VIETNAM TRIP REPORT

Thailand-Vietnam Experience Sharing Workshop on National Centralized Drug Procurement and Price Negotiation

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HANOI, VIETNAM

HITAP International Unit (HIU)

Disclaimer Page

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Abbreviations

ARV	Antiretroviral
BHSP	Basic Health Service Package
DOH	Department of Health
DHS	District Health System
GPO	Government Pharmaceutical Organization
HITAP	Health Intervention and Technology Assessment Program
HIS	Health Service Management Software
HSPI	Health Strategy and Policy Institute
HTA	Health Technology Assessment
iDSI	International Decision Support Initiative
MOH	Ministry of Health
NCDPC	National Centralized Drug Procurement Center
NHIPCM	National Health Insurance Policy Consulting Committee
NHSO	National Health Security Office
NLEM	National List of Essential Medicines
PSS	Provincial Social Security
SHI	Social Health Insurance
UC	Universal Coverage Scheme
UHC	Universal Health Coverage

VMI	Vendor Management Inventory
VSS	Vietnam Social Security
WHO	World Health Organization

Introduction

Health Intervention and Technology Assessment Program (HITAP), Ministry of Public Health through the International Decision Support Initiative (iDSI) has been working in Vietnam since 2014. iDSI has supported Ministry of Health (MOH) Vietnam in realising Universal Health Coverage (UHC) through a different approach, to instil health technology assessment (HTA) principles and capacity at multiple levels of priority-setting.

As part of our collaboration with Health Strategy and Policy Institute or HSPI, the focal HTA unit within MOH Vietnam and iDSI, there are several of successful collaborative projects. Three HTA studies i.e. cost-effectiveness of pegylated-interferon in treatment of chronic hepatitis C infection, the study on the diffusion of magnetic resonance imaging device, and cost-effectiveness of trastuzumab in patients with HER-2 positive breast cancer have been conducted in the context of Vietnam and have been a valuable input to inform a national policy in Vietnam. In addition, a wider impact of HTA is observed in a study of reviewing the Basic Health Service Package (BHSP). The recommendation to specify medical indications for high cost medicines and medical devices could lead to a significant budget saved of National Health Insurance namely the Vietnam Social Security Scheme (VSS).

The impact and usefulness of HTA can enhance the uptake of HTA. HTA is considered by stakeholders in Vietnam as effective tool, and increasingly used to improve the efficient use of healthcare resources. The following are example of the application of HTA in Vietnam by various stakeholders. Several HTA studies have been conducted universities in Vietnam. The Department of Health Insurance's policy under MOH for having information on cost-effectiveness submitted for inclusion of new medicines for the reimbursement list has been in place since March 2017. HTA group under the National Health Insurance Policy Consulting Committee (NHIPCM) has been established since 2016. The members of HTA group are responsible for advising and consulting for NHIPCM in technical review for HTA's evidence. The first HTA Guideline in Vietnam where is in the stages of development will be used by Health Insurance Council established by VSS. Lastly, the National Centralized Drug Procurement Center (NCDPC), MOH is newly established in late 2016 as one of key policy to reform drug procurement aiming price control and quality assurance.

Thai experts including HITAP were invited to attend several meetings to share Thai experiences on UHC, Thai healthcare system, HTA, and key priorities issues related to UHC such as procurement and price negotiation. In June 2018, NCDPC organized the Thailand-Vietnam Experience Sharing Workshop on National Centralized Drug Procurement and Price Negotiation from 28 to 29 June 2018 in Hanoi, Thailand and invited HITAP staff i.e. Netnapis Suchonwanish, Nitichen Kittiratchakool, and Waranya Rattanavipapong together with representatives from National Health Security Office (NHSO) and Government Pharmaceutical Organization (GPO) to attend the workshop to share Thai experience on drug procurement and strategies for price negotiation.

Summary of the workshop

Thailand-Vietnam Experience Sharing Workshop on National Centralized Drug Procurement and Price Negotiation

A high proportion of drug-related public expenditure is allocated to the procurement and supply of drug at different levels in Vietnam i.e. central level, regional level, and health facilities level. Moving to effective centralized procurement for health products can yield huge budget savings across the country. Therefore, the National Centre for Drug procurement (NCDPC) under Ministry of Health (MOH) is nominated and established in late 2016 as one of the key policies to reform drug procurement and finally impact to price control and quality assurance. With support from the United States Agency for International Development, NCDPC organized Thailand-Vietnam Experience Sharing Workshop on National Centralized Drug Procurement and Price Negotiation on 28-29 June 2018 to learn from Thai experience on drug procurement and price negotiation, with the aim that the lessons learnt from Thai model and knowledge can be customized and applied in the context of Vietnam.

Centralized Procurement in Vietnam

Nguyen Tri Dzung, the director of NCDPC introduced NCDPC and the centralized procurement system in Vietnam. The NCDPC is the center under MOH and established under the Resolution No.112/NQ-CP on 30 December 2016 with the two main functions: to organize centralized procurement and price negotiation of priority medicines. In Vietnam, drug procurement and supply are conducted in 3 levels: central, provincial, and health facilities which are more than 26,000 public health facilities across Vietnam.

Criteria of drug selections subjected to national centralized bidding basically come from the high budget of drug consumptions across the country, such as medicines for treating NCDs, cancer, diabetes, cardiovascular diseases and numbers of medicines required intensive supply chain management in Vietnam. In general, the bidding can be undertaken by the provincial Department of Health (DOH) or the assigned units. The winning venders have to commit the supply to each level of facilities in every province even occupied under other ministries. Criteria for drug selection at the provincial level are the items in

essential medicines list with high consumption in the provinces or item requiring intensive supply chain management.

Apart from the bidding at central and provincial levels, the individual procurement by each health facilities with different items can be conducted separately if the drug utilization profile can't be converged. The health facilities can select the items and sign a contract with the suppliers directly.

At the central level, process is explained in Figure 1. NCDPC collects and reviews drug quantification data submitted by hospitals and the provincial DOH. In 2017, NCDPC organized centralized drug bidding for 22 drugs which saved approximately 477 billion Vietnamese Dong (21 million USD) to the government budget. One of challenges is how to forecast the proper demand represented the actual utilization. Then the NCDPC will develop internal reference prices referred from the historical bid-winning prices of health facilities from MOH and VSS websites. If they're not available, the prices will be obtained from manufacturers later. All the items will be divided into two categories: originators and generic products. Bargaining plans are prepared according to geographical regions i.e. North, Center, and South and socioeconomic regions. MOH is responsible for evaluating and selecting contractors. Evaluation is based on a review of validity of technical and financial proposals, qualification and experience of the contractors. The results of evaluation will be summarized and ranked in a scoring system. The contractor with the highest total scores will be invited to the price negotiation. Lastly, NCDPC will negotiate with the selected contractors on the framework agreement including supply capacity, the committed volumes and prices of the products.

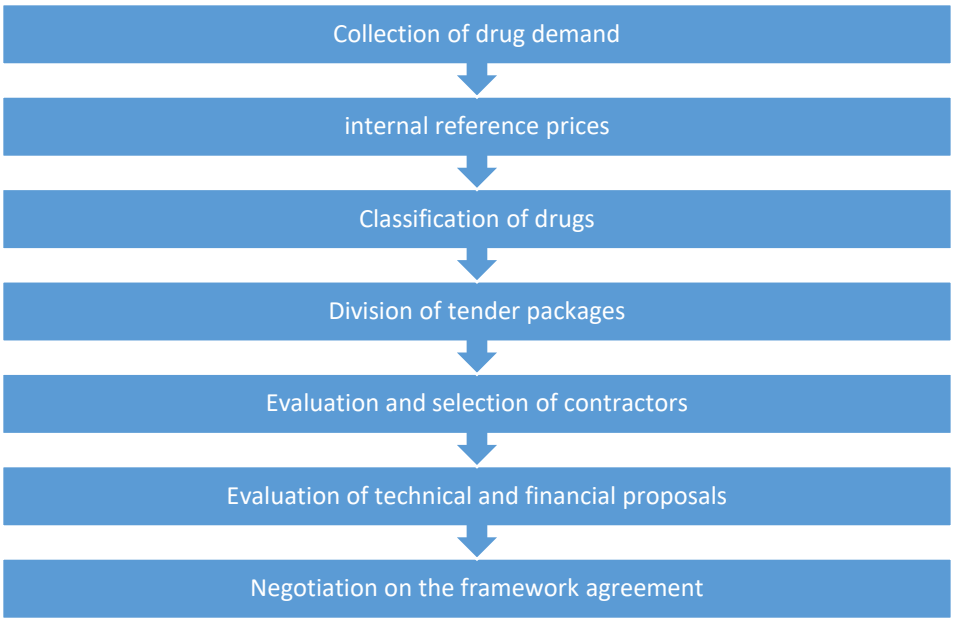


Figure 1. Bidding steps at the central level

Regulation, List and Methods for Drug Price Negotiation in Vietnam

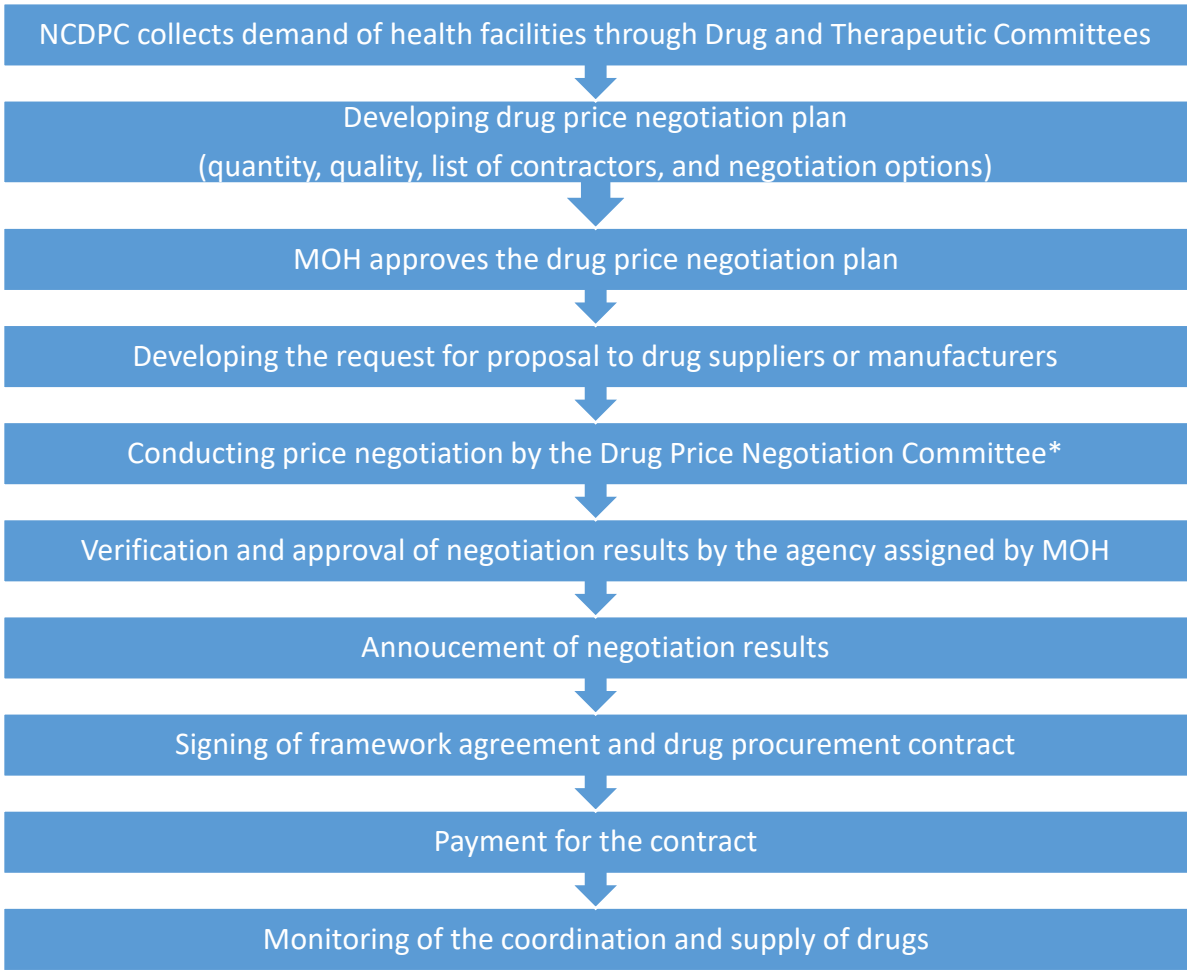
Ha Noi Ngay the vice director of NCDPC presents the process of drug price negotiation in Vietnam. Law on public procurement stated that price negotiation shall be applied to procurement of drugs which there are monopoly or oligopoly, branded originators, rare disease medicines, patent medicines and to other intensive supply chain control items. Following that, MOH Vietnam issues the list of medicines subjected to price negotiation and NCDPC will further organize the price negotiation process.

The following are criteria for selection of the drugs subjected to price negotiation:

- Competitiveness – on the basis of the needs of health facilities. There is low or no competitiveness in terms of price
- Branded originators
- Rare disease drugs
- Supply capacity – drugs are produced by one or two manufacturers
- intensive supply chain control – narcotic drugs, psychotropic drugs, and precursors

Example of drugs subjected to price negotiation are Cerebrolysin, Imipenem+ Cilastatin, Sorafenib, Rituximab, Docetaxel, Oxaliplatin, and Paclitaxel.

Process and steps of drug price negotiation is demonstrated in Figure 2. The whole process takes one year.



*The Drug Price Negotiation Committee chaired by Deputy Minister of Health, and consist of Deputy Director of VSS, Director of NCDPC, Director of the Public Procurement Agency, representatives from MOH departments, Head of Pharmaceuticals and Medical Supply Department VSS, Department of Price Management, Ministry of Finance.

Figure 2. Process and steps of drug price negotiation in Vietnam

The information required for price negotiation are:

- Sale price in manufacturing country or in ASEAN countries
- Sale prices of drugs in Vietnam with similar quality and comparative clinical efficacy
- Contractors' commitments to production capacity, quality assurance, and service delivery system
- Certificate of analysis provided by contractors

Management and payment of ARV drugs for insured patients

Tran Manh Hai, Specialist of VSS provides information about management and payment of antiretroviral (ARV) treatment for insured patients in Vietnam, which includes a situation of ARV management, requirement for management and payment of ARV drugs from 2019, and solutions and roles of concerned agencies.

Currently, the management of ARV drugs in Vietnam has been financed by three sectors. President's Emergency Funds for AIDS Relief (PEPFAR) and Global Fund support HIV patients in HIV projects, while the rest patients are supported by state's budget. The health facilities in 63 provinces are responsible for monitoring ARV drugs distribution and treatment process of patients through their management applications which are various among provinces. EPIMS is mostly used in Vietnam, it is implemented in 32 provinces. However, it is separated from hospital information system (HIS). The data form health facilities is transferred to provincial HIV/AIDS agency which is responsible for summarizing and estimating ARV drugs demands. Then, the requirements are sent to the Vietnam Administration for HIV/AIDS Control that acts as distributor manager (see Figure 3). Furthermore, Vietnam faces with redundant prescriptions because of no national HIV/AIDS patients database management.

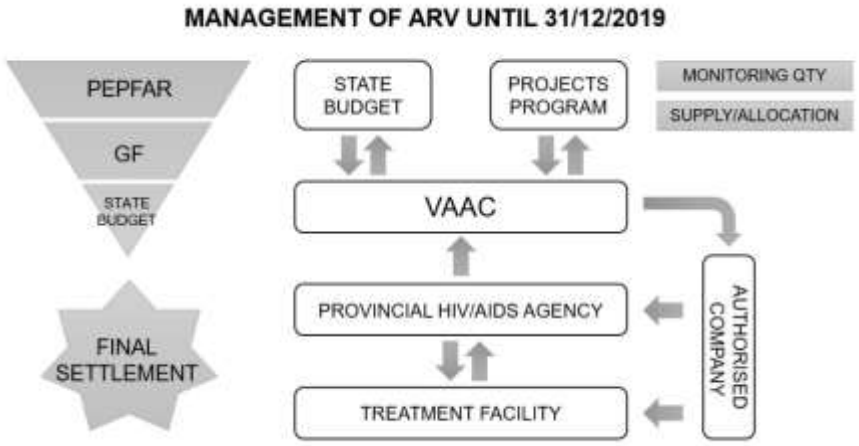


Figure 3. Management of ARV drugs for insured patients

Additionally, the policy of establishment a central procurement in ARVs drugs funded by the Social Health Insurance (SHI) has been come up with the drive of the Prime Minister's Decision on 15 November 2016. Therefore, in 1 January 2019 the new management of ARV drugs will be implemented as shown in Figure 4. The Central Procurement Center, the Center for Claim Review and Multi-Line Payment, and Provincial Social Security (PSS) or District Social Security will contribute in the new system. For payment of ARV drugs, the budget will be subsidized by SHI in case of uncovered by other sources. However, there is an overlapping prescriptions of ARV drugs because the medical record of patients are not consolidated.

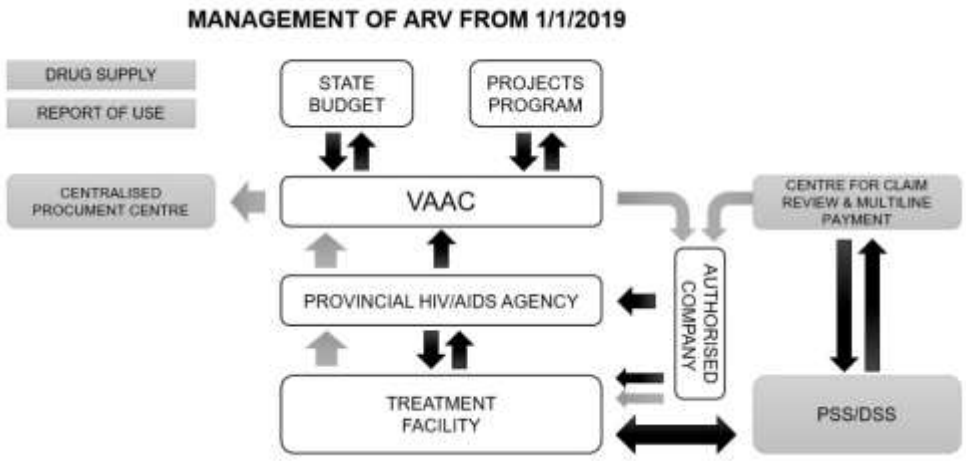


Figure 4. Management of ARV for insured patients

Following this, the government plans to develop and link electronic database at a national level. Involving agencies of this issue are MOH, VSS, healthcare facilities, DOH, specialised agency, and PSS. Roles of each organization are described below.

MOH and VSS:

- Develop national database, and issue the authorization code for managing the HIV/AIDS patients information system
- Develop central management of all medical records at the central level
- Establish a private cloud for ARVs drugs providers in order to provide the data exchange
- Develop an online software that integrates HIS and EPIMS

Healthcare facilities:

- Generate a list of ARV patients
- Verify medical history via health insurance card or ID
- Encode and track ARVs separately by source
- Link data immediately at the end of the examination visit or treatment course

DOH, specialised agency, and PSS:

- Assist and coordinate the medical facilities in the locality
- Monitor the use, allocation, supply and payment of drugs

Overview of Health System in Thailand and Thailand's UHC development

Netnapis Suchonwanich, Former Deputy Secretary General of NHSO and Advisor of HITAP shared an overview of Health System in Thailand and Thailand's UHC development to the audience. There are three health insurance schemes in Thailand:

- Civil Servant Medical Benefit Scheme covers government employees, dependent and retirees (7.66% of population),
- Social Health Insurance covers private sector employees (18.07% of population), and
- Universal Coverage or UC covers the rest of population (74.27% of population)

UC scheme has been launched since 2002 with the aim to ensure that Thai people can access to effective healthcare services when needed and to provide effective protection impoverishment or catastrophic illness expenditure of beneficiaries' household. UC scheme is managed by NHSO and under the supervision and control of the National Health Security Board, chaired by Minister of Public Health. The internal operation in NHSO is divided into two main sections, the head quarter and regional offices. The head quarter office is responsible for policy and planning, fund administration, developing service models, system support as well as monitoring and evaluation. Regional Health Security Offices take responsibility for administering and monitoring the fund management at the regional level.

In addition to National List of Essential Medicines (NLEM), NHSO initiates the UC benefit packages of non-pharmaceutical products. The benefit packages cover an essential and high-cost care, such as coverage for renal replacement therapy, kidney transplantation, kidney dialysis, heart surgery, and cancer treatment. In principle, the development of benefit packages is guided by an evidence including HTA.

The Criteria for adopting new interventions into the benefit packages are cost-effectiveness, catastrophic prevention, budget impact, ethical concerns and supply side capacity to scale up new intervention (feasibility).

One of the NHSO mandate is to develop a mechanism that support the work of the healthcare providers (contractors) under UC scheme. The main contractors are MOPH hospitals (70%), private hospitals and clinics. Figure 5 shows the existing health service deliveries system in Thailand.

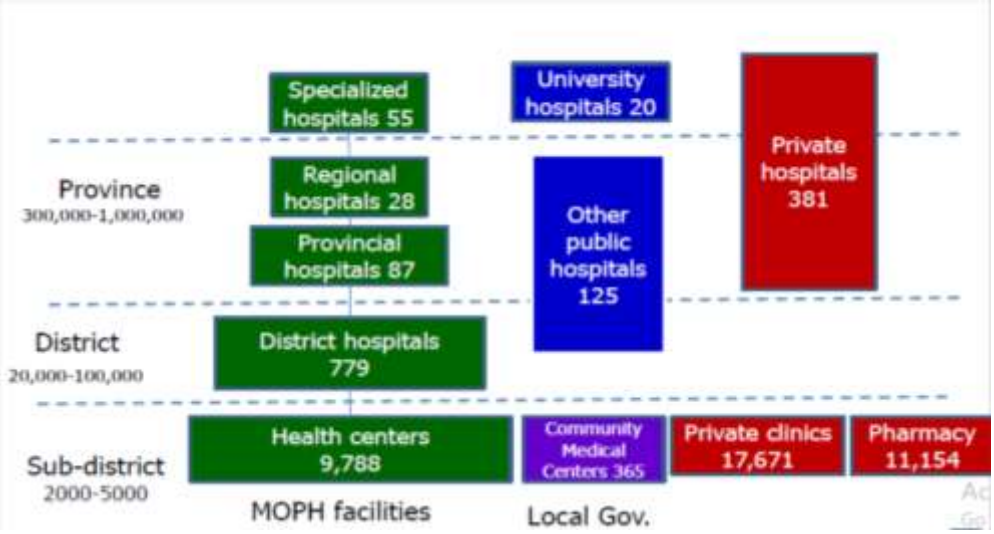


Figure 5. The existing health service deliveries system in Thailand

All of health services providers have to be registered and approved for quality accreditation before becoming the contracting units in the UC scheme. To assure the sufficient service providers in UC scheme at the beginning of UCS implementation, every public facilities have compulsory announced as the providers in UC scheme regarding to the cabinet's resolution in 2002. For private providers (hospitals or clinics), they can individually apply the registration and be approved for quality accreditations before becoming the providers in UC scheme.

In general, the district health system (DHS) in Thailand will be designed as a contracting unit of primary care or main provider network represented as a gate keeper for outpatient care. Beneficiaries in the nearby area are automatically assigned to their local DHS. Patients can be referred to provincial hospitals or regional excellent centres by the specialists' approvals. However, in remote area, the patients bypassing primary care units to the main contractors without referral are still liable for reimbursement regarding to the geographic convenience. The NHSO also developed system to protect UC beneficiaries such as a hotline 1330 to provide information services and complaints managements.

Every fiscal year, the UC scheme is financed by general tax revenue. The NHSO proposes the annual budget per capita calculation mainly according to unit cost of services provided. The capitation comprises of labour cost, material cost, public utility cost, and depreciation. The UC budget is divided into numbers of sub-funds:

- Basic healthcare: outpatient general services; inpatient general services; health promotion and disease prevention services; rehabilitation services; high cost care and accident & emergency care; targeted services; and no-fault liability

For some special diseases which need more intensive interventions have to be requested for extra budget line such as :

- Antiretroviral (ARV) drugs
- Renal replacement therapy
- Secondary prevention for NCD
- Long-term care
- Etc.

Several strategies have been come up in order to achieve the accessibility to essential medicines by assigning the government pharmaceutical organization (GPO) which is the state pharma to conduct the national central bargain. This policy has a big impact not only to reduce drug purchasing budget every year but also secure continuity of the supplies by conducting the collective bargaining for more than 10 project approximately 125 items of special access items such as oncology medicines, ARV drugs, orphan drugs and vaccines etc. Nevertheless, the distribution of all the products are delivered through Vendor Management Inventory (VMI) programme directly to every main contractors with monitoring system by using the tracking process.

Antiretroviral (ARV) Drugs Procurement under Thai UHC

This presentation is given by Somruethai Supungul, Project Manager, Bureau of medicines, medical supplies and vaccine management at NHSO. At the beginning of UCs' implementation, ARV drugs were not included in the benefit package due to high budget impact. The number of patients who access to ARV

drugs were relatively low. Until the compulsory licensing have been introduced for many ARV items and GPO has locally produced a fixed-dose combination of ARV drugs regimen at a low price, the NHSO board has make a decision to include the ARV drugs into UC benefit packages in order to increase the access. Eventually, ARV drugs (Effevirenz and Lopinavir/Ritonavir) were integrated into UHC in 2006. And more ARV drugs were listed in NLEM during 2010-2012.

The same like the management for the special access medicines, the ARV drugs are implemented by conducting a centralized management. Drugs procurement and inventory are managed at the national level and delivered to the service providers according to their own dispensing data submitted to the NHSO. All the data will automatically generate the purchasing orders and transfer to the GPO for issuing the delivery order by hospitals later.

Figure 6 shows the national procurement mechanism managed by NHSO. Technical and general specification about medicines' profiles are obtained from Pharmacopoeia and the recommendation from World Health Organization (WHO). Demand forecasting comprises of purchasing plan and plan for price negotiation. Purchasing plan is developed based on clinical protocol and compared with utilization rate from the previous year. Budget impact analysis is estimated for developing the budget control in price negotiation by using the international reference prices.

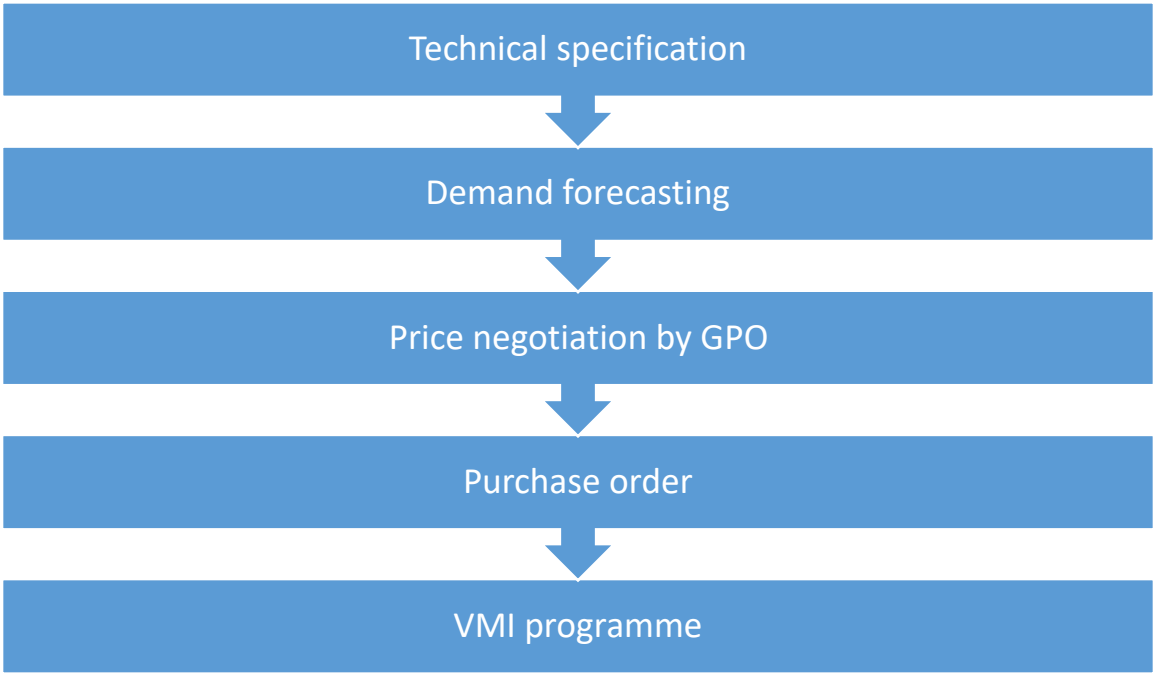


Figure 6. The national procurement mechanism managed by NHSO

Inventory Management and Distribution System in Thailand

Kasinee Juthasawat from Supply Chain Management Division at GPO presents Inventory Management and Distribution System in Thailand. The GPO's roles are

- To manufacture, sell, and supply qualified pharmaceutical products and medical supplies across the country
- To provide the affordable price for pharmaceutical products and medical supplies necessary for all Thais in order to ensure the accessibility to health needs
- To research and develop the innovations both in pharmaceutical products and medical supplies to catch up with the expectation to the patients and health professionals

So far, there are three types of medicines that are managed by GPO: GPO products, local products, and imported products. The delivery system through VMI is implemented and facilitate the inventory management for MOPH and NHSO by order. The VMI system has been developed by using the centralized database with the automatically data exchange with NHSO's dispensing data by using Java message

service. The application can reduce the hospitals' burden and make better allocate their stock as it will monitor the stocks and process to replenish if they meet the reorder point. The online system will enhance inventory accurately and avoid stock out or overstock. Figure 7 depicts an overall process of VMI.

Figure 7. An overall process of Vendor Managed Inventory

Medicine prices and access to medicine

Netnapis Suchonwanich shares the experience on how to use the HTA in benefit package development and price negotiation. In fact , HTA is a key factor for improvement of patient access to essential medicines. Health Economic Working Group and Price Negotiation Working Group are supporting the Subcommittee for NLEM in the selection process of new drugs in NLEM. Local cost-effectiveness and budget impact analyses approved by Health Economic Working Group will be submitted to Subcommittee for NLEM for their consideration. The medicines with cost-effective result are likely to be included in NLEM. For those that are not cost-effective under the threshold of 160,000 THB (5,000 USD) per QALY gained, but considered to be more effective compared to standard treatment, price negotiation can be conducted by Price Negotiation Working Group.

A framework of price negotiation review includes clinical aspects, country contexts, epidemiological data, costs, local cost-effectiveness and budget impact analyses, and price negotiation model. Benchmark price

will be identified by using information on cost-effectiveness result, international reference price, domestic reference price, and clinical practice guidelines. Different models of price negotiation have been developed. For example, value-based pricing, volume purchase, market competition, voluntary licensing, risk sharing, choose one price, and medicine patent pool. Finally, the negotiated price will be announced in Royal Thai Government Gazette on National List of Essential Medicines.

Discussion

After the presentation, there is a session for questions and answers. The discussion is around asking Thai experts to share experience on the process and mechanism related to procurement and price negotiation that are implemented in Thailand.

Drug bidding organized at different levels – In Thailand, NHSO's central procurement is selected and organized for some special access items. For example: monopoly medicines (to increase the power of negotiation), vaccine (as it requires an efficient delivery system), and orphan drugs (lack of interest by pharma).

Collecting drug demands from health facilities for ARV drugs – NHSO collects the utilization data by hospitals from the online application which special designed for HIV. Every patient is required to register in the system. The case manager in the hospital has to key in the health service and dispensing data into the system on a daily basis (30-45 days) for making reimbursement process. By this mechanism, NHSO can obtain the demand from each hospital. However, buffer stock is still needed to allow adjustment to the meet the safety volume. Every MAY, the demand forecasting is done at the central level for the next fiscal year purchasing.

Frequently of negotiation process – NHSO conducts negotiation once a year.

Classification of drugs between branded originators and generics – NLEM states generic names. Prescription of originator in the hospitals are allowed but the reimbursement will be referred to generic one if there is local availability as the payment mechanism for out-patients in UCs is designed by using capitation. So, it means that the providers have to subsidize the risk of the additional costs for the originators.

Pricing in Thailand – For medicines in NLEM, negotiated price by Price Negotiation Working Group will be referred as NLEM price at national level. However, at this step there is no central procurement. After medicine included in NLEM, MOPH can bargain the price with generics, and make a contract (fixed price with flexible volume) with manufacturers. The reference price is now set and used for a procurement for every public hospital. Basically, the health insurance including NHSO can refer to NLEM or MOPH prices for their procurement or negotiate again with collaboration with GPO for central bargain.

IT system – IT system play a very crucial role in procurement and payment mechanism. It makes the service utilization data submitted to NHSO more accurate. Well-designed IT system that link to all stakeholders e.g. health insurance, MOH, providers, is useful for collecting data for M&E purpose. Central reimbursement in Thailand requires pre-authorization which link to hospital laboratory, hospital registration and beneficiary enrolment system.

Medicine price used in HTA – Medicine price used in the economic model isn't necessary to be final price. The price negotiation working group can negotiate the price again until it meets the affordability. In addition, HTA will allow the price comparison and compete between different medicines in the same disease/therapeutic use.

Prevention and promotion interventions – Prevention and promotion interventions basically designs by calculating another capitation called "PP capitation" under the capitation per head got from the government. In some PP benefit packages, the NHSO may design the vertical program for particular PP activity in order to strengthen the access. The payment mechanism of vertical program is pay by fee schedule.

Thailand's HIV/AIDS database – Before the implementation of UC in Thailand, the Department of Disease Control had registered the HIV/AIDS patients by using the client server program called "NAPHA". After the implementation of UCS, the legacy system and all the data have been migrated to web-based application called "NAP" program. This program generates new identification number called NAP ID number due to confidential purpose. During transitional period, data cleansing and registration of missing patients were required to cover the uninsured into the program. Thai experts recommend Vietnam government to firstly implement national ID number and use health security ID number in patients who do not have the national

ID number. In addition, overlapping prescription of medication can be avoided by defining the specific hospital for each patient, so that they cannot received ARV drugs from more than two hospitals.

Sharing the software used for ARV management – Thailand is willing to share the software used for managing ARV drugs, but there is a major concern about the difference in pharmaceutical management system between both countries. In Thailand, hospitals are responsible for submitting data of ARV drugs needed to NHSO. Then, the NHSO will verify the data and send the purchase orders to GPO which are in charge of monitoring and summarizing the requirement by hospitals. The Information will be issued the delivery order for GPO or sent to pharmaceutical companies for ordering and then the ARV drugs will be delivered to each hospital. This means that there is no payment among hospitals, GPO, and pharmaceutical companies. The management through software may not match with Vietnam's context.

Budget allocation for HIV/AIDS patients – Patients can be divided into two group according to diagnosis and indication. In case they visit the hospital due to non-HIV indications (routine), these are paid by DRG. In contrast, if they come to hospital because of indication related to HIV, they are supported by HIV subcategory fund for the medicines or other services listed (voluntary counselling) and reimbursed with DRG or capitation for other routine services

Source of high cost drugs – Actually, high cost drugs are defined as the high cost drugs or drugs used in rare cases. The name list of them is raised to the development of NLEM of Thailand processed by the Working Groups of National Experts' on NLEM subcommittee. Additionally, most of the high cost drugs in NLEM E(2) category are defined as special access items, and are funded by central reimbursement and distributed by using smart VMI system and setting the buffer stock not more than 1.5 months.

Contribution of GPO on all drugs used in Thailand – GPO is responsible for delivering approximately 300 items which is equal to 10% of all drugs used in Thailand. Average regular time to delivery is about 5 – 7 days after receiving the orders. In case of any problems, time to delivery depends on supply, but it is not more than two weeks. For the other 90%, the medicine prices are controlled by using standard price and also control the quality by initiating price performance approach for drug procurement.

Estimation of drug requirement – In Vietnam, VSS assigns healthcare facilities to estimate the quantity of drugs requirement and submit to VSS. This leads to difficult controlling because of the inaccurate demands. Thai experts recommend VSS should monitor the requirement every three months, because if there are any mistakes or errors, they can correct it in time. Furthermore, pharmaceutical companies may support VSS by matching data of real consumption amount with the requirement from hospitals to identify the precise amount of the utilization.