Thai people have the right to receive public health services, and the poor have the right to treatment or other services in public health free of charge, whereby the state is responsible for providing effective and comprehensive public health services, as well as enhancing people's knowledge of basic health care and disease prevention. According to the principles of the 2016 Constitution, Chapter 3, Rights and Liberties of the Thai people, Article 47, "A person shall have the right to receive public health services. A poor person is entitled to free access to public health services as provided by law. A person shall have the right to free protection and eradication of dangerous communicable diseases from the State;" and Chapter 5: Duties of the State: "Equipping the people with basic knowledge related to health promotion and disease preventionThe state must continually develop health care services to have higher guality and standards."

 Table 1: Summary of Characteristics of Difficult-to-access Medical Supplies, Classified by Type

Medical Supply Type

EXPENSIVE DRUGS

Such as drugs that have been licensed over a patent^c and E(2) drugs, etc.

Special Characteristics

- Medicines for patients with specific needs: These include a drug that the patient must receive continuously, and which requires a special central mechanism for regulating access in order to ensure drug quality (e.g., ARV drugs for HIV). Procurement is under the joint responsibility of the three government national health insurance schemes.¹³
- **2** The drug is very expensive, and presents problems of affordability for society and patients, including:

2.1 Original drugs under patent and, thus, there is no competition in the market. A drug with a single (monopoly) or few (oligopoly) sellers requires a mechanism from the government to negotiate a fair price, and manage pricing to provide medicines in the health system, such as compulsory licensing (CL) over drug patents to enable local production of generics and/or can import cheaper drugs to serve the people.³

2.2 Drugs included in the sub-list E(2) with the highest level of strict control. This is because E(2) is a list of drugs that are likely to be inappropriately prescribed.

Both types of drug lists must have a prescribing approval system, continuous recording of usage data, and reporting of results.¹⁴

^c A patent is an important right issued to the rights holder to protect an invention or product design in accordance with Article 31 of the Intellectual Property Rights Agreement related to trade under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). In the case of medical supplies, when a pharmaceutical company develops a new drug, it will apply for a patent to monopolize the production and distribution of the drug8, which can set a high price cap on the drug for up to 20 years. According to the Thai Patent Act at the Department of Intellectual Property, which acts as a consideration agency, once a company receives a patent, it will be protected from the date of application until the expiration date of the patent, to prevent other generic drug manufacturers to take any commercial action on the drug or its invention.

Medical Supply Type

ORPHAN DRUGS: ANTIDOTE (ANTI-TOXINS), & ANTI-SNAKE BITE SERUM

Special Characteristics

- 1 Drugs that are necessary for the treatment of specific diseases which have no substitute or alternative at the time needed.¹⁵
- 2 Drugs that need to be immediately accessible for therapeutic use to save life and prevent disability of patients. There is often a shortage of these medicines due to the limited number of medicines in the reserve stock. Or, these are drugs for toxic substances not typically found in the country. Or, the service unit does not have a reserve stock or does not know the source of the drug reserve stock.¹⁶
- 3 Medicines that require a minimum purchase guarantee. Due to the uncertain use requirement (because disease incidence is low) or the needed supply cannot be predicted in advance. As a result, pharmaceutical companies are reluctant to produce/service such drugs because of investment risks.⁴

MEDICINES THAT REQUIRE SPECIALIZED KNOWLEDGE AND SYSTEMS TO MANAGE

Medicines to be procured, stored, and distributed through a standardized cold chain to maintain efficacy and reduce wastage of limited medicines, including vaccines.¹² Also, this includes a drug that requires a drug inventory management system to address the problem of expired drugs and misuse, such as Continuous Ambulatory Peritoneal Dialysis (CAPD)⁷ dialysis fluid, etc.

NON-PHARMACEUTICALS

such as medical devices and prosthetic organs

Products necessary for the treatment process such as:

- 1 Expensive prostheses⁵ including stents which support the coronary artery wall, artificial intraocular lens for surgical treatment, etc.
- 2 Various medical devices such as condoms, Tenckhoff line, and peritoneal dialysis line for patients with end-stage CKD for CAPD services, etc.¹⁷

The characteristics of the above medical supplies lead to limited access for UCS beneficiaries, especially in the case of very expensive drugs and artificial organs. Access to these life-saving interventions is often limited to the population living in urban areas, or the wealthy,¹⁸ or those with special provisions in their health insurance, such as government civil servants.¹⁹ Without a revised procurement and management system, there is the risk of inequality of health access, both qualitatively and quantitatively.⁷ This imbalance can be attributed to two factors as follows:



Limitations on the potential of the service unit to provide medical supplies for specific diseases:

Because the management of such pharmaceuticals requires experienced personnel and specialized knowledge for optimal management according to the nature of each type of medical supply.³ There is also the cost of stockpiling ultra-expensive pharmaceutical groups. With a small number of patients and an unstable disease incidence at the service level, it can become a huge budget burden to stock of these drugs. In particular, there is a risk of procurement under the per-capita lump-sum budgeting method that limits the expenditure ceiling according to the patient's benefits list, and collateral rights.¹⁷



Lack of supervision of medical supplies at the policy level: This is due to the lack of planning and designing a central mechanism and policy for the management of medicines with serious and systematic access problems,²⁰ combined with an inefficient procurement process. The process of stockpiling and distributing certain costly medical supplies is not conducive to public access both physically and economically.¹³

Such restrictions affect the country's drug security as a result of the shortage of quality medical supplies for specific diseases in the health care system.²¹ Those restrictions also affect the health of the patient and confidence in the system. This is because patients have to wait for a long time to receive their specific medical supplies or are unable to receive adequate and timely medicines. This can lead to disability or death from disease/conditions while waiting for the life-saving drugs or devices. This inequality is unacceptable given the vision and mission of the UCS.²²

For this reason, the NHSO has developed a bargaining and procurement mechanism at the national level as a central mechanism for managing essential medical supplies for specific groups that affect public access and require centralized management. This system has three main objectives as part of the process of enhancing people's access to essential medical supplies and healthcare, and improving budget management and the health service system as follows:



To support access to medical supplies among the critically ill with rare and/or chronic disease, and to protect patients from bankruptcy due to medical bills.¹⁸



To set up a governance system that covers medical supply management tasks. This is done in order to provide medical supplies that meet the needs of certain disease groups. The aim is to provide good quality, cost-effective medicine that is sufficient for use in each patient, as well as to promote continuous service development⁷ leading to the rational use of essential medical supplies and ensure the availability of essential healthcare services when needed.



To increase cost-effective use of the budget, resulting in the sustainability of the service system. This is to inspire confidence in the ability to provide essential services to patients, reduce workload, motivate service units,³ ensure the ability to manage problems according to the specifics of the medical supplies, and promote good governance in every step of system implementation.

In administering the bargaining and collective procurement mechanisms at the national level, the NHSO has adopted WHO guidelines for enhancing people's access to essential medicines and rational use of medicines. It is the principle that drives the working process of the mechanism across the following four dimensions:

Ensure Availability of Quality Product by providing adequate quality and standard medical supplies in the system to meet the patient's needs.

2

Improve Equitable Access to ensure fair access to medical supplies for the public through experienced agencies to distribute medical supplies quickly, and provide access to facilitating channels for people in every area, every disease, and every right, equally.

3

Encourage Appropriate Use (right person, right disease, right time, right amount), and having an information system to collect patient data to control the use of said supplies.

4

Keep Costs Affordable for cost-effective procurement to enhance the sustainability of the service system, and to control budget.

3 MODEL OF MEDICAL SUPPLIES PROCUREMENT

Bargaining and procurement mechanisms at the national level are managed in parallel with the procurement of routine services and other medical supplies and services in the benefits package which is under the per capita budget system of the Universal Coverage Scheme that is procured by the participating service provider.⁷ This mechanism is a process to manage medical supplies that are needed only for groups with access problems. Those medicines must be included in the National Essential Drugs List. This type of medical supplies is budgeted in the form of a disease-specific fund/medical supply fund, and provides support for such medical supplies to service units together with the management of the medical record keeping system for follow-up and evaluation. The nationally-managed medicines account for only 5% of the total annual drug consumption in the country.13 Details are shown in box 1.

THE CENTRAL PROCUREMENT SUPPLIES

(approximately 5% of the total national drug consumption per year).³ This is a group of essential medicines under NHSO's special projects. In 2019, there were 10 projects with 143 items of medical supplies with a total value of 14,290 million baht, namely:

- ARV drug project
- Drugs under Compulsory Licensing (CL)
- Orphan Drug and Anti-Toxic Drug Project
- Expanded Program for Immunization (EPI) and Seasonal Influenza Vaccine
- Drug Schedule E(2)
- CAPD and Erythropoietin (EPO) project
- Tenckhoff (TK) peritoneal dialysis project for CAPD patients
- TB Drug Project
- Device and Prosthetic Organ Project
- Condom Project for HIV Prevention

PROCUREMENT AT THE SERVICE UNIT

(95% of the total national drug consumption per year).³ Service units procure according to the drug list of the service unit. There are various procurement models such as retail procurement, consolidated procurement at the regional level, etc., consisting of the following:

- General medical supplies
- Other medical supplies and medical services in the UCS benefits package which is under the per capita budget under the National Health Security rights
- Essential medical groups that are funded according to the disbursement price ceiling conducted by centralized bargaining where the service unit is the procurement operator.

Box 1: Model of Medical Supply Procurement for Public Health Services

Medicines procured under a national bargaining and procurement mechanism can be divided into the following two groups:



The group of medical supplies supported by the central sector: Service units will be supported/compensated with medical supplies, and the management system covers the selection, procurement, and distribution of supplies. The medicines in this group are subject to "Risk Pooling"²³ in order to manage risks and to ensure access to specific essential medicines that require a central mechanism. This is to strengthen the security of medicines to prevent adverse consequences of life-threatening disease and reduce loss of life, disability, and socio-economic loss of patients from specific diseases and conditions that are so costly to manage that they can bankrupt households and need special systems to control the national budget burden.²⁴



The group of medical supplies for which there is financial support²⁵ according to the specified disbursement ceiling. This is a group of pharmaceuticals procured through a centralized bargaining process by assigning the service unit to be the procurement operator. Medicines in this group have the following characteristics:

- 2.1 There is a distributor which is a government agency that is specifically responsible for such supplies(e.g., Clopidogrel)that can be manufactured by the Government Pharmaceutical Organization (GPO) for domestic use;³
- **2.2** There is more price competition in the market system, or there are three or more vendors; and
- 2.3 Bargaining can be conducted nationally where the supplier agrees to sell at the same price for all government health insurance schemes and all service units in all areas, such as Clopidogrel, Risperidone, Sertraline, Erythropoietin, etc.

LEARNING IN PARALLEL WITH THE DEVELOPMENT OF A NATIONAL BARGAINING AND PROCUREMENT MECHANISM

The establishment of a national bargaining and procurement mechanism for medical supplies can be considered as a process of 'learning along with development' by the NHSO and its implementing network. The NHSO has chosen a national bargaining and procurement mechanism to manage essential medical supplies to address problems of accessibility. The mechanism is not aimed solely in terms of empowering purchasing bargains or optimizing pricing. It also aims to standardize service delivery that provides all citizens with the right to access the same medical supplies nationwide.¹⁴ This includes receiving the same formulations of drugs, say, for people living with HIV (PLHIV) who need life-long ARV treatment (ART). The system also aims to protect the right to treatment without the risk of bankruptcy, such as treatment for end-stage chronic renal disease. The system aims to create a paradigm shift in the attitudes of providers that support patient access to medical supplies.8

In 2006, the NHSO started to play a more direct role in procurement of medical supplies for the country. For example, the Expanded Program on Immunization (EPI) was initially managed by the Department of Disease Control (DDC) of the Ministry of Public Health (MOPH). However, that function was transferred to the NHSO in 2006. The same was the case with procurement of ARV drugs under the AIDS Fund. The government established the fund in the initial amount of 2,796 million baht. However, the price of ARV drugs was already expensive, especially if 2nd and 3rd line treatments were required for PLHIV with drug resistance. Thus, the budget for ARVs could quickly get out of control, thus limiting access for thousands of PLHIV. Lack of access would undermine national policy to control the HIV epidemic and reduce AIDS mortality.⁸ In order to manage such problems, NHSO worked with Civil Society organizations (CSO) such as the AIDS Patients Association, the International AIDS Organization, the Joint United Nations Program on HIV/ AIDS (UNAIDS), and others to jointly study, plan, and arrange measures to bargain and procure ARV drugs to maximize cost-effectiveness. This was done in parallel with the development of a PLHIV database and the design of an effective ARV distribution system. As a result, at the time of this paper, PLHIV have continuous access to quality medicines, a better quality of life, lower rates of opportunistic infections, and significantly reduced AIDS mortality.

National integrated management of ARV drugs for PLHIV increased access to medicines for PLHIV in all respects. The following are some highlights:

- Development of a national PLHIV database enabled integrated treatment planning and patient support;⁹
- Production of GPOvir by the GPO for domestic use for general AIDS patients. This greatly facilitated procurement planning and drug distribution. The GPO uses a Vender-Managed Inventory (VMI) system to deliver ARVs directly to service units to control the quality of medicines. This allows PLHIV to receive medication regularly, and reduces the risk of drugresistant infections and AIDS death.⁷
- ³ 'Use of patent rights' (CL) for two ARV drugs that are prototypes under patent protection. The MOPH enforced CL to be able to import and produce generic formulations of costly ARV drugs, including Efavirenz (as a replacement for 1st line formulations with side effects), and Lopinavir/Ritonavir (for use in cases of drug-resistance). The CL measure meant that about 10,000 PLHIV now had access to ARVs tailored to their condition when, before, less than 1,000 PLHIV could access these drugs due to prohibitive cost.⁸
- 4 Enhance the use of ARV formulations together across all three government health insurance funds (harmonization) including the UCS (Gold Card), the Social Security System (SSS), and the Civil Servants Medical Benefit Scheme (CSMBS). This harmonization now meant that if, say, a PLHIV, transferred from one government health insurance to another, there would be no change in their benefits package regarding ARV drugs.²¹

5 THE ROLE OF THE NHSO UNDER THE CENTRAL BARGAINING AND PROCUREMENT MECHANISM



As a representative of the people, the NHSO plays a key role in promoting systematic access to medical supplies. The NHSO is connected to a network of working groups to promote participation and transparency in bargaining and procurement at the national level as follows:

The NHSO is a coordinator that enhances participation from all sectors,³ especially patient groups, CSO, service units, medical associations, royal colleges, pharmaceutical companies, etc., to create a brainstorming platform that operates in the form of a board/committee at all levels. This platform allows input of opinions and suggestions about the design of the management of each type of pharmaceutical with access problems. The NHSO is responsible for soliciting opinions and suggestions, proposing these to the Board/Sub-Committee, and then reporting the results of the progress at each step to the working team to lead to a common policy/solution.



The NHSO manages disease funds and medical supplies under special projects. The NHSO plays a major role in supporting resources and information to drive efficient delivery of medical supplies to patients, and operates through various networks such as Rajavithi Hospital Service Unit, the Ramathibodi Hospital Poison Center, Siriraj Hospital, the GPO, the DDC, the Department of Medical Sciences, the Food and Drug Administration (FDA), etc. These network members participate in the planning, establishing a quality control system for pharmaceutical products, organizing a pharmaceutical inventory system that emphasizes transparency, and monitoring/reporting results at every step as follows:

- 2.1 Development of a record-keeping system that connects to databases on patients, service units, and medical supplies.²⁹ This is a database for effective management of medical supplies to supervise, monitor, and assess the use of pharmaceuticals both by patients and providers in accordance with the rational use of medicines. This system helps to verify both quantitative and qualitative outcomes.
- 2.2 Planning, directing, and coordinating departments with specific expertise. During 2007-17, the NHSO played a major role in procuring medical supplies under special projects through the GPO. The NHSO assigned the network of Rajavithi service agencies together with the GPO to be responsible for procuring, bargaining, purchasing, stocking and distributing drugs on behalf of the NHSO. The NHSO is responsible for overseeing, checking and paying the scheduled installments to the Rajavithi Hospital network, and supervising/monitoring the work, as well as giving advice to various agencies.²⁶



FACTORS CONTRIBUTING TO THE DEVELOPMENT OF AN EFFICIENT AND EFFECTIVE CENTRAL BARGAINING AND PROCUREMENT MECHANISM

Key findings that led to the establishment of a central bargaining and procurement mechanism for medicines that have accessibility problems are efficiency and good governance through participation of network partners from all sectors. This participation is facilitated by a board/ subcommittees and working groups, and information systems for managing inventory²¹ according to the details as follows:

6.1 DEVELOP MECHANISMS FOR PARTICIPATION FROM ALL SECTORS

In order to implement a comprehensive bargaining and procurement mechanism at the national level, there is a critical need for mutual agreement, coordination, and collaboration from multiple sectors. The structure of the committees/sub-committees and working groups of various agencies is organized by area of expertise which is considered as the center of the bargaining and procurement mechanism at the national level. One can compare it to a living organism, where the central mechanism is the "brain and heart" of the system, which then mobilizes participation from the network of working groups in all sectors³ consisting of the following:



Service recipient groups, including patient groups and representatives from Civil Society



Service provider groups, including the entities under the National Health Security Board and agencies under MOPH, such as the Rajavithi Service Network, DDC, Department of Medical Sciences, FDA, service units under MOPH, NHSO, the 13 health regional offices, etc.



Academic groups and experts such as researchers from various universities, the Health Systems Research Institute, the Health Intervention and Technology Assessment Program, the Association of Cardiac Physicians, the Thai Red Cross Society, the Toxicology Center, various royal colleges, etc.



Various stakeholders such as the GPO, the Saowapa Institute, the Military Pharmaceutical Factory under the Ministry of Defense, the pharmaceutical industry groups, pharmaceutical companies, etc.



Figure 2: Structure of the Central Bargaining and Procurement Mechanism (2018-present)

Representatives from these agencies share a central role in the implementation of medical supplies management under special projects, including design, decisionmaking, and policy recommendations. They provide a diverse perspective covering economics, medicine, social sciences, and other fields. The process relies on empirical evidence such as research studies on treatment effectiveness and budget impact, etc., to consider costeffectiveness, necessity, meeting the needs of the people, and ensuring the most efficient operational planning.

The structure of the Board and working groups under the central bargaining and procurement mechanism consists of the following:³

6.1.1

The National Health Security Board is chaired by the Minister of Health, with the Secretary-General of the NHSO as the secretary of the Board. Its main role is related to the management of medical supplies under special projects, namely, the list of items in the benefits package, approval of NHSO operations, preparation of annual budgets, and the appointment of subcommittees and working groups responsible for the central bargaining and procurement mechanisms of medical supplies at the national level.

6.1.2

The sub-committees are divided into the following two entities according to the time period as follows:

6.1.2.1

Subcommittee for Selecting Essential and Problem with Acessibility Medical Products for beneficiaries in the UCS (2009-17).

This subcommittee was appointed on March 24, 2009 with 21 representatives from various sectors, consisting of academics, representatives from the MOPH, the National Drug System Development Board, disease specialists, representatives of Civil Society and patients' advocacy groups, etc. In the beginning, the NHSO took care of the management of the whole process of essential medical supplies at the national level. However, after this subcommittee was formed, eight working groups were established to jointly drive the policy of increasing people's access to medicines, namely:

- 1 Working Group on the drug administration system development for drugs, non-drug products and medical science materials
- 2 Working group on developing VMI system audits, disbursement of ARV, TB, E(2) drugs and CL drugs
- 3 Working Group for coordinating and developing a joint working system between the NHSO and GPO
- Working Group for information system development for drug and medical product management as a joint project between the NHSO and GPO
- 5 Working Group on the cooperative program to increase access to iron stimulants for Thalassemia patients in the UCS
- 6 Working group on the development of vaccine procurement and distribution through the VMI system
 - Working Group for developing policy to solve orphan drug problems
- 8 Working Group on developing and driving pharmacy policy in the UCS

6.1.2.2

The Subcommittee on the Preparation of Plans for the Procurement of Medicines, Medical Supplies, and Essential Medical Devices according to special projects (2018 - present) was established on October 18, 2018 as per the resolution of the National Health Security Board. The aim was to improve the mechanism to bargain and purchase medical supplies at the national level to ensure that the supply of necessary medical supplies under special projects is consistent with the framework prescribed by the National Health Security Act.

This sub-committee has representatives from outside the NHSO, with the Permanent Secretary of Health as chairperson. There are representatives from relevant government agencies, both inside and outside MOPH, representatives of Civil Society, public hospital networks, representatives from private hospitals, and related NHSO plan administrators. There is a joint secretariat function with representatives of the Drug and Medical Supply Administration (of the NHSO), other representatives of the NHSO, representatives of the network of Rajavithi Hospital service units, the GPO, and the Public Health Administration Division, for a total of 36 people. This group is responsible for making proposals, planning for procurement, assessing demand for items, regulating and controlling operations, bargaining drug procurement, supervising procurement, overseeing quality control according to the planned requirements and in accordance with the specified qualification, and supporting the management system to have a reliable continuity. Two working groups have been appointed under this sub-committee as follows:

1 The Working Group to Bargain the Price of Essential Medical Supplies for Special Projects

2 The Monitoring and Evaluation Working Group for the Preparation of Essential Medicine Plans for Special Projects

6.2

DEVELOPMENT OF INFORMATION SYSTEMS TO ORGANIZE BARGAINING AND PROCUREMENT MECHANISMS AT THE NATIONAL LEVEL

The information system for organizing bargaining and procurement mechanisms at the national level is an important foundation for the medical supplies disbursement transaction system that connects the NHSO, service units, patients, and agencies involved in medical supplies stocks, and distribution. The objective is to record the prescription of medicines under the bargaining mechanism for the management of support charges. The system is intended to optimize the management of medical supply stocks and distribution. This information system will be able to process/report the results of the use of medicines, along with documentary evidence of treatment of patients receiving a particular medical product. The information recorded in this system can be used to manage the stockpile and distribution of medical supplies. The operator can prepare a summary of the situation of using various types of medical items for inspection and reporting of results to relevant agencies. It can also be used as a reference in purchasing planning as well.²⁸ The system consists of two database systems as follows:

6.2.1

Information system for managing medical supplies under special projects.

This is a data record system designed according to the type of medical supplies under different special projects. There are objectives and procedures for use according to the specifics of each type of pharmaceutical. That information is recorded by the service and draws upon documents relating to the individual patient's disease condition. The information includes the number and type of medical supplies used in each prescribing cycle, as well as documents/details for requesting approval for the use of various medical supplies, etc. This information system can be divided into three main sub-systems as follows:

6.2.1.1

Disease Management Information System (**DMIS**)¹⁷ is a data record system for patients with various types of chronic diseases who receive medical supplies and services continuously. The system is organized into subsystems by disease type, such as the National AIDS Program (NAP)²⁹ for PLHIV, the DMIS-Tuberculosis (TB)³⁰ for TB patients, and the DMIS-Continuous Ambulatory Peritoneal Dialysis (CAPD) for end-stage chronic renal disease who receive continuous peritoneal dialysis services. The NHSO develops and maintains the database system.



Accounting system by type of medical supplies.

This is a data record system for requesting approval for the use of specific medical supplies. For each order, the service unit will request approval to be prescribed by specialists by the NHSO. There is the E(2) drug disbursement system for specific items, orphan drugs, and anti-poison drug reimbursement system. There is a disbursement system for the coronary artery wall stent. The NHSO is the developer and administrator of this database.²⁶

6.2.1.3

Vender-Managed Inventory (VMI) is an information system developed by the GPO in collaboration with the NHSO for managing the inventory of essential medical supplies under a special program with compensation for the disbursement of medical supplies collected by the GPO and delivered by a distribution company.³ The VMI can be divided into the following two situations:

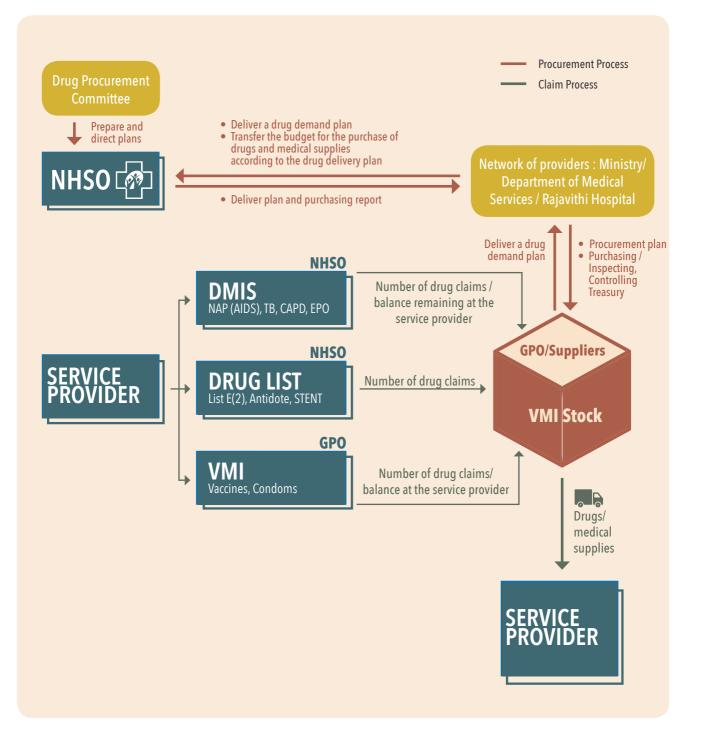
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In the case of medical supplies reimbursement, the amount is according to the use and demand of the service unit. The service unit has been approved to disburse medical supplies from the NHSO through, for example, the DMIS system for AIDS-specific pharmaceutical groups, TB and end-stage renal disease and/ or from the E(2) drugs list system. The system supports procurement of orphan drugs of the anti-toxin group and antivenom serum, as well as stents supporting the coronary artery wall, among others.⁷

In the case of ordering the use of the EPI vaccines, seasonal influenza vaccine, and condoms for HIV prevention, among others.³⁰

The VMI system determines a high-low threshold for the appropriate amount of medical supplies to stock at each service facility in order to avoid overstocking of medical supplies or insufficient stocks for demand volumes. In the approval process for disbursement, the service units must record their login information in accordance with the requirements for approval to order medical supplies for patients from the NHSO. Once approved, they can provide medical supplies to patients/target groups. When approved to order medical supplies, the system will record the data to prepare the disbursement amount, which is forwarded to the GPO's warehouse (twice a month) in the form of a purchase order. This is to provide an approved dose distribution of pharmaceuticals, delivered directly to the medical storeroom of the service unit.¹⁷ The system produces a summary of the monthly purchases separately by each service unit (Figure 3).



6.2.2

Medical service data recording and processing system or "e-claim"

(https://eclaim.nhso.go.th/webComponent/) for medical supplies with compensation in cash payment. This system is a central database to record the medical services of the service unit, and for service units to seek approval for support/ compensation as expenses for medical supplies services from the NHSO according to the specified criteria and conditions.¹⁷

7 PROCESS UNDER THE CENTRAL PROCUREMENT MANAGEMENT MECHANISM

The process under the central procurement management mechanism consists of three main components: Selection, procurement, and reserve stock and distribution, as described in more detail below:

Selection: [Co-operated by the Selection Sub-committee and NHSO]

- 1. Solicit recommendations on medicines that are difficult to access and require centralized management from experts from the Civil Society and patient groups.
- 2. Prioritize drug types to conduct a study and analyze safety, efficacy, cost-effectiveness, and policy impact for consideration and scrutiny according to the hierarchy.
- 3. Define and submit drug lists to the National Health Security Board for entry into the process central bargaining, and procurement mechanisms.

Procurement : [Co-operated by Rajavithi Network, the GPO, Sub-committee of the Supervisory Working Group to Monitor Procurement, and NHSO]

- Central bargaining consists of planning procurement requirements for budget approval. There is a specification of the pharmaceuticals, procurement, collective bargaining, pricing to purchase, and quality assurance of pharmaceuticals.
- 2. Central procurement consists of procurement according to the relevant regulations and budget allocation to the Rajavithi network in installments to pay the GPO according to the contract period.

Stocks & distribution: [Co-operated by Rajavithi and the GPO Network, Sub-Committee of the Supervisory Working Group to Monitor Procurement, and the NHSO]

- 1. Delivery of medical supplies to the warehouse with an inspection along with quality control supervision according to the specified properties.
- 2. Replenishment of stock medicines through VMI system (maximum period of 3 months). Supervise and monitor distribution of medical supplies to service units according to compensation criteria. Follow up on usage data and prepare a report on budget expenditure and receipt/dispensing of medical supplies, consisting of results of procurement and inventory management. Economic value access to medical supplies (number of patients receiving medical supplies) and distribution information.

7.1 SELECTION

The selection of pharmaceuticals is the default process of the central procurement management mechanism for essential medicines that have access issues. The procurement of these supplies falls under special project management under the National Health Security Board. The process starts with accepting a proposal and opinions from all sectors to lead to the selection of essential medical supplies are difficult to access. It must be a drug that is included in the National List of Essential Drugs. Long-term commitment costs are studied, and the findings must be considered and screened by the working group in the following steps:³

> Acceptance of suggestions, opinions, and problems in accessing essential medical supplies from patients, Civil Society, and service provider groups such as specialists, experts, medical associations, the Royal Colleges, and other stakeholders. This leads to the selection of essential medical supplies that are difficult to access, and it must be a drug included in the National List of Essential Drugs. Once all the accessibility issues are compiled, then there is a process of allocating priority/urgent need to be taken into consideration in a comprehensive study.¹²

2 Safety, efficacy, cost-effectiveness studies on economic and policy impact are conducted by a team of academics and experts in health economics. Those findings help inform plans and purchasing guidelines, and designing a concrete database system for the backup and distribution of medical supplies. The working group will study the information and make decisions based on empirical data, academic evidence, efficacy, quality, and safety. Price information must always be consulted when making decisions. However, ultimate selection is not based on lowest price. Instead, the consideration of the efficacy, safety, and the need to protect people/patients from bankruptcy is paramount.³⁴

3

- 4 Presenting the results of the study to the Subcommittee on the benefits package of the UCS.
- 5 Fiscal Subcommittee looks at the cost -- both short-term and long-term impact.
- 6 Strategic Coordination Subcommittee allows all parties involved to consider and screen.
- 7 The list of medical supplies will be considered by the National Health Security Board.
- 8 Presentation with the NHSO Board, presided over by the Minister of Public Health to consider and approve the procurement under a special project.

Once approved, the medical supplies will enter the central procurement management mechanism in accordance with the procurement process under a special project to be discussed next. In the case of essential medical supplies procured under the special program with ongoing supply, the working group will report the results of procurement of medical supplies under special projects on a project-by-project basis to the National Health Security Board annually. They will request approval for procurement under special projects.

In case medical supplies have the following three attributes, they will be removed from special projects and are classified as medical supplies with financial compensation for which the disbursement ceiling will be set:

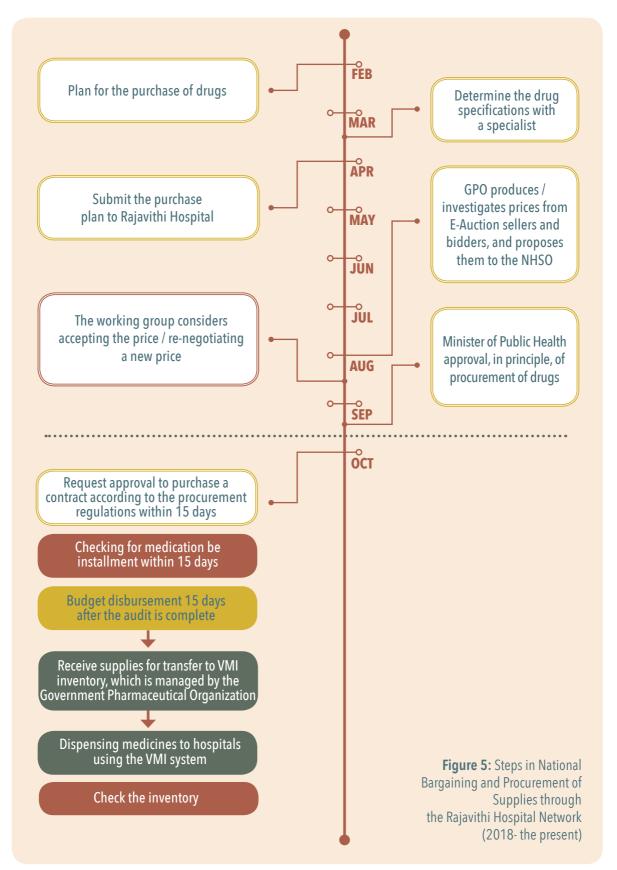
- There is a distributor which is a government agency that is specifically responsible for providing medical supplies
- 2 There is more competition in the market system, or there are three or more vendors
- 3 It is possible to negotiate nationally, whereby the supplier agrees to sell at the same price for all government health insurance schemes with uniform sales to service units in all areas.

The NHSO will announce management guidelines with the latest updated medical supplies list on a regular basis according to the fiscal year for service units and related agencies.

7.2 THE PROCESS OF PROCURING MEDICAL SUPPLIES UNDER SPECIAL PROJECTS

The medical supply planning process (one cycle takes approximately 18 months)³ consists of four sub-steps:

- **1** Planning for purchasing requirements
- 2 Establishing pharmaceutical specifications
- **3** Bargaining and procuring consolidation
- 4 Estimating the stock, and distribution of the supplies (Figure 5).



7.2.1 PLANNING NEEDED PROCUREMENT (FEBRUARY - APRIL)

The working group prepares a plan for the purchase of medicines and necessary medical supplies under a special project. The working group is co-secretariat by the Bureau of Medicine, and Medical Supply Management, the Rajavithi Hospital service network, the GPO, and the Division of Public Health Administration (MOPH) are primarily responsible for the preparation of demand plans for medical supplies under special projects, according to the following steps:

The working group prepares a plan for medical supplies for the fiscal year, which is then passed on to the Rajavithi service network as the center of drug supply. The amount of medical supplies that must be purchased will be calculated according to the number of beneficiaries with treatment rights under each special project. There will also be a plan to procure essential medical supplies. The estimation will calculate the quantity for use in a period of 13 months (1 month over the fiscal year to allow time for procurement for the next fiscal year). There is consideration of immediate or continuous use (e.g., vaccines and ARV drugs). Procurement plans are for 15 - 18 months of use¹⁹ to prevent shortages during the next fiscal year procurement of medical supplies.13

In the budget estimation, the median price is used. The price is determined by the National Drug System Development Board, or by the price of the medicine/product that has been negotiated (single-distributor drug), or by the price of a drug that was purchased in the previous year. The price is multiplied by the quantity obtained from the actual use estimate³ as follows:

2

ESTIMATE	FORMULA FOR CALCULATION	
New drug in the benefits package	Incidence or prevalence of the disease or condition x drug price	
Drugs currently in the list	Data on reimbursement through VMI x drug price	

- 3 Upon completion of the annual procurement plan, the Working Group submits the plan to the National Health Security Board for compilation and submission to the Cabinet for budget approval.
- Once the budget has been approved by the Cabinet, the National Health Security Board will allocate the budget to the Working Group in order to adjust the procurement plan in accordance with the budget received.⁷
- 5 When the plan adjustment is complete, the working group will publish/announce said plan on the designated website, and deliver a procurement plan to the Rajavithi network of service units in order to prepare the medical product specification as the next step (by April).

7.2.2 CHARACTERISTICS OF MEDICAL SUPPLIES (MARCH-APRIL)

The Rajavithi Hospital Network plays a major role in coordinating the appointment of the working group to prepare the criteria, establish rules/conditions for purchasing medical supplies, and prepare specific characteristics of medicines (Medicine Specification) to be used as basic information for purchasing essential medical supplies. The 9th National Health Security Board meeting dated August 18, 2017, resolved to establish a network of service units linked with Rajavithi Hospital to be responsible for the supply of necessary medical supplies according to a special project, together with the GPO.³¹ There are two specific features as follows:

Establish a working group to formulate the criteria,³ consisting of specialists in various fields such as immunology, hematology, pediatrics, etc., and representatives of various agencies such as the Department of Medical Sciences, the FDA, pharmacists, university hospitals, the GPO, etc., in order to jointly determine appropriate characteristics and obtain quality pharmaceutical products that will be accepted by the treating physician. The working group will refer to the guidelines on drug supervision in the National List of Essential Drugs and treatment guidelines for disease management (both domestic and international) or the finished product specification and inspection according to the standards set forth in the drug textbook (pharmacopoeia), or standards from other parts of the world, such as the United States Pharmacopeia, British Pharmacopoeia, and European Pharmacopoeia, etc.³

2

When the working group has finished considering the specifications of the medical supplies, the Rajavithi service network will proceed with the procurement of supplies as follows:

1 Appoint a delivery inspection committee. This consists of specialist physicians and personnel from the Rajavithi network of service units participating in the inspection and quality assurance of drugs. Purchasing conditions are established to ensure the quality of co-purchased drugs and follow-up to assess the quality of drugs after purchase. Standard requirements for medical supplies must be certified by the relevant agencies in every production model.

2 Assign the GPO as a supplier and purchaser by delivering the purchasing demand plan, characteristics of pharmaceutical products, together with the name of the pharmaceutical company according to the type of medicine, to the GPO to search, select, and contact pharmaceutical companies/distributors for further bidding.

7.2.3 PROCURE, BARGAIN, AND PURCHASE MEDICAL SUPPLIES FROM THE CENTRAL LEVEL (AUGUST-OCTOBER)

The Specific Medicines Procurement Working Group under the GPO will proceed with the procurement of prescription drugs. Electronic procurement information will be disclosed along with purchasing information via the information network system of the Comptroller General Department (Electronic Government Procurement, or e-GP). This information will be presented as part of the announcement to invite pharmaceutical companies to submit bids. Next, there is consideration of proposals, announcement of the winner, and announcement of selected prices, contracts, and contract management on the website of the Comptroller General Department. Then, the GPO will proceed as follows:

Contact and coordinate with pharmaceutical companies to submit technical data to the GPO, including capacity, distribution, and quotations to be used for consideration and consolidation of bargains, which will take into account the qualification of bidders, determine whether the product has the correct specifications as declared, and meets the set criteria. The appraisal ratio consists of a price guideline and a price-performance assessment.³⁶ Bargain medical supplies with the manufacturer or distributor using the reference drug price ceiling according to the median price announced by the National Drug System Development Board provided that: If the latest purchase price is lower than the price announced by the National Drug System Development Board by not more than 15%, use the median price according to the announcement. Or, if the price at last procurement within two years, is lower than the price announced by the National Drug System Development Board by more than 15 percent, use the most recent price.⁷

2

3

4

Report monthly on the progress in drug procurement and the value saved in procurement at the meeting of the Purchasing Plan Subcommittee. Then, propose the said price to the Drug Price Bargain Working Group. Consider the appropriateness of the price. If there is agreement, let the GPO bid the price to the Rajavithi network for further purchasing.

Once a qualified distribution company can be selected, the GPO will present the selection results and a negotiated price to the Purchasing Plan Subcommittee and the administrators of each fund to consider seeking approval for the purchase of medical supplies at prices agreed with pharmaceutical companies. The next step is to enter into a purchase agreement between the GPO, Rajavithi service network, and selected pharmaceutical companies. The Rajavithi service network receives and inspects medicines according to the qualifications or specified in the purchase agreement. In addition, the purchase contract includes a list of medicines contracted with one supplier and more than one supplier. In the case of contracts with more than one merchant, then enter into a contract of 60:40, which is a purchase contract with the winning merchant in the proportion of 60 percent of the purchase amount and contracts with other traders totaling not more than 40 percent of the purchase limit.37

Box 2:

Quality assurance of medical supplies under the central procurement management mechanism $^{\rm 21}$

Assurance of medical supplies is a very important management challenge under the central procurement management mechanism, as supplies are administered to beneficiaries or patients across the country. For example, there must be quality assurance of medical supplies before purchasing, especially pharmaceutical items procured under Thailand's CL enforcement. Although such an approach usually results in a substantial reduction in the price of medical supplies, the treating physicians need to have full confidence in prescribing medicines through a national bargaining and procurement mechanism.

For this reason, the NHSO has joined with the GPO to design additional quality assurance by providing confirmation of the quality analysis of pharmaceutical products by a Third Party Lab (e.g., the Department of Medical Sciences). For any group of pharmaceuticals for which there is no qualified domestic diagnostic agency, such as some cancer drugs, the GPO will send samples of the medical supplies to a foreign laboratory for examination. For imported vaccines for use in the EPI program, there is a "Lot Released" process conducted by the Depajorrtment of Medical Sciences every time. Only those medicines that have been analyzed to confirm their quality are distributed to the system.

Quality assurance at the national level can build confidence in the quality of the medicines provided and save the budget for the diagnostics of the service units. In the case of drug quality problem trouble-shooting after procurement, there is a system for monitoring and reporting drug quality problems. In some cases, WHO will be informed to monitor the problem on a global scale.⁷

7.3 DRUG STOCKS & DISTRIBUTION

The principle of drug storage and backup is to maintain the quality and efficacy of medical supplies by checking the stability of the medical supplies, rotating expired medicines to be disposed of, and bringing new drugs into the system.³⁰ There has to be proper management of a stock of sufficient quantities for prescribing, as well as controlling the prescribing process by experts. The filing process takes place after the completion of the purchase agreement between the GPO and the drug manufacturer. The manufacturing or importing company ships the medical supplies to the GPO warehouse/ pharmaceutical company warehouse before being delivered to the service unit or host hospital. The GPO will enter received goods into the VMI system up to a maximum stock of up to three months' supply in the medical inventory in each service facility. Supplies are transferred directly to the service unit to reduce the workflow, and which can be divided into the following three types of medical supplies:

7.3.1

National List of Essential Drugs, sublist E(2) drugs, and specific list¹³ E(2) drugs that are selected for a collective bargaining and procurement mechanism under the NHSO. This covers the list of drugs to be procured under a CL order, such as Efavirenz, Clopidogrel, Lopinavir/Ritonavir, Letrozole, Erlotinib and Imatinib, etc.²¹ which are essential for specific diseases, where there is no substitute for another drug, or the drug is very expensive and must be provided in the health care system for treating a select group of patients. In addition, when the prescribing of this type of drug creates a burden on the budget of the service unit and on the national budget, it is necessary to control use to be appropriate. Therefore, there must be a national management system to check and approve drug disbursement by a medical professional before treatment (pre-authorization of non-emergency) cases, and post-authorization in case of emergency).⁷ There has to be a system for monitoring the distribution of drugs to the designated service units. This is to ensure that the prescribing of drugs by the providers and the use of drugs by the service recipients are in accordance with the principles of rational use of medicines.

Generally, the stock for E(2) drugs is classified according to the purchasing agreement model. They will be stored in stock at the GPO. (There are six drug lists, including Doctaxel 20mg / 80 mg vial which have been approved under a CL order.) The stock may be stored at the pharmaceutical/distribution company's warehouse (which applies to 21 drugs). Distribution of E(2) drugs under a special project will be done through the pharmaceutical inventory management system in conjunction with the VMI system. The system will check the instructions for use according to the approval criteria. If the criteria are met, the VMI system will forward the list and quantity information to the GPO or the pharmaceutical company for preparation and further delivery.³

7.3.2

Orphan drugs in the anti-toxin group and snake venom serum¹⁶ can be considered as a special-case innovation in terms of providing adequate drug stocks from the survey of scarce antidotes, leading to systematic advocacy of anti-toxic drug stock policy by using GIS technology. This process involves the design and establishment of anti-poison backup data for each service level, including an express local drug delivery network.

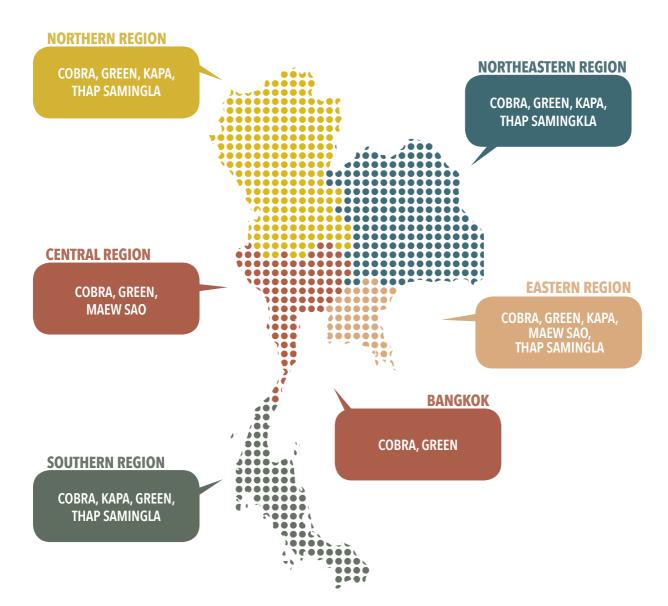
This requires collaboration between both public and private agencies²⁰ in information management and drug prescribing through consultation from the Ramathibodi and Siriraj Hospital Poison Centers, Animal Poison Clinics, Saowapa Institute, Thai Red Cross Society, and other related service units across the country. The contribution of such a system has resulted in a clear enhancement of the orphan drug supply system by establishing an accounting system for orphan drugs and anti-toxic drugs which uses GIS technology to assist in the real-time antidote retrieval process, obtaining the medicine quickly, and distributing drugs according to the severity and prevalence of the disease/condition, such as antivenoms provided in stock in all provincial hospitals across the country or snakebite antivenom. Distribution is in accordance with the epidemiology/risk management of potential venomous snake bites in each region.

Table 2: Summary of orphan drug stocks of anti-toxin group³

ITEM	STOCK LOCATION	USE OF THE ITEM	REIMBURSEMENT
 Dimercaprol Esmolol Methylene Blue Sodium Nitrite Sodium Thiosulfate Diphtheria Antitoxin 	Regional hospital; Provincial hospital; University hospital; or District hospital (in cases of remote location)	In the case of a hospital that is a backup source of medicines, supply must be drawn from the drug in the stocked project or drawn from other stock sources. In the case of a hospital that is not a drug stock, such as a community/ district hospital, draw from the drug stock. In the case of private hospitals (participating in the UCS), draw supply from the drug stock source. In the case of other private hospitals (non- UCS), contact the Ramathibodi Toxic Center	Withdraw medicine from the orphan drug reimbursement program, whereby community hospitals reimburse transportation costs under the OP referral system. For private hospitals, use the emergency drug reimbursement system of each fund.
Antivenom (Polyvalent/ Monovalent)	Regional hospital; Provincial hospital; University hospital; or District hospital only for Monovalent antivenom by species of snake	Withdraw the drug from the stocked project stores or withdraw from another stock source. Note: In the case of community hospitals, take medicines from the stocked project, and refer the patient to a regional, provincial, or university hospital	Withdraw medicine from the program for compensation for orphan medicine where community hospitals reimburse transportation costs according to the referral service system in and out of the province and for outpatient services. In case of accidents and emergency illnesses, for private hospitals, use the emergency drug withdrawal

system of each fund.

STOCK OF SNAKE ANTIVENOM SERUM BY SNAKE SPECIES BY REGION



In addition to being able to save the lives of those who have been poisoned, systematic management of drug stocks can also reduce the budget for organizing the antivenom serum of the service unit, and strengthen the national security of antivenom and antivenom serum.

Figure 6 Stock of Snake Antivenom Serum by Snake Species by Region Source: Kanitsak Chantraphiphat, "Management to solve the problem of essential medicines, shortage of orphan-anti-toxin groups, National Health Security Office". (2017)

7.3.3

Vaccines: In 2010, the National Health Security Board approved the NHSO to provide and manage the supply of EPI vaccines under a special program.¹² Originally, during the years 1977 - 2008, the DDC of the MOPH was the main agency responsible for the procurement and distribution of EPI vaccines. Orders were processed through the Regional Disease Prevention and Control Offices in all 12 regions to the Provincial Health Office (PHO) for distribution to the provincial/district hospitals and on down to the Primary Care Unit in each locality. The process of distributing vaccines in such a manner introduced many layers of complexity. There was no effective management system for vaccine stockpiles and distribution under the cold chain. As a result, there was considerable wastage due to expired or mishandled vaccines. Distributing vaccines in each disbursement cycle took too long, and it was expensive to store and prepare vaccines for transferring from one point to another. As a result, the number of vaccines received by the service unit was often not well-matched with the needs of the target population.

THE FORMER EPI VACCINES DISTRIBUTION CHANNEL

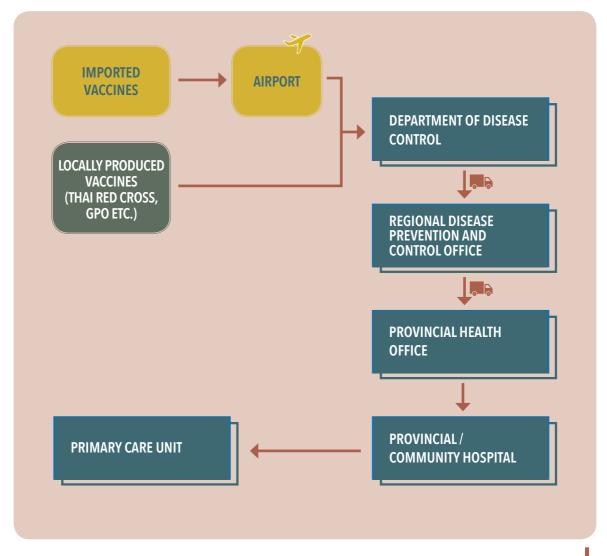


Figure 7: System of Vaccine Distribution prior to 2010 Source: Vaccine Management Group Division of Vaccine Preventatble Diseases. (2019). "Textbook of Vaccines and Immunization in 2019." MOPH In 2010, the NHSO, together with the DDC and the GPO, organized vaccine management through the VMI system. The DDC joined the NHSO and the GPO and established a working group to develop a systematic vaccine procurement and distribution system under the VMI. They jointly developed the distribution system and managed the vaccine inventory using a Cold Chain Management System. This included monitoring and evaluating the results of vaccination services, as well as establishing a network to monitor and evaluate vaccine administration under the VMI, which can optimize the cold chain in vaccine transport and storage to maintain effectiveness and reduce wastage. This new system could also reduce the cost burden by reducing unnecessary transit points/ stock warehouses to increase the speed and accuracy of vaccine distribution quantities. The list of centrallymanaged vaccines by the GPO include the EPI series,³⁹ influenza vaccine,³¹ and rabies vaccine.⁴⁰

Since 2010, in the management of the distribution of the EPI vaccines through the VMI system,⁴¹ both domestic and foreign vaccines are stored in the GPO warehouse (adhering to cold chain requirements). This is the process of maintaining the quality of vaccines from the manufacturer to the recipient by storing it at a temperature between 2 - 8 degrees Celsius)²⁵ and in a suitable environment.⁴² This ensures that vaccines maintain quality and effectiveness throughout storage and pointto-point transportation. The vaccine is distributed to the service provider in each delivery cycle each month. The service unit must record the on-hand inventory of vaccines, after which the VMI system calculates the quantity to be delivered for the warehouse to prepare the products, and forwards that information to the distribution company for further delivery to the service unit³⁰ with a lead time of 5 days.³¹

VMI VACCINE DISTRIBUTION MODEL

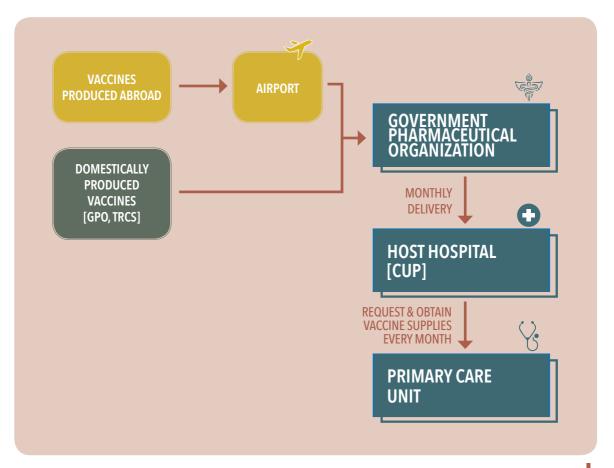
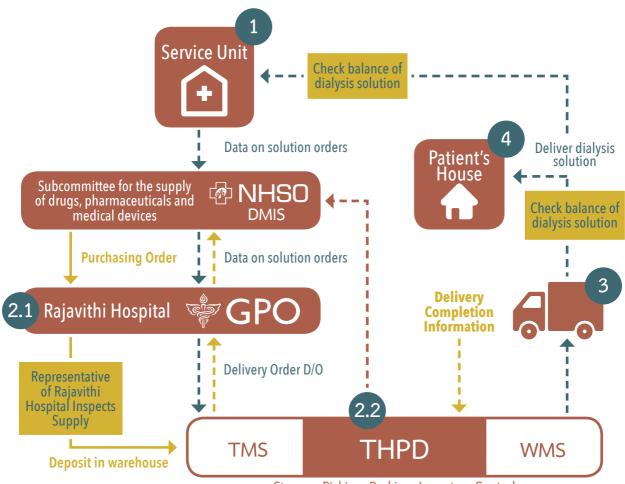


Figure 8: VMI Vaccine Distribution Model: 2010 - Present Source: Netnapis Suchonwanich. Thailand's essential drug procurement system: past, present, problems, obstacles, and systems that need to be prepared, Critical Medicine, Newsletter of Drug Surveillance Information Center (Feb.), Faculty of Pharmacy, Chulalongkorn University Year 10 / Issue 41 / April 2019.

7.3.4

Delivery of dialysis fluids to the patient's home:³⁵

The NHSO encourages patients with end-stage renal failure to use peritoneal dialysis (PD) services as the first priority as it is the most effective treatment, it is more convenient for the patient, the patient enjoys a better quality of life, it is more economical for the patient and household, and it overcomes obstacles to access (by reducing distance and transport burden).⁷ In order to provide a continuous supply of medicines/supplies for these patients, the NHSO partnered with the GPO and Thailand Post Co., Ltd. to transport CAPD dialysis fluids through the DMIS_CAPD system program. The service unit can order up to 150 bags of solution per month (and order up to two months' supply at a time). Data must be checked daily to determine the most accurate number of patients who need dialysis fluids, since loss of life can occur on a daily basis. Reviewing patient data means no wasted dialysis fluid and transit time. Thailand Post Co. then transports the medicine/solution to the patient's home along with conducting a quick assessment of the amount of solution remaining at the patient's house in order to ensure adequate back-up of supply. That information is also transmitted via Smartphone so that clinical personnel can adjust or re-calculate the amount of the next dialysis fluid order needed.¹⁷



Storage, Picking, Packing, Inventory Control

Figure 9: Distribution of CAPD Solution to the Patient's Home 8

RESULTS OF IMPLEMENTATION OF THE CENTRAL PROCUREMENT MANAGEMENT MECHANISM

This section presents results of the implementation of the NHSO and related network partners under the central procurement management mechanism for critical pharmaceutical groups with accessibility issues. Over more than a decade of implementation, it was found that there has been an increase from two projects with 32 medical supplies in 2007, to ten projects with 143 medical supplies in 2019 that are under the special program to supply medicines/supplies to the service unit. The addition of the list of pharmaceuticals distribution points is due to the expansion of service coverage and disease specificity in accordance with the dynamics of the country's treatment technologies and socio-economic advancement. This improvement also demonstrates the development of benefits and effective management based on the NHSO's three-dimensional principles: Population Coverage, Disease Coverage, and Treatment Coverage.¹³ The goal is to protect the life, health, and wellbeing of patients, households and society, and protect patients from bankruptcy due to enormous medical bills, and mitigate the effects of chronic, serious, and rare diseases. Such a mechanism can increase the efficiency of drug administration, increase drug security, reduce unnecessary procedures and costs, reduce budget burden, and enhance access to essential healthcare services,⁴³ which can be summarized as follows:

8.1

INCREASE ACCESS TO EXPENSIVE AND ORPHAN DRUGS

Over a nine-year period (2010 - 18), access to expensive and orphan drugs under the NHSO's special program has significantly increased, as detailed below:²⁶

- Patient access to the E(2) drugs sub-list increased from 4,446 in 2010, to 32,644 in 2018
- Patient access to clopidogrel increased from 84,455 in 2011, to 280,783 in 2018
- Patients access to orphan drugs and anti-toxic drugs increased from 134 in 2012, to 5,312 in 2018

Figure 10: Increased Access under Special Projects of the NHSO: 2010-18



Source: Sakulbumrungsil. Thai Drug Systems 2020: The Impact of Drug Financing System under Thailand Universal Health Coverage (UHC) on the Performances of Drug System, Journal of Health Science, Health Technical Office, Ministry of Public Health Vol. 29 Special Issue, January - February 2020: 59-70.

8.2 COST-EFFECTIVENESS AND BUDGET SAVINGS

The central procurement management mechanism is a central mechanism capable of adjusting/balancing the price-to-volume ceiling as one of the strategies to *'Increase Negotiation power'*²¹ from total purchase volume per session. Prices can be managed appropriately and, in some cases, medical supplies can be purchased at more than 90 percent of the mid-market price (annual reference drug prices published from the MOPH Pharmaceutical Information Center), resulting in significant savings compared to purchasing pharmaceuticals from the same list in the same amount.

Economic value = [reference drug price minus negotiated drug price] multiplied by unit⁷

as shown in the table below for an example list of medical supplies:

Table 3: Examples of Prices of Medicines under the Special Project Compared with Central Procurement Prices (2019)

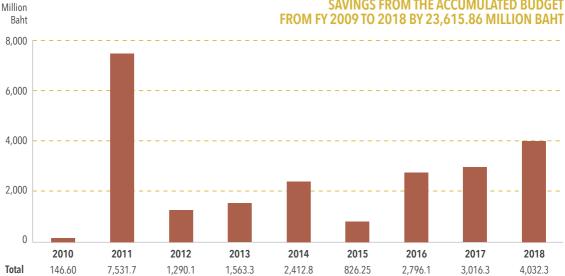
MEDICINE	UNIT	MEDIAN DRUG PRICE PUBLISHED BY THE PHARMACEUTICAL INFORMATION CENTER, MOPH (BAHT)	DRUG PRICE FROM COLLECTIVE BARGAINS UNDER A SPECIAL PROGRAM OF THE NHSO (BAHT)	SAVINGS PER UNIT OF DRUG (BAHT) (% OF CENTRAL PRICE)
Rituximab 100 mg	bottle	15,630.56	2,401.08	13,229.48 (85%)
Imatinib 100 mg	pill/ tablet	914.85	69.122	845.728 (92%)
Letrozole 2.5 mg 3x10's (BX)	pill/ tablet	153.37	20.797	132.573 (86%)
Dasatinib 70 mg 60's (BX)	pill/ tablet	2,588.53	1,539.91	1,048.62 (40%)
Trastuzumab 440 mg (VI)	bottle	45,000.00	15,006.75	29,993.25 (7%)
Trastuzumab 150 mg (VI)	bottle	15,329.00	5,347.83	9,982 (65%)

Source: Netnapis Suchonwanich. Thailand's essential drug procurement system: past, present, problems, obstacles, and systems that need to be prepared, Critical Medicine, Newsletter of Drug Surveillance Information Center (Feb.), Faculty of Pharmacy, Chulalongkorn University Year 10 / Issue 41 / April 2019.

One of the empirical outcomes of the national collective bargaining and procurement mechanism is the economic value of E(2) drugs (Clopidogrel and ARV drugs) that have had 'cumulative budget savings' during 2009 - 18 of up to 23,616 million baht (Figure 11).

Figure 11: Cumulative Savings (baht) from Purchasing Clopidogrel and Antiretroviral Drugs (2010-18) Source: Kanitsak Chantrapipat, Development for access to essential medicine benefits in the health insurance system, 2018.

The savings in procurement of budgets, especially for expensive pharmaceuticals such as some E(2) drugs, have led to further increases in benefits and other additional health services for UCS beneficiaries, such as the orphan drug project in the antivenom group and antivenom serum, the EPI program, and other special programs.¹⁶



SAVINGS FROM THE ACCUMULATED BUDGET

8.3

MANAGEMENT OF MEDICAL SUPPLIES LEADING TO THE EXPANSION OF SPECIALIZED THERAPEUTIC SERVICES

Procurement operations under the central procurement management mechanism include the planning and specification of pharmaceuticals, and the provision of regulatory sourcing, resulting in obtaining good quality medical supplies. The drugs are more affordable because the system combines purchasing volumes to increase negotiation power.⁵

Providing quality medical supplies in the system has led to improvements in treatment, as is the case with the procurement of drug eluting stent-DES coated coronary stents. Since 2009 until the time of this paper, the NHSO has been working with the Cardiovascular Intervention Association of Thailand to standardize the prescribing of these medical devices, with the GPO handling procurement. This has enabled the procurement of DES stents with indications of high therapeutic efficacy for coronary artery disease at a price of 30,000 baht (down from the original price of 85,000 baht) per unit. Currently, the NHSO can also purchase DES coils for only 12,000 baht per piece, which is lower than the price ceiling of the Comptroller General Department that allows expenditure of up to 35,000 baht per piece.⁴⁵ The management mechanism not only saves budget, but it also leads to more effective advocacy for heart treatment policies for patients across the country. There are "centers of excellence," and regional cardiac treatment services for patients across the country. This is helping to reduce congestion of the larger service units, shorten the waiting time, and reduce the burden of patient expenses as well.

Another outstanding example of the management system is the provision of intraocular lenses where the NHSO has co-specified pharmaceuticals with the ophthalmologists group. This enabled the NHSO to buy hard lenses for only 800 baht (comared to the market price 6,000 baht) and folding lenses for only 2,800 baht (compared to the market price 20,000 - 30,000 baht). These savings are supporting the development of cataract surgery treatment nationwide along with the development of a mobile cataract surgery unit starting from a network of ophthalmologists Ban Phaeo Hospital and Suphamit Hospital Suphanburi Province, expanding out to patients across the country. This outreach service is 20-50 times cheaper than the price of surgery at a private hospital, making it possible to provide a wide range of services to the public as well.



MANAGEMENT OF MEDICAL SUPPLIES THAT CREATES NEW TREATMENT APPROACHES FOR BENEFICIARIES

The selection process for medicines under this central procurement management mechanism has led to the provision of effective and affordable therapeutic technologies to provide people with more equal access to health care.²³ One case is the procurement of Bevacizumab injection under the list of E(2) for the treatment of age-related macular degeneration and diabetic macular degeneration.⁴⁶

The NHSO has collaborated with the Health Intervention and Technology Assessment Program and the Retina Society of the Royal College of Ophthalmologists. Together, they lobbied for adding injectable Bevacizumab (formerly a cancer drug) to the National List of Essential Drugs in 2012 under the E(2) drug sub-list for the treatment of macular degeneration caused by aging, types with abnormal blood vessels, and diabetic macular degeneration. In 2013. Thailand became the first country in the world to list Bevacizumab in its List of Essential Drugs for retinopathy. Bevacizumab injection is primarily intended as a replacement for Ranibizumab injection for the treatment of conventional macular degeneration. Previously, the price was inaccessibly high (45,000 baht per injection), meaning that the vast majority of macular degeneration patients were unable to access treatment, and suffered disabilities. However, the NHSO system was able to reduce the cost of administering Bevacizumab injection to as little as 500-1,000 baht per injection, which is cheaper than the traditional drug Ranibizumab. The registration fee for Ranibizumab injection was reduced to approximately 1,400 million baht. In addition, service applications were expanded to include Bevacizumab injection to treat retinal vein thrombosis as a collateral benefit, starting in 2019.46



MANAGEMENT OF MEDICAL SUPPLIES THAT CONTRIBUTE TO DRUG SECURITY FOR THE PEOPLE

Management of pharmaceuticals is optimally conducted through a central procurement management mechanism, allowing all parties involved to know the demand and supply of different drugs and medical supplies. The system uses information technology to collect, process, and share the relevant data. This will not only help determine the budget and manage the drugs in each procurement cycle, it also allows pharmaceutical companies to have clear production and import plans. This is especially important for the rare drug group and wherever there are limitations, as in the case of management of orphan drugs and anti-venom drugs. This has led to policy advocacy to develop the orphan drug manufacturing industry in the group of anti-venom drugs and snake anti-venom serum for own use in the country.¹⁵ This also supports establishing a backup network for anti-venom and anti-venom serum according to the incidence of poisoning by region.

However, there remain some critical issues related to processes under the central procurement mechanism, such as transparency, accountability, promoting stakeholder participation, and building confidence in the quality of medical supplies at both the personnel and service levels which the NHSO needs to address. These issues can be summarized as follows:

Using the GIS technology: The network is centered around a toxicology center attached to Ramathibodi and Siriraj Hospitals. The center serves as a backup drug distribution and medicine service. It also provides consultations on patient care 24 hours a day.¹⁷

The comprehensive pharmaceutical management system for orphan medicines, anti-venom and snake anti-venom drugs group makes it possible to save the lives of people who have been poisoned, quickly and efficiently. The success in increasing access to these types of drugs can increase the survival rate for poisonous snake bite to 98% in those who receive the drug.²¹ Thailand's management of these drugs has been hailed by the WHO as a "best practice" that can be leveraged to strengthen orphan and anti-toxin security networks in Southeast Asia and the Asia-Pacific region. That recognition should be a source of great pride for the country.¹⁶

8.6

FACILITATING PATIENT ACCESS TO MEDICAL SUPPLIES

One of the main contributions of the central procurement management mechanism is the reduction of barriers to patient access to healthcare, both financial and physical. This is especially the case for patients in the disease group with ultra-high treatment costs. The mechanism aims to ensure continuous treatment and access to quality and safe medical supplies without the patient having to worry about the burden of medical expenses and the need to travel to receive services in some special cases. For example, in the case of end-stage renal disease patients, the NHSO, together with the Friends of Nephrology Association, lobbied for the "PD First" policy to provide services to patients across the country under the UCS. In addition, the delivery of dialysis fluids to the patient's home was arranged by the GPO in cooperation with the Thailand Post Co. through its network of delivery points across the country. As a result, patients have more access to treatment, better quality of life, and increased survival rates.35

8.7 REDUCING STEPS IN THE PROCESS TO INCREASE COST-EFFECTIVENESS AND EFFICIENCY OF THE PHARMACEUTICAL SYSTEM

Systematic management of pharmaceutical inventory together with the use of information systems for disbursement of medical supplies address the challenge of aligning medical stocks with consumption needs.²⁷ The system also improves distribution efficiency. In the case of ARV drug resupply, the NHSO has developed a PLHIV database, and works with the GPO to manage the backup and distribution of ARVs through the VMI system for drug delivery from the GPO's pharmaceutical inventory directly to the service point.

Management of this pharmaceutical inventory system has resulted in a change in the storage and distribution of ARV drugs, which can reduce provincial and regional drug stock depots, and increase the speed and accuracy of stock quantities for distribution for just-in-time delivery. This has resulted in savings of approximately one billion baht in 2009 from the 4.382 billion baht expenditure in the 2008 budget.⁸ The savings from ARV drug administration was used for the development of other drug management projects, including a project to promote 100% condom use, and increasing public access to other essential medical supplies such as CAPD and the influenza vaccine program for at-risk populations.

9 STRENGTHS, CHALLENGES AND AREAS FOR IMPROVEMENT

When analyzing the national pharmaceutical management system of the NHSO, a study by Chutima Akkaleephan et al in 2020³ found that organizing a central procurement management mechanism not only benefited patients by improving access to health services, it also benefitted the service unit by reducing the burden of procurement of specific medicines. The system removes the burden on the health care facility to decide whether or not to add this or that drug to the health care provider's list of medicines. If the hospital has the capacity and conditions to be able to order medical supplies without worrying about the burden of managing medical supplies with the money of the service unit under the per capita budget, that also reduces the process of procurement of hospitals that must comply with the laws and regulations of government supplies management as well.

The system clearly improves the efficiency of services, and it could achieve the following main objectives:

- Patients have access to essential medicines without financial barriers; thus, there is more equal access to essential medical supplies
- 2 The system achieves a balance between reasonable drug prices and Thailand's affordability³⁹
- 3 The system is able to make appropriate corrections to deficiencies of administration (governance) of the integrated pharmaceutical system in terms of drug availability, ¹⁵ and maintaining a balance between drug prices, costs, and competition among drug manufacturers/ distributors, where conventional mechanisms are unable to operate effectively.³



In terms of service engagement and trust, the NHSO has positioned its role as a central platform where all stakeholders can voice their opinions, articulate views, and participate in planning to enhance 'Shared Public Policy Ownership.'²⁹ Stakeholders can join to create a body of knowledge from a comprehensive study of impacts, in terms of effectiveness, safety, and economics.⁷ They can gain experience in managing individual pharmaceutical supply challenges with a dedicated team of professionals, with quality assurance of pharmaceutical products from production through the preparation of specific properties of pharmaceuticals. All of these processes have bossted confidence of service providers under the NHSO system.³



There is transparency in terms of verifiable and cost-effective management. The NHSO has established a database system that connects service providers, deploys distribution guidelines using information technology, and practices efficient budget management. The NHSO uses the information to monitor, track, and evaluate performance and make collaborative decisions based on an empirical analysis of evidence.²¹ This is done together with the committees/ sub-committees and working groups in every step. There is also a clear time frame and criteria for evaluating budget management and the pharmaceutical cycle, as well as providing two-way communication channels to the people and all relevant sectors which can translate the plan into action in the most efficient way.



For support of the pharmaceutical supply system, the NHSO has established a conceptual framework, goals, visions, plans, and timeframes to mobilize human resource groups/ partners, working groups, and experts to plan financial management, organize the process of recording data regulations and guidelines, as well as having a strong determination to work for the public good in accordance with the principles of good governance.³

From the review of related literature, it was found that the arrangement of bargains and collective procurement mechanisms at the national level has the following strengths, challenges, and areas for improvement:

9.1 THE STRENGTHS OF THE CENTRAL PROCUREMENT MANAGEMENT MECHANISM

Operations are based on the principles of good governance.¹¹

1

6

- 2 There are clear procedures and standards for implementation, with a focus on participatory learning, knowledge management, education, and planning. There is research as a basis for academic knowledge related to clinical, pharmaceuticals, economics, finance, and policy impacts in all respects.
- 3 There is a communication system that emphasizes mutual decision-making, and the opinions of all sectors are taken into account.⁶
- 4 There is an information technology system to keep track of the relevant, up-to-date information. There is efficient drug management that is verifiable and transparent. Budget management is cost-effective and sustainable.
- 5 There are working network partners and experienced personnel with expertise and understanding of the pharmaceutical supply system and each type of accessibility problem.
 - The Thai mechanism can be a model of "good practice" in adding structural procurement efficiency at the national level that fosters participation, transparency, accountability, and good governance.

9.2 CHALLENGES AND AREAS FOR IMPROVEMENT

1

Proactive dissemination of results:

The NHSO has carried out annual data collection on the economic value of pharmaceuticals under special projects provided through the central procurement management mechanism. However, the main objective of the collection of such information is to report the results of the procurement to the National Health Security Board and deliver them to the related agencies as requested on a case-by-case basis only. Therefore, in order to publicize and disseminate the work of the NHSO, as well as to promote the corporate image in its policy implementation, the NHSO may consider collecting and disseminating information in terms of economic value-per-purchase of individual medical supplies per purchasing cycle. Reports of that information should highlight the budget saved from the mechanism of procurement, and how the savings are used to improve health services and produce benefits for other diseases/health conditions under the UCS.



Challenges in organizing chemotherapy drugs:

Chemotherapy is a high-price treatment that ranks in the top three on the list of the highest-value medicines disbursed from each facility's drug inventory. These drugs have specific characteristics that require a central mechanism of management, and that is one of the challenges facing the NHSO in managing budgets. The comprehensive chemotherapy drug management system needs to be refined. From the literature review, there were no clear and systematic guidelines for such a management system. Thus, problems continue to fester, such as insufficient supply of drugs when needed, delays in drug delivery to the patient, accumulation of near-expiring medicines, preventable patient death before the end of the treatment process, loss in compensation from health funds for this group of drugs, etc.⁴⁷ 3

Modification of the management structure: The management restructuring took place from 2018 - present, with a shift from the NHSO-GPO as the purchasing operator to the MOPH-Rajavithi Network as the operator. This modification of the working style increased transparency and participation from stakeholders in all the subcommittees and working groups. However, there are concerns in terms of priorities from the reduction of the role of the Drug Selection Subcommittee to just a working group under the Planning Sub-Committee. This structural modification may result in limiting the focus of the working group to purchasing planning instead of considering medical supplies that are essential to the needs of the people. Another issue is the expanding membership of subcommittees from various agencies and departments. The increase in members may cause a delay in making timely decisions, and there may be gaps in communication because each work process has more people involved. With too many actors, a sense of true ownership of the work has withered. This may require long-term consideration related to the effectiveness of this structure for the management of pharmaceuticals under special programs.³

4

The budget for supplying medical supplies under special projects is increasing every year due to the expansion of coverage of medical supplies and higher survival rate of patients, especially those with chronic diseases requiring life-long treatment.¹³ That trend may threaten the viability of the budget in the long run. Therefore, the working group may need to focus on the study of available therapeutic technologies, rigorous cost-effectiveness to support sustainable fiscal management and planning, and support parallel projects for promotion and prevention to reduce the incidence of costly NCDs and epidemics. For example, this could include the development of earlystage nephrotic screening services, development of media/channels to educate the public about prevention of NCD, etc.

SUMMARY

Over a decade in operation, the NHSO has initiated the development of a central bargaining and procurement mechanism to create health services that truly meet the needs of patients and society on the basis of good governance. Such a mechanism is not only a sustainable way to increase people's access to health services. It also strengthens the participation of stakeholders in the design and advocacy of a joint medical service delivery policy. This leads to upgrading and improving the implementation guidelines of service units to be more efficient, timely, with greater coverage of disease, and boosting confidence in the treatment service system and the quality of medical supplies and services received.

The mechanism of bargaining and procurement at the national level is a mechanism that produces good results across every component. That includes the selection, procurement, reserve stock, and distribution of medical supplies that meet the needs of the people. The cost-effectiveness in use of budget is maximized by the increased negotiating power via larger aggregate purchase volume, as well as helping to control budgets, and manage the limited supply of essential medicines for a sustainable, systematic drug inventory management system. This leads to expanding services to cover different types of diseases, greater use of treatment technology, and truly meet the vision and mission of the UCS to cover all beneficiaries in an equal and quality way.

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CENTRAL NEGOTIATION AND PROCUREMENT FOR ACCESSIBILITY OF ESSENTIAL MEDICAL SUPPLIES AND EFFICIENT USE OF RESOURCES

Project on Knowledge Management, Lesson Learnt Reflection and Dissemination of National Health Security Office [NHSO]

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FIRST PUBLISHED e-book 2021

NATIONAL HEALTH SECURITY OFFICE

The Government Complex Commemorating His Majesty the King's 80th Birthday Anniversary 5th December, B.E.2550 (2007) Building B 120 Moo 3 Chaengwattana Road, Lak Si District, Bangkok 10210 Phone : 02-141-4000 (Office hours) Fax : 02-143-9730 - 1 Website : www.nhso.go.th GPS : 13.8828179, 100.5652935 E-mail : Internhso@gmail.com Facebook : https://ww.facebook.com/NHSOInter

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