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Socialist Republic of Viet Nam: Strengthening the Policy and Institutional Framework of Social Health Insurance

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Asian Development Bank
NATIONAL PLAN FOR THE DEVELOPMENT OF HEALTH TECHNOLOGY ASSESSMENT IN VIET NAM

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I. BACKGROUND

Implementing the goal of universal health care coverage is a top priority in health policies in many countries, including Viet Nam. To achieve universal health care coverage, it is necessary to mobilize large financial resources. However, that is not a sufficient condition to ensure the goal of universal health care coverage. Another very important factor is the need to allocate and use available resources efficiently. The World Health Organization's report on universal health care coverage in 2010 pointed out that wasteful investment and use of medicines and medical technology is one of the main causes of inefficiencies in health service delivery. Increasing efficiency in the use of resources for health becomes even more important for low- and middle-income countries such as Viet Nam, where health costs are increasing while financial resources are still very limited. Therefore, determining a reasonable priority in the allocation of health financial resources including the health insurance fund is a very important issue for policy makers. One of the effective tools to help policy makers decide in prioritizing is the health technology assessment (HTA) [1]. The primary objective of the HTA is to assist policymakers in making evidence-based policy decisions regarding the application of health technologies. This is especially important in determining priorities for allocating health care resources to achieve universal health coverage with limited resources. [2]

Recently, in 2014 the World Health Organization issued Resolution No. WHA67.23 on Health Intervention and Technology Assessment in support of universal health coverage, which affirmed the important role of HTA in providing evidence for the prioritization, selection, use, and management of health interventions and technologies for prevention, health promotion, diagnosis, treatment, and health promotion [3]. Resolution requires member states establish the national systems of HTA, national capacity building on HTA.
The Viet Nam’s health system is now emerging a number of priority policy issues in which the Health Technology Assessment will make an important and practical contribution to the development of these policies. The priority policy issues are:

- Development of an appropriate package of health care benefits
- Selection of drugs and medical services covered by health insurance
- Strengthen the rational use of drugs and medical services, develop standard treatment guidelines.
- Determining drug and medical service prices in line with the health insurance fund’s ability to pay and the state budget.

While there is high demand from health policy formulation for HTA evidence the Health Technology Assessment is still relatively new in Viet Nam. Evaluation of health technology assessment in Viet Nam is currently almost undeveloped in terms of both research and use of research results in policy making. In order to develop a sustainable, comprehensive and solid health assessment system to meet the requirements of effectively supporting the development of health policies, especially the health insurance benefits policy, the Asian Development Bank supports the Ministry of Health. The Vietnamese health sector develops a national plan to develop a medical technology assessment system in Viet Nam. [4, 5]

II. SITUATIONAL ANALYSIS OF HEALTH TECHNOLOGY ASSESSMENT IN VIET NAM: A SWOT ANALYSIS

A. Achievements – Strengths

(i) The interest and awareness of the role of HTA have been improved. Understanding HTA has reachable lifted, especially for
policy makers. Units and organizations including international organizations, NGOs, the private sector and businesses have cooperated to organize a number of seminars and conferences on HTA. The focal units to organize seminars on HTA include; Health Strategy and Policy Institute (HSPI), Health Economics Association, Health Insurance Department, Hanoi University of Public Health, Viet Nam Social Security. These seminars were chaired by leaders of the Ministry of Health with the participation of representatives of the parties and international experts presented and consulted at the seminar. Through seminars, knowledge and awareness of HTA has been enhanced and at the same time created consensus and connections between research units and policy-making agencies

(ii) **Legislation for HTA.** There have been some contents related to HTA mentioned in a number of legal documents:

- Resolution 20-NQ / TW of the Central Committee on strengthening the protection, care and improve people's health in the new situation has stressed the need for "Building an equitable, quality, efficient and integrated health system"

- Decision No. 122/QD-TTg 10/01/2013 of the Government on the National Strategy to protect, care for and improve people's health for the period 2011-2020: “Developing standards and implementing health technology assessment to identify efficacious, effective, low-cost health interventions that ensure quality of health services"

- On August 31, 2018, the Ministry of Health issued Decision No. 5315/QD-BYT promulgating principles and criteria for building a list of modern drugs covered by health insurance in which for the first time evidence of Budget impact and
cost-effectiveness scientific evidence are included as criteria for new drugs added to the formulary.

On January 11, 2021, the Price Negotiating Council - Ministry of Health issued the Decision of the Chairman of the Drug Price Negotiating Council, promulgating a set of criteria for evaluating brand-name drugs on the list of drugs subject to the application of the law. method of price negotiation according to Circular 15/2020/TT-BYT dated 10/8/2020, in which the criteria of cost, efficacy of treatment and evidence of cost-effectiveness are among the promulgated criteria.

(iii) **Conducted a draft of process guidelines on HTA implementation.** Health technology assessment is a new field, with strict requirements and principles on methods and procedures to ensure research results are consistent with the requirements of policy development, scientific rigor, quality evidence. HTA results are eventually should be acknowledged and used by stakeholders. The World Health Organization has recommended that member countries consider developing national guidelines on the process and methods of implementing HTA. Responding to that requirement, in 2018, the Health Strategy and Policy Institute (HSPI) with the technical support of HITAP - developed a draft of the process guidelines for the implementation of the HTA. The draft was submitted for comments at a stakeholder workshop. At the same time, HSPI has also developed a Draft Guidelines on methods of conducting Health Technology Assessment with the participation of experienced experts in the fields of health economics and pharmaceutical economics. In 2020, the Health Insurance Department coordinated the development of the Pharmaceutical Economics Reporting Guidelines. These are
important initial efforts to develop the National Guidelines on HTA to improve the quality of HTA evidence for policy development.

(iv) **Conducted a number of HTA studies that provide evidence for health policy formulation.** A number of HTA studies have been carried out according to the process associated with the need for policy formulation right from the time the research topic is identified. These topics focus on a number of high-cost drugs and technical services, accounting for a large proportion of total health insurance payments, and are in the group of drugs being considered for addition or adjustment in the drug list covered by health insurance such as: Evaluation of the cost-effectiveness of Trastuzumab in the treatment of breast cancer, Evaluation of the cost-effectiveness of Peg-Interferon in the treatment of chronic hepatitis C, Evaluation of the use of 14 drugs and 3 techniques diagnostic imaging has the highest health insurance reimbursement 2015 (CT, MRI, PET CT). The results from these studies have provided evidence for policy development on the scope of health insurance benefits including Circular No. 35/2016/TB-BYT issued on September 28, 2016 Promulgating the list and rate of health insurance benefits, payment conditions for medical technical services within the scope of benefits of the participants of health insurance; Circular No. 30/2018/TB-BYT promulgating the list and payment rates and conditions for chemical drugs, biological products, radioactive drugs and markers within the scope of benefits of health insurance participants. Recently, in response to the request of the National Drug Procurement Center, the Health Strategy and Policy Institute has conducted a study to synthesize evidence on the effectiveness, cost-effectiveness of 4 drugs on the list of drugs on the list of drug price negotiations in 2018. The results of this study have been used and contributed to the success of the drug price
negotiation in 2018 with the cost savings from the price reduction of 4 drugs estimated at more than VND 500 billion.

(v) *Training and capacity building HTA has achieved certain achievements:*

- **Short-term training:** the training courses on HTA have been held separately or in the form of side meetings of the Annual Conference on Health Technology Assessment since 2018. The content of these training courses includes topics related to the methods of conducting HTA such as cost analysis, systematic review, model building, etc. The training courses were attended by a large number of participants from the Ministry of Health, research units, universities with training in health economics/pharmaceutical economics, hospitals, and pharmaceutical companies.

- **Long-term training at home and abroad:** In recent years, the training of postgraduate human resources in health economics and medical assessment has been interested in the units that are implementing HTA such as the Health Strategy and Policy Institute, the Hanoi University of Public Health, Hanoi University of Pharmacy, University of Medicine and Pharmacy in Ho Chi Minh City, Hue Medical University ... Particularly during 4 years from 2016 to 2019, HSPI has had 02 researchers graduated Master training programs in Health Economics abroad and other 02 researchers completed the doctoral training program on health technology assessment in Thailand. In the country, although there is no code for training in health economic/health technology assessment, there are still PhD students who successfully defended topics in this field according to the industry code of Pharmaceutical Management Organization. The number of master’s and
doctoral theses on health economic evaluation has increased in recent years.

- International cooperation: Through specific projects and programs at a number of units, the Ministry of Health has strengthened international cooperation in training, research and information exchange, connecting with international organizations. International health assessment such as HITAP, IDSi, HTAsiaLink, HTAi, WHO.

B. Limitations- Weaknesses

(i) Governance of HTA system

- Do not have legislative requirements to formalize the incorporation of the results of HTA in health care decision making. There is no regulations required the use of HTA evidences in developing health policies in general and policy on health insurance benefits in particular. There is no regulation on the organization of the implementation of the HTA, the roles, responsibilities and coordination of the stakeholders in the process of carrying out the HTA from the stage of selection of the research topic to implementing the HTA, using the results in policy formulation and finally conducting impact assessment of the use of HTA evidence in policy formulation.

- Do not have HTA focal point agency yet. There is no formal mechanism to link HTA unit and policy makers. This unit will play an important role in coordinating the HTA activities and connecting between the implementing units and the users of the HTA results.
Awareness of the importance of health technology assessment among key people involved in the development of health insurance reimbursement policies is still incomplete and inconsistent. This leads to the lack of attention and use of evidence HTA in policy making and decision making, especially in the process of developing health insurance benefit packages.

(ii) **Health information system and database for HTA**
- Heath information system is not well managed, fragmented and inconsistent. There is low availability of database used in HTA such as clinical trial data, health service cost data, payment threshold data. This is significant barrier for HTA development since HTA is a highly analytical and multidisciplinary process which requires a wide breadth of information.
- Difficult to collect local data or data is inaccurate.
- Information technology infrastructure has not yet supported the HTA.

(iii) **Human resources for implementing HTA**
- There is still a gap in capacity of the team to carry out the HTA: both in quantity and quality of human resources for implementing HTA. HTA involves many fields including drugs, medical devices, clinical practice, health promotion, disease prevention and health policy. HTA exercise not only requires technical skill such as systematic review, data analysis but also include interpersonal skills for working with stakeholders and communications skills to transfer messages to non-technical partner.
• The coordination between research units is not good. Limited cooperation and information sharing among experts/researchers, leading to waste of resources as well as inconsistencies in methods and results of pharmaceutical economic evaluation.

• There is no training code for either health economic or HTA yet.

• There has not been adequate and sustainable source of funding for the implementation of HTA activities. Currently, the HTA activities are mainly funded from international cooperation projects or from a number of multinational pharmaceutical companies. Securing funding from public financial sources, including the state budget and social insurance, is an important factor for the sustainable development of HTA as well as helping to control the issue of conflicts of interest.

(iv) **The use of the results of HTA research** in developing policies is still quite limited, not systematic and without a standardized process.

• Decision No. 5315/QD-BYT promulgating principles and criteria for building a list of modern drugs covered by health insurance which requires and encourages applicants to submit a pharmaceutical economic assessment report (including a cost-effectiveness assessment report and a budget impact assessment report) but there are no specific instructions on the application process, standards of pharmaceutical economic evaluation reports as well as principles, criteria and rating scale for pharmaceutical economic evaluation reports.
C. Opportunities

(i) Decision 5315/QD-BYT dated August 31, 2018 of the Ministry of Health on principles and criteria for building a list of modern drugs covered by health insurance

- Require all new drugs to have a budget impact assessment
- Encouragement of cost-effective assessment reports in Vietnam

(ii) The development of the revised Law on Health Insurance has been included in the policy agenda of the Ministry of Health 2021-2022. This is an opportunity window for the advocacy of legislation of HTA evidence requirements in developing health insurance benefit policies.

(iii) International support: WHO Resolution: in 2014, at sixty seventh health assembly adoption of WHA 67.23/2014 on health intervention and technology assessment in support of the UHC. In this Resolution, WHO has emphasized the role and importance of HTA in support of universal health coverage to inform policy decisions, including priority-setting, selection, procurement supply system management and use of health interventions and/or technologies, as well as the formulation of sustainable financing benefit packages, medicines, benefits management including pharmaceutical formularies, clinical practice guidelines and protocols for public health programmes. Requiring Member States to establish national HTA systems, to encourage systematic use of independent HTA in support of UHC by providing evidence and information for key decision-making books include prioritizing, selecting, managing the supply and use of medical technology as well as developing sustainable benefit policies. Strengthening the link between HTA and management and administration. Develop national guidelines on the methods, procedures and monitoring
systems to ensure transparency, quality, and compliance with the policies of regulatory studies. Consolidate and promote HTA in other areas and programs at the national level such as health system research, health workforce education, health system strengthening, and health care coverage. Strengthening national capacity for regional and international network activities, promoting cooperation in sharing resources/information. Develop and implement a national strategic plan on capacity building for HTA. Identify gaps in promoting and implementing evidence-based health policy, improve information systems, research capacity, seek technical assistance from other Member States or international organizations.

(iv) The Association of Southeast Asian Nations (ASEAN): In the ASEAN Health Cluster 3 (AHC3) Work Plan for 2016–2020, there is a need to provide insights into the current status, capacity, and needs of HTA institutions in the ASEAN region to inform the development of the future work plan and further build the capacity of AMS to undertake HTA.

(v) The promotion of information technology application and digital transformation in the health sector are a favorable premise for the building of a database to facilitate HTA development including electronic medical records, health insurance payment data, personal health records, etc. The 10-year socio-economic development strategy for 2021-2030 has clearly stated the task: “to build and put into operation an integrated system, connecting and connecting institutions. large databases, especially data on population, health, education, insurance.”
D. Challenges

(i) In the context of rising health costs related to the burden of NCDs, rapid population aging along with the need to access new drugs, expensive new medical technologies put great pressure on the state budget for health as well such as the Health Insurance Fund. The increasing demand for HTA evidence requires a timely response while the development of HTA is still limited.

(ii) Providing evidence in a timely manner, meeting the requirements of policy makers is always a big challenge for HTA research units. In order to comply with strict requirements on the process and method of HTA, it takes time and resources, while the requirements for providing evidence for policy development are often limited in time.

(iii) There is always a conflict of interest among stakeholders in the field of HTA, posing challenges for effective and appropriate management and handling conflict of interest.

(iv) The implementation of the policy of renovation and organizational arrangement of the political system is lean, effective and efficient; streamlining, downsizing: resolution 120/2020 / ND-CP on the establishment, reorganization and dissolution of units of public service. Under this policy guidelines, there is strict control over the formulation of any new agency.

(v) The promotion of digital transformation in the medical field is an opportunity for the development of HTA, but it also comes with the challenge of data security and patient safety.
III. OBJECTIVES

A. General objective

Developing a system of health assessment to promote the use of medical assessment in formulating effective and sustainable health insurance benefits policies.

B. Specific objectives

(i) To build up structure and operational mechanism for HTA system works in an appropriate, feasible and effective manner.
(ii) To improve the capacity to implement timely, effective and quality health technology assessment for health insurance policy development.
(iii) Promoting the use of HTA evidence in developing health insurance benefit policies.
Figure 1: Theoretical framework for developing a strategic plan for the development of medical technology assessment in Viet Nam

- Better health for all people

Impact

- Access to healthcare for all people

Long-term outcomes

- Equitable, efficient, effective use of resources for health

Intermediate outcomes

- Institutionalizing HTA

- Political commitment
- HTA providing evidence for policy decision making
- HTA scientific rigor

Outputs

- Stakeholder's participation
- Legislative requirements
- Focal point agency
- Guidelines/Roadmap
- Project/studies
- Trained human resources

Activities

- Training
- Guiding/Consulting
- Coordinating stakeholder's participation
- Mobilizing resources
IV. ACTIVITIES

A. Objective 1: To build up structure and operational mechanism for HTA system works in an appropriate, feasible and effective manner

Activity 1: Establishment of the focal point HTA unit under Ministry of Health: Functions and tasks of this unit is connected between the HTA implementing agencies and policy making bodies who eventually use HTA results. This focal unit is responsible for coordinating and implementing health assessment activities to serve the development of health insurance benefits policy and at the same time organizing the appraisal of HTA reports. On the basis of appraisal results, it provides reliable and valuable evidence to advise and propose policies on health insurance benefits [6, 7]. This unit acts as the technical focal point for HTA of the Ministry of Health. Regarding organizational structure, in the short-term, it is advised to establish a task force – a working group on health technology assessment under the Department of Health Insurance - the focal point for health insurance policies in Ministry of Health. The human resources of the working group are staff with expertise and experience in the field of health economics / HTA, who are working in units and organizations that have played an active role in this field in recent years. The staff are mobilized to work for the working group under the part-time regime, with specific tasks assigned. After a certain period of operation, this HTA working group can be consolidated and upgraded to be a HTA focal point agency under the Ministry of Health. A project on establishment of this HTA focal point agency will be developed with full functions, tasks, scope of activities, human resources and regular operating budget allocation.
(i) Implementing unit: The preparation of contents and procedures for proposing the establishment of a Health Assessment Working Group will be carried out by the Department of Health Insurance.

(ii) Funding for the operation of the working group will be provided from the budget of the Ministry of Health, funds mobilized from international organizations, programs, projects and other lawful funding sources.

(iii) Expected results: The decision to establish a focal point on HTA was issued.
Activity 2: Formulation of Network on Health Technology Assessment in Viet Nam. The network was established with the main function of connecting researchers, policy makers and beneficiaries in information sharing activities, supporting research to evaluate pharmaceutical economics, as well as strengthen the application of the results of pharmaceutical economic studies and policy formulation and decision-making problems. The network has missions that include:

(i) Communicating and raising awareness about the role of HTA in health policy development
(ii) Collecting and building database on the research products
(iii) Building a shared database for the HTA
(iv) Coordinating activities for capacity building, training, sharing experience and guiding HTA implementation.
(v) Connecting with international and regional HTA networks
(vi) Consulting, proposing policies and regulations on the use of HTA in health policy development

- Implementation: Network on Health Technology Assessment in Viet Nam will be operated by the Executive Board assisted with Secretariat Group. The network has its operational regulations and its own website.
- Funds for operation of the Network: mobilized from the contributions of members and mobilized from international organizations, programs, projects and other legal funding sources.
- Expected output: The Network on Health Technology Assessment in Viet Nam is established

Activity 3: Development of process guidelines for HTA implementation in support health insurance package policy développement in Viet Nam

(i) The success and effectiveness of a HTA study depends not only on the quality of the evidence presented, but also on the research implementation process. These are two factors that are especially
important in the field of HTA because the participation of stakeholders in the health industry assessment process has a great influence on the policy-making process [8, 9]. Thus, it necessary to have a process guideline for the implementation of a HTA to ensure a transparent, systematical approach and to mobilize the participation of relevant stakeholders. This guidance document should outline the basic principles involved in determining the key steps and necessary actions to be taken in the HTA process, who is involved in those activities, and basic principles when performing such activities [8]. The HTA process is usually divided into 4 main phases based on the time frame of the study, including (i) selection of research topics; (ii) HTA research implementation; (iii) validation of research results (after research results have been provided); (iv) use research results in formulating payment policies.

(ii) Implementing unit: The development of the process guidelines for the HTA implementation in Viet Nam will be carried out by the HTA Task Force in collaboration with the Health Strategy and Policy Institute, who developed the draft of this Guide in 2018.

(iii) Expenses: From the budget of the Ministry of Health allocate to the Department of Health Insurance and the Health Strategy and Policy Institute.

(iv) Expected Outputs: Process guidelines for the HTA implementation in Viet Nam is issued by the MOH

B. Objective 2: To improve the capacity to implement timely, effective and quality health technology assessment for health insurance policy development
**Activity 1:** Implementing domestic training on HTA specialized for undergraduate and graduate degrees at medical and pharmaceutical universities and research institute.

In order to create sustainable and quality human resources for the field of health technology assessment, specialized training programs at undergraduate level, master's and doctoral programs in health technology assessment will be developed, officially approved and implemented at a number of medical pharmaceutical universities, medical research institutes in Viet Nam. Specific activities include:

(i) Develop and approve the training syllabus

(ii) Having training code on HTA/Health economic and assigning training volume target for training entities.

(iii) Recruiting, conducting training, building output evaluation criteria for trainees.

(iv) Develop and implement mechanisms to encourage enrollment for registered students, as well as recruitment policies for graduates specialized in medical technology assessment.

- Implementing unit: Medical and pharmaceutical universities, research institutes in health of Viet Nam
- Funding: Funding from the state budget, regular funding, or autonomy/partial autonomy of universities. Mains n funds from the scholarship fund, encouragement be mobilized from the budget support programs, projects and other legal funding.
- Expected output: Having training code on Health economics/HTA. Number of undergraduate and graduate students in Health Economics/HTA.
Activity 2: Organizing short-term training, training workshop on HTA/Pharmaco-economic. Organize re-training, short-term training on HTA for researchers, lecturers and staff who are implementing HTA activities. The content of the training courses focused on the topics of HTA methodology and application in Viet Nam, guidance on the preparation of dossiers and reports on HTA. These training courses can be organized by different units and organizations who interested in HTA capacity development. However, information about these training courses should be transferred through the Viet Nam Health Technology Assessment Network to increase connectivity and coordination of training activities in this field.

(i) Executing unit: Units and organizations with the function of training and improving research capacity of Health Economics / HTA.

(ii) Funding: from the state budget allocated to units and organizations. Funding from the contributions of participants, mobilized from the support funds of programs, projects and other lawful funds.

(iii) Expected output: Number of short-term training courses on HTA/Pharmaceutical economics held. Number of attended trainees.

Activity 3: Developing method guidelines on HTA implementation. Health technology assessment is a new field, with strict requirements and principles on methods and procedures to ensure research results are consistent with the requirements of policy development, scientific rigor, quality evidence. HTA results are eventually acknowledged and used by stakeholders [10, 11]. The World Health Organization has recommended that member countries consider developing national guidelines on the process and methods of implementing HTA [12]. Promulgating this Guidelines to achieve the following objectives: (i) standardization of HTA report submitted in applicant dossier for new drugs
included in health insurance payments; (ii) improve the quality and strengthen the development of HTA in Viet Nam; (iii) assisting policy makers in making decisions based on evidence for the application of medical technology by providing HTA review checklist developed on the basis of this method guidelines.

This document will provide guidance on how to conduct a Health Technology Assessment, including updating and providing guidance on how to apply the basic principles of how to conduct a health technology assessment in real-world conditions. of Viet Nam. In this Guide, the scope of the HTA focuses on drugs, biological products, medical equipment and supplies, procedures, procedures, and surgery that are covered by health insurance. This guideline is intended to serve mainly the audiences directly involved with the development of the HTA report and the appraisal and use of this report, specifically: policy makers, researchers in the field of HTA, pharmaceutical companies are required to prepare a budget impact assessment report and a pharmaceutical economic assessment report to submit together with the application for inclusion of new drugs on the list of health insurance payments.

(i) Executing unit: The focal point of the HTA assessment, the units and organizations that carry out the HTA research.

(ii) Funding: from the state budget allocated to units and organizations. Funding from sources mobilized from support funds of programs, projects and other lawful funds.

(iii) Expected Outputs: Guidelines for the implementation of the HTA issued by the MOH

**Activity 4**: Improving technical infrastructure to facilitate HTA development: determining cost effective threshold for Viet Nam and strengthening health information system and database for HTA.
Viet Nam has not yet identified a cost-effective threshold as a basis for cost-effectiveness assessment of health interventions based on incremental costs to achieve an additional 1 QALY (ICER) identified. Currently, the assessment is still based on the payment threshold based on GDP per capita set by WHO, specifically:

(i) Very cost-effective intervention: if ICER is less than 1 GDP per capita
(ii) Cost-effective intervention if ICER is greater than 1 GDP per capita and less than 3 GDP per capita.
(iii) Not cost-effective intervention if ICER is greater than 3 GDP per capita.

In fact, many countries have conducted surveys and studies to determine the payment threshold in accordance with the national context, priorities and ability to pay for health [13]. Research to identify cost-effective thresholds should be planned and implemented within the framework of this National Plan for the Development of HTA in Viet Nam.

Design of a HTA study requires many different types of data at the national scale. The lack of data or inaccurate data greatly hinders the study, not being performed or if done, the results will be less reliable [12, 13]. In recent years, Viet Nam has made great progress in building national database especially the national database on health insurance. This database of the Viet Nam Social Security has covered more than 90% of the population with information on medical examination and treatment covered by health insurance of about 170 million visits per year. Decree No. 43/2021/ND-CP dated March 31, 2021 introduced information in the database as well as regulations on the mechanism of information collection and sharing. However, to facilitate HTA in support policy development, it needs to regulate the access, use and sharing
data among stakeholders. In order to improve the information and data system for HTA, specific activities should be carried out as follows:

(i) Conducting an inventory of data and information requirements required for the HTA;
(ii) Mapping the available data sources in the country to meet the data and information requirements needed for the HTA in Viet Nam;
(iii) Develop rules and mechanism for sharing and using national data in the HTA in Viet Nam.

- Executing unit: The HTA focal point agency, the units and organizations that carry out the HTA research.
- Funding: from the state budget allocated to units and organizations. Funding from sources mobilized from support funds of programs, projects and other lawful funds.
- Expected output: Viet Nam's cost-effective threshold is determined and published. Regulations on data sources available to HTA and national data use and sharing mechanism.

Activity 5: Promoting international cooperation in the field of Health Technology Assessment. Compared with many developed countries in the world and in the region, Viet Nam is a newcomer in the development of HTA. Cooperation, exchange of experiences and taking advantage of international support are strategies to achieve the goal of developing HTA in Viet Nam. The strengthening of international cooperation is done through network activities on HTA in the region and around the world, through projects and programs with development partners, through seminars, international forum on medical technology assessment, visiting prestigious pharmaceutical economic evaluation units in the region and in the world.

(i) Executing unit: The HTA focal point agency, the units and organizations that carry out the HTA.
(ii) Funding: from the state budget allocated to units and organizations. Funding from sources mobilized from support funds of programs, projects and other lawful funds.

(iii) Expected outputs: Units and individuals conducting HTA research participate in international cooperation projects, regional and international HTA networks.

C. **Objective 3: Promote the use of evidence of health technology assessment in formulating health insurance benefits policy**

**Activity 1:** Advocating for the inclusion of regulations on the use of HTA results in formulating health insurance benefits policies into the revised Law on Health Insurance.

The program to develop the Law on Amending the Law on Health Insurance is a very good opportunity for legalizing the requirement to use evidence from the HTA for decision-making on health insurance benefits in order to increase efficiency in resource allocation and use of limited funding of the Health Insurance Fund. To achieve this goal, it is necessary to carefully prepare a policy advocacy plan including the following main contents:

(i) Prepare necessary technical documents to be used during the campaign,

(ii) Develop a detailed advocacy plan, including: objects to be influenced, identify the content and ways of conveying information to the objects to be influenced, and develop key message points for each object to be influenced, communication activities, determine resources to carry out communication activities, implementation schedule.

(iii) Implement the campaign plan.

(iv) Monitor and evaluate results.
• Executing unit: The HTA focal point agency, relevant units and organizations in the HTA.
• Funding: from the state budget allocated to units and organizations. Funding from sources mobilized from support funds of programs, projects and other lawful funds.
• Output expected: the Health Insurance Law has provisions on the use of HTA results in policy development entitlements.

**Activity 2:** Develop and officially issue standard procedures and criteria for decision-making, especially in formulating policies on health insurance benefits.

Although there is no law on the use of HTA evidence in formulating health insurance benefits policy, Decision 5315 has initially established the requirement for HTA to meet the criteria for inclusion of new drugs on the list of drugs covered by health insurance. To effectively implement this regulation, it is necessary to develop a document on the HTA appraisal process and publish it widely to all relevant units to increase awareness and unify HTA practice. The content of the document on the HTA appraisal process should cover all stages of the HTA appraisal from (i) receiving and preliminarily reviewing the HTA application; (ii) official examination; (iii) supplement of required documents and re-examination (if necessary); and (iv) acceptance of results & conclusions. Administrative processes and stakeholder involvement should be clearly defined at each stage. Information on estimated timeframes should be included in this document to avoid delays in HTA implementation & validation.

In addition, in order to synchronize and systematize the process of implementing and evaluating HTA, a set of standard evaluation criteria should
be developed based on the current situation of using health technology assessment and the demand for HTA application in Viet Nam. Within each component, a list of criteria should be agreed upon with specific requirements in terms of compulsivity, necessity, and transparency. This set of criteria is an important tool for the appraisal and use of the results of the HTA.

(i) Executing unit: The HTA focal point agency, relevant units and organizations in the HTA.
(ii) Funding: from the state budget allocated to units and organizations. Funding from sources mobilized from support funds of programs, projects and other lawful funds.
(iii) Expected output: the standard process and criteria in decision-making to develop policies on health insurance benefits are issued.

Activity 3: Organizing seminars, panel discussion on health technology assessment, pharmaceutical economic assessment in Viet Nam.

One of the important factors influencing the use of HTA results in policy formulation is the awareness and consensus on the role of HTA evidence in making policy decisions. Therefore, it is necessary to organize workshops and seminars on health technology assessment, pharmaceutical economic assessment in Viet Nam with the participation of policy makers, officials from the Ministry of Health, Viet Nam Social Security and related agencies.

(i) Executing unit: The HTA focal point agency, relevant units and organizations in the HTA.
(ii) Funding: from the state budget allocated to units and organizations. Funding from sources mobilized from support funds of programs, projects and other lawful funds.
(iii) Expected output: Number of managers, policy makers attending seminars, seminars
V. TIMELINES AND DELIVERABLES

Period 2021-2023: The following activities will be carried out:

(i) Approving the Development Plan for HTA in Viet Nam to the year 2025
(ii) Establishment of a task force on health technology assessment under the Department of Health Insurance
(iii) Establishment of the Viet Nam HTA Network
(iv) Advocate to include regulations on the use of HTA results in formulating health insurance benefits policies into the revised Law on Health Insurance.
(v) Develop and officially issue standard procedures and criteria in decision-making, especially in formulating policies on health insurance benefits.
(vi) Promulgating the method guidelines on HTA implementation
(vii) Organize training, short-term training on HTA/pharmaceutical economics
(viii) Improve the information system and database for the HTA
(ix) Participating in the regional and global network of HTA
(x) Development of international cooperation projects and programs on HTA
(xi) Organizing seminars and panel discussion on health technology assessment, pharmaceutical economic assessment in Viet Nam

Period 2024-2025: The following activities will be carried out:

(i) Establishment of the HTA focal point agency under the Ministry of Health
(ii) Issuing process guidelines on the implementation HTA for the development of health insurance benefits policy
(iii) Implement specialized training at undergraduate and graduate levels on medical technology assessment at a number of medical pharmaceutical universities and research institutes.

(iv) Determining the cost-effectiveness threshold of Viet Nam
REFERENCES

1. Oortwijn, W., D. Mathijssen J Fau - Banta, and D. Banta, *The role of health technology assessment on pharmaceutical reimbursement in selected middle-income countries.* (1872-6054 (Electronic)).


4. *CADTH 2018-2021 strategic plan: Transforming how we manage health technologies in support of better health, better patient experience, and better value.* 2018.


10. Tantivess, S., A. Teerawattananon Y Fau - Mills, and A. Mills, *Strengthening cost-effectiveness analysis in Thailand through the*
establishment of the health intervention and technology assessment program. (1179-2027 (Electronic)).

