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Exploring alternative funding mechanisms to improve patient access to innovative medicines

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Abstract

Background Despite the existence of universal health coverage for citizens in Thailand, patient access to innovative medicines remains a challenge given the rapid pace of scientific development and high cost of new therapies. Thai policymakers currently focus almost exclusively on incremental cost-effectiveness ratios (ICERs) and budget impact without considering flexibilities for decision-making. Payers are deprived of tools to manage financial and clinical uncertainties resulting in severely restricted access for patients. This research aims to identify the potential funding mechanisms and implementation approaches in the Thai context to improve access to high-cost innovative medicines.

Methods A research program was conducted in two phases; focus group discussions with 21 key stakeholders and further in-depth interviews with senior Thai key stakeholders. The first phase sought participants' ranking of the top five selected financing mechanisms according to feasibility and attractiveness. The second phase utilized in-depth interviews to explore implementation approaches within the Thai context.

Results Managed entry agreements (MEAs) and ring-fenced funding for innovative medicines were viewed favorably. These approaches were deemed easier to implement, providing an acceptable balance of risk and effort between all parties in the ecosystem and efficiently improving patients' outcomes. High-cost innovative medicines for oncology, rare diseases, and life-threatening diseases with no alternative treatments were recommended as prioritized therapy areas for MEAs. A key priority is a need for a framework to implement MEAs into the current Thai health technology assessment (HTA) process. Additional key considerations included the need to integrate innovative funding mechanisms and establish pilot projects to test the viability of MEAs in Thailand.

Conclusions In conclusion, all participants acknowledged and endorsed using tangible financial-based solutions (MEAs and ring-fenced funding) for Thailand. Prioritizing equal access to innovative medicines by such initiatives will go a long way in promoting a healthier and more productive Thai society.

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Keywords Financial strategies, Health technology assessment, High-cost innovation, Cancer therapy, Patient access, Thailand

Background

Thailand is an exemplary success story of a healthcare system achieving universal health coverage (UHC). Since its introduction in 2002, more than 99% of the population has been covered by one of three public insurance schemes: 72% by the Universal Coverage Scheme (UCS), 8.5% by the Civil Servant Medical Benefit Scheme (CSMBS), and 18.5% by the Social Security Scheme (SSS) [1].

Although Thailand is classified as an upper middle-income country (UMIC), Thailand has relatively low reimbursable access to high-costing drugs such as anti-cancer and rare diseases drugs [2, 3]. While the number of regulatory approvals when benchmarked to the World Health Organization - Essential Medicines List (WHO-EML) and the National Comprehensive Cancer Network (NCCN) recommended drug lists are high (97.5% and 78% respectively) [4], reimbursable access is considerably lower. The problem is especially severe for innovative therapies, with novel drugs for some advanced cancers receiving between 0 and 20% reimbursable access [5].

The variations in access under the three public insurance schemes have been associated with concrete differences in survival outcomes. Patients under Thailand's CSMBS public insurance scheme have slightly greater access to reimbursable high-cost anti-cancer drugs than SSS or UCS patients [4]. This results in significantly poorer 5-year overall survival among UCS or SSS patients than CSMBS patients, especially in colorectal cancer [6]. Another challenge is the health technology assessment (HTA) process and funding mechanisms used for the reimbursement of therapeutics in Thailand. Despite Thailand's relatively mature HTA methods, which prioritize cost-effectiveness and budget impact, reimbursement and access to new cancer and rare disease drugs remain challenging. These challenges stem from immature clinical and economic evidence, uncertainty in cost-effectiveness results, and affordability issues [7].

While numerous healthcare systems within Asia and globally have addressed the challenge of novel oncology and rare disease drug access using flexible evaluation methods and funding mechanisms [8], Thailand uses almost none of these tools systematically. Additionally, the three public health insurance schemes have been funding drugs with incremental cost-effectiveness ratios (ICERs) well below the established threshold, as well as medications considered suitable for over-the-counter drugs. However, these schemes have not yet extended coverage to more advanced drugs for catastrophic illnesses, such as cancer.

A common financial mechanism for financing high-cost technologies is managed entry agreements (MEAs), which are arrangements between pharmaceutical firms and healthcare payers that allow for coverage of new medicines while managing uncertainty around their financial impact or clinical performance. A systematic review exploring financing strategies to facilitate access to high-cost anticancer drugs found that MEAs for high-cost drugs were implemented in 38 countries [9]. Although mechanisms such as MEAs are widely used in higher-income settings, UMICs with limited resources could benefit greatly from adopting them [10, 11].

Another example will be ring-fenced funds (RFFs) such as the United Kingdom (UK)'s Cancer Drug Fund (CDF) and similar funds in Australia, Italy, and Hong Kong which set aside a portion of the healthcare budget to be allocated to classes of novel, high-cost therapeutics – typically for treating cancer or rare diseases [12–14]. For instance, the CDF is a separate source of funding for cancer drugs in the UK, initially introduced as a stop-gap measure to provide for drugs for rare cancers. Several other mechanisms pertaining to evaluation methods have also been explored. Coverage with evidence development (CED) allows innovative drugs with uncertain clinical data (e.g. early phase trials) to be reimbursed in exchange for evidence generated by the manufacturer. National Institute of Care and Excellence (NICE)'s former End-of-Life Criteria (EoL) which applies to drugs indicated for patients with a short life expectancy (e.g., < 24 months) and should extend life by a specified period compared to current standard of care, applies the assumption underlying the higher ICER threshold for EoL technologies is that society values time at the end of life more highly and is willing to pay more. and Applying different ICER thresholds for different therapeutic areas/domains, to account for the higher expected ICERs for highly targeted anti-cancer and rare disease treatments [15, 16]. Given the lack of ASEAN comparators and the low prevalence of alternative funding mechanisms outside of the high-income countries, Thailand could potentially pave the way to modernize HTA for high-cost drugs within the Association of Southeast Asian Nations (ASEAN), if they adopt such approaches to better manage uncertainties in decision-making.

The National Health Security Office (NHSO) has made attempts to improve access to cancer medicines. Only 17 of 43 cancer medicines were accepted for consideration into the National List of Essential Medicines (NLEM), 10 were rejected due to suboptimal effectiveness evidence, and 16 were never further evaluated due to not

meeting the cost effectiveness threshold value of Thai baht (THB)160,000/ Quality-Adjusted Life Year (QALY) [17].

Thailand implemented compulsory licensing (CL) for seven patented drugs—Efavirenz, lopinavir/ritonavir, clopidogrel, letrozole, docetaxel, erlotinib, and imatinib—between 2006 and 2008. Studies later confirmed that CL positively impacted public health without reducing foreign investment during the period from 2002 to 2008 [18]. However, Thailand has since discontinued the use of compulsory licensing, as it is no longer regarded as a sustainable solution to address issues related to medicine access. Moreover, implementing CL measures can result in significant trade pressures, including the possibility of trade sanctions and being placed on intellectual property protection watch lists, further complicating its feasibility [19].

Thailand has utilized some Voluntary Licensing (VL) agreements, such as for Tenofovir in 2006 and Sofosbuvir in 2014. However, VL is not commonly employed because it depends on the willingness of the patent-holding pharmaceutical company to negotiate, a process that can be time-consuming and may involve conditions that are unfavorable to the requesting country [20]. Although the Medicines Patent Pool (MPP) has helped streamline the VL process, its scope remains limited. While the MPP plays a vital role in facilitating access to medicines for selected diseases and products, it covers relatively few areas—particularly oncology, where many innovative drugs remain outside its reach [21].

The objectives of this research were to (1) identify potential funding mechanisms being used globally that could be applied to Thailand; (2) consider the challenges and opportunities related to the implementation of the shortlisted mechanism(s) to propose a customized Thailand-specific framework as a policy recommendation for the implementation of access solutions for innovative medicines.

Methods

The study was conducted sequentially in two phases as action research. First, a focus group discussion was convened to identify the feasible alternative funding mechanisms that could be implemented into Thailand's healthcare system. Second, in-depth interviews were conducted among selected stakeholders to explore the practical implementation of the shortlisted mechanisms with a proposed framework.

Phase I: Identifying feasible alternative funding mechanisms

A focus group discussion was convened among key stakeholders involved in the HTA, drug reimbursement policy and patient advocacy. The stakeholders were carefully selected based on their expertise and roles in healthcare financing policy in Thailand. The participant pool included policymakers (representatives from the Ministry of Public Health, the National Health Security Office, the Social Security Scheme, the Civil Service Medical Benefits Scheme, the NLEM Sub-Committee, the Price Negotiation Committee, and the Rare Disease Working Group), academic researchers (from medical and pharmacy schools actively conducting research to support policy decision-making), clinicians (delegated from the Thai Society of Clinical Oncology, the National Cancer Institute, and the University Hospital Network), and patient advocates (Thai Cancer Society).

To ensure transparency and mitigate potential conflicts of interest, all participants were required to sign a Conflict of Interest (COI) declaration form stating explicitly that they had no financial or other conflicting interests with Roche Thailand, the pharmaceutical company sponsoring this study. Twenty-one key stakeholders participated in the first phase workshop, including policymakers ($n=7$), academic researchers ($n=8$), clinicians ($n=4$), and patient advocates ($n=2$).

To provide a common baseline understanding for all participants, the issues related to access to high-cost medicines in Thailand were explained. Five potential financial mechanisms, identified from a targeted review (i.e., MEAs, RFFs, CED, flexible ICER thresholds, and EoL criteria) [4] were detailed to the participants. They were encouraged to freely discuss these mechanisms and then asked to rank each one on a 7-point Likert scale (with 0 being lowest feasibility/attractiveness and 7 being the highest feasibility/attractiveness) based on two domains:

1. Feasibility: Considerations included success in other countries, data availability, data analysis capacity, and the burden of implementation and maintenance.
2. Attractiveness: Factors included high levels of stakeholder buy-in, win-win scenarios for various parties, enhanced access to innovation beyond conventional acquisition costs and QALYs, and evidence supporting positive outcomes.

Content analysis from the focus group discussion was used to identify the most preferred financial mechanisms, which includes analysis on the opportunities and challenges to implementing such mechanisms.

Phase II: Exploring the practical implementation of the shortlisted mechanisms with a proposed framework

In-depth interviews were conducted with seven senior key stakeholders, representing payers, policymakers, health economics experts, academia or researchers and clinicians who actively participated in the phase I

workshop. For phase II study, patient representative was excluded because of the limited familiarity with healthcare financing strategies which hindered their ability to provide valuable information. Prior to the interviews, the key stakeholders were asked to participate in an experience sharing workshop (i.e. second workshop) provided by three experts from Italy, South Korea, and Singapore who specialized in HTA and alternative funding solutions to guide discussions on the customized implementation of an innovative medicines funding framework in Thailand.

A semi-structured discussion guide, developed specifically for this study and in Thai, was face validated by two experts from Chulabhorn Royal Academy (CRA). The interview guide focused on the implementation steps including six main areas: (1) current drug reimbursement landscape; (2) proposed strategic roadmap for funding of innovative medicines; (3) priority and criteria setting; (4) decision making for drug reimbursement; (5) feasibility of MEA options in Thailand; and (6) monitoring and re-evaluation. As a reference for discussion on MEAs, the South Korean MEA framework was used as a model to generate ideas on how the Thai healthcare system, including criteria and process, could be structured. The English version of this guide was included as Supplementary Material 1.

Thematic analysis of in-depth discussions at the workshops was undertaken to identify overarching themes, opportunities, and challenges associated with different funding models, where a preferred mechanism was identified. The various stakeholders' perspectives gathered from the second workshop and in-depth interviews related to the preferred mechanisms implementation were subsequently utilized to develop a customized alternative financing and decision-making framework for Thailand. To address differences in viewpoints among stakeholders, we analyzed shared opinions as aggregated perspectives and incorporated the optimal intersection of stakeholders' priorities into the framework to minimize inconsistencies and overlaps.

Results

Viable alternative financing mechanisms for Thailand – MEAs and RFFs

Based on the ranking of mechanisms described above with a highest possible score of 7, participants expressed the most interest in simple, financial mechanisms such as MEAs (i.e., 5.6 for feasibility, 6.0 for attractiveness) and RFFs (i.e., 4.8 for feasibility, 5.2 for attractiveness) rather than methodological solutions such as flexible ICER thresholds (i.e., 4.3 for feasibility, 4.8 for attractiveness) and EoL-type criteria (i.e., 3.9 for feasibility, 4.5 for attractiveness) (Table 1). MEAs were considered most attractive (6.0) to participants for multiple reasons, including their ability to address clinical and financial uncertainties, minimal administrative infrastructure especially financial-based agreement, and the ability to improve healthcare budget efficiency while expediting patients' access to treatments. Participants' response and perceptions of the advantages and disadvantages of each mechanism were aggregated and described in Table 1. All stakeholders viewed that having these funding levers in place in Thailand would enhance patient access and shift the focus away from ICER threshold for decision-making. Participants also highlighted the importance of stakeholder alignment (such as policymakers and clinicians) and the identification of structured implementation steps in delivering process changes of this magnitude.

Additionally, the importance of Thai-specific HTA evidence and the hopes for Thailand as a regional leader in evidence generation were a priority across several discussions. Thai-specific HTA data was noted as being the sole acceptable evidence development that would fulfil the requirements of several mechanisms such as an outcomes-based MEA, ring-fenced funds re-assessment, or CED despite its complexity of implementation and insufficient infrastructure. While several of these solutions were deemed to be feasible, the participants again highlighted the importance of stakeholder alignment within the Thai healthcare system to incorporate these advancements into routine practice.

Proposed framework for the implementation of MEAs in Thailand

Building on the previous phase, which identified MEAs as the most appropriate and straightforward solution for Thailand, the second workshop and in-depth interviews primarily focused on MEAs. Participants generally have positive perceptions towards these mechanisms. Success stories from other countries were encouraging for MEAs adoption in Thailand but participants emphasized that strong political will would be required for MEAs to be successful. Furthermore, barriers pertaining to MEAs were explored, and participants suggested that the lack of data infrastructure for patient-level data collection, practical capacity concerns, and inconclusive views of the appropriate governing body of its implementation as potential issues.

Key findings from the workshop and the interviews were then synthesized into a proposed MEA framework that could potentially be implemented in Thailand (Fig. 1).

Prioritization – eligibility criteria for diseases and treatments

Most interviewees agreed that oncology, rare diseases, and life-threatening conditions should be the focus therapeutic areas where relevant drugs should be categorized under the umbrella of "innovative medicines" to be

Table 1 Thai stakeholders' perceptions on selected funding and evaluation mechanisms

Mechanism	Advantages	Disadvantages	Feasibility* Average rating	Attractiveness* Average rating
1. Managed Entry Agreements (MEAs)	- Ability to address clinical and financial uncertainties (i.e., able to manage the government healthcare budget while expediting patients access to treatments) - Financial-based MEA model preferred as it requires minimal upfront administrative burden or additional infrastructure.	- Concerns about complexity of arrangement when instituting national MEAs, especially in a country where equity is a major component of healthcare culture. - Long-term, multi-stakeholder engagement required to establish the specificities of sustainable framework between budget holders and manufacturers.	5.6	6.0
2. Ring-fenced funds (RFFs)	- Easy to implement as it involves setting aside funds	- Salient concerns centered around equity between disease areas (while acknowledging that severe disease states should be prioritized) - Sustainability of procuring and maintaining exclusive funds.	4.8	5.2
3. Coverage with evidence development (CED)	- CED could be combined with MEA or RFF-type solutions - Allow for generation of Thai-specific evidence.	- Major concerns are about mechanisms for withdrawal of a drug once initially reimbursed through CED. - Concerns on infrastructure required for evidence collection and appraisal.	4.7	5.1
4. Flexible ICER Thresholds	- Participants noted this was intuitively appealing and would incorporate disease severity.	- Little evidence in the Thai context informing the WTP threshold. - Challenges in addressing equity concerns across multiple diseases.	4.3	4.8
5. End-of-Life (EoL) Criteria	- None mentioned.	- Concerns on how exactly these would be implemented and how exactly thresholds would change. - Low interest due to the limited knowledge and absence of data showing how the Thai population values QALYs and WTP at EoL.	3.9	4.5

*Average ratings of feasibility and attractiveness were calculated from the sum of all ratings with the Likert-scale from zero to seven divided by the total number of participated stakeholders

Abbreviations: ICER – incremental cost-effectiveness ratio, WTP – willingness to pay, QALY- quality-adjusted life year

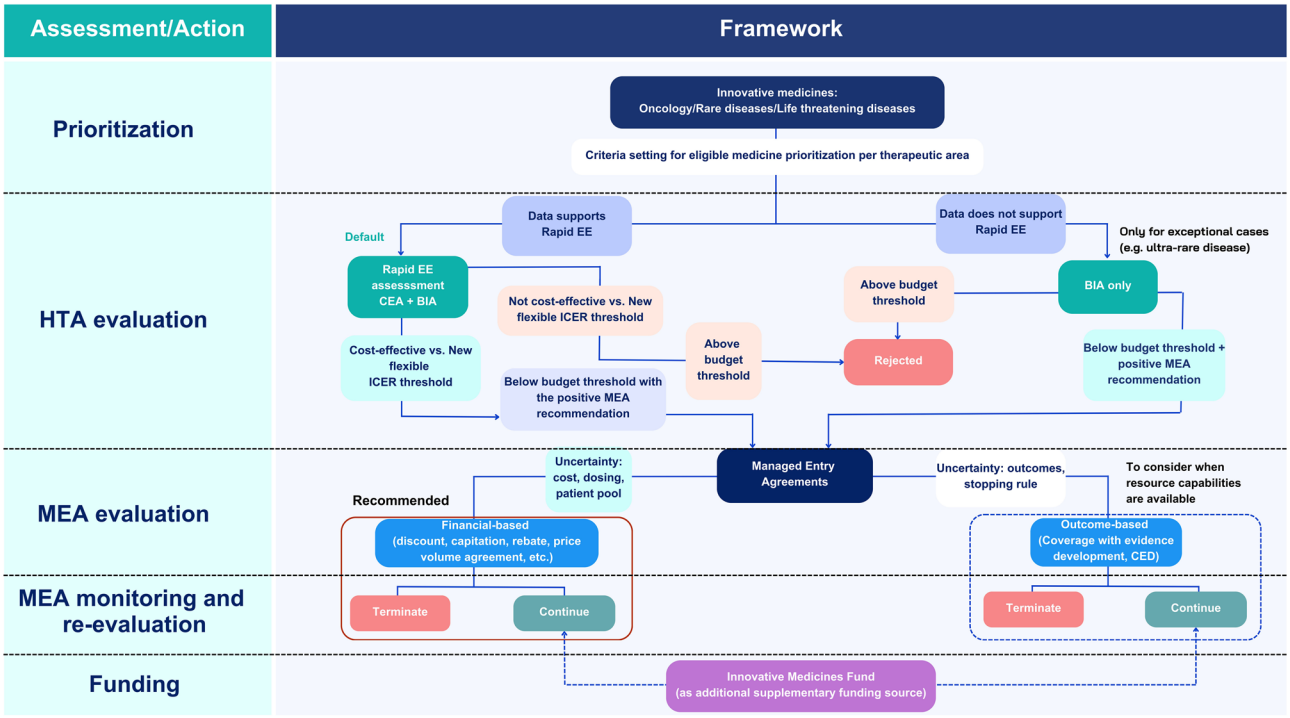


Fig. 1 Proposed framework on MEA implementation. Abbreviations: EE – economic evaluation, BIA – budget impact analysis, ICER – incremental cost-effectiveness ratio, MEA – managed entry agreement, PVA – price-volume agreement, CED – coverage with evidence development

evaluated under a new MEA framework. All stakeholders opined that specific eligibility criteria are required to identify appropriate diseases and treatments with a clear definition of the term "innovative medicines". Most stakeholders agreed that the current NLEM listing principles of safety, efficacy, cost-effectiveness, and acceptable budget impact should be considered when establishing eligibility criteria for MEA inclusion.

The recommended criteria include: (1) high unmet medical need with no or limited treatment options available with promising clinical efficacy and outcomes for the given disease; (2) severe or life-threatening impact to patients; (3) addressing equity or practice variation issue(s) for innovative treatment access for patients. These criteria should be considered during an assessment by the drug committee while recognizing that innovative medicines, particularly those targeting rare diseases, often present with lower strength of evidence, marginal incremental clinical benefit, and uncertain cost-effectiveness outcomes.

Approach for the adoption of MEAs into the current Thai HTA process

While stakeholders did not reach a clear consensus on how to adopt MEAs into the Thai HTA process, experts suggested two distinct approaches for consideration: (1) integrating the MEA approach for the evaluation of innovative medicines into the current NLEM processes, or (2) creating a separate evaluation pathway with an appointed committee working in coordination with NLEM processes. The first option was identified as a more preferred approach.

HTA evaluation – evaluation approaches

Most of the recommendations focused on cost-effectiveness and budget impact criteria. Specifically, the suggestions included increasing the current ICER threshold which is approximately 5,000 United States Dollar (USD)/QALY and considering a higher budget impact level specific to this framework. The ICER threshold could potentially be established based on referencing available global data with consideration of adjustments made in respect of Thailand's gross national income (GNI) per capita, healthcare budget and disease burden. However, there was no concrete opinion on the values to be set for revised thresholds. While one interviewee suggested that the ICER threshold should remain unchanged, it was noted that some high-cost drugs may have unfavorable cost-effectiveness that exceeds the current Thai ICER threshold. As such, these drugs should not be automatically excluded from the reimbursement decision-making process.

Interviewees opined that innovative medicines should not be subject to the traditional full HTA review and should be distinct due to the limited availability of Thai clinical data and the necessity to ensure timely equitable

access to innovative medicines to patients in Thailand. Two possible pathways like the South Korean framework [8] were suggested for adoption in Thailand: a "default" and an "exceptional" pathway.

"Default" pathway The "default" pathway would cover eligible innovative drugs that do not fulfill either the ICER threshold or the lack of Thai data under the existing evaluation pathway. Most stakeholders suggested conducting a simplified cost-effectiveness analysis (CEA) alongside with a budget impact analysis (BIA) with a potential adaptation of Thai parameters be used as initial proxy and/or considering a previously conducted CEA where the drug was evaluated and approved for reimbursement by an established HTA agency (e.g., Canadian Agency for Drugs and Technologies in Health (CADTH), NICE).

"Exceptional" pathway This pathway would allow CEA exemption especially for high-cost life-saving drugs that is established for short-term treatment of rare or orphan disease (as defined by Thailand's Ministry of Public Health) that has a severe or life-threatening impact on patients in the immediate or short-term with no current available efficacious treatment.

Both proposed approaches may shorten timelines by removing the need for a full economic evaluation requiring Thai data which may be difficult to obtain in the interim, thereby facilitating earlier access to innovative medicines. However, it is important to note that these medicines must be affordable to the healthcare system so the budget threshold will need to be established for the specific therapeutic area.

Type of MEA

Stakeholders expressed a strong preference for financial-based MEAs as it addresses concerns relating to healthcare budget control and have a simpler infrastructure for data collection and implementation.

Interestingly, some stakeholders also expressed interest in exploring outcome-based agreements as a potential long-term solution for Thailand. The development of a centralized clinical data infrastructure is hence necessary to collect clinical outcomes data for the implementation of outcomes-based MEAs.

MEA monitoring and re-evaluation

To successfully implement MEA in Thailand, stakeholders cautioned on the appropriate resource and capability building needs required for relevant healthcare professionals to ensure adequate planning and execution at hospital level. Data parameters for each type of selected MEA model should be clearly set and monitored to ensure high data quality and measurement of outcomes that can be utilized to inform NLEM decision-making.

The evaluation of MEA outcomes to inform decision-making for the drug listing or delisting is crucial. MEAs provide opportunities to gather additional evidence to reduce clinical or economic uncertainties. Clear data collection objectives and measurable indicators within the conditional period will be required to address the original uncertainties in the appraisals for a final decision [17, 22].

Funding

While there was no clarity on the most appropriate source of funding for MEAs, some respondents (especially payers) suggested the establishment of a separate ring-fenced fund as a supplement to support innovative medicines reimbursement to balance budget allocation across multiple therapeutic areas and ensure long-term financial sustainability. The proposed MEA under the ring-fenced fund could improve equitable access for eligible patients across the three public health insurance schemes.

Key considerations for MEA pilot projects to demonstrate proof-of-concept

The implementation of an MEA framework is a significant endeavor, most interviewees recommended that pilot projects should be undertaken to ensure feasibility on a nationwide scale in Thailand. Relevant key areas were discussed with interviewees.

The scale of pilot implementation Majority opined that pilots should be conducted on a nationwide scale to ensure patient access equity. Healthcare resources and capability building would need to be adequate to ensure proper testing at hospital level.

Drug selection process The scope of drugs and the proposed drug selection criteria should be clearly defined and presented for relevant stakeholders. A hearing process is needed.

Budget allocation and cost containment mechanism The payers must estimate and allocate annual budget for drugs which will be utilized under MEAs mechanism.

Agreements A fixed period (e.g. 2–5 years) with annual MEA outcomes evaluation to assess the effectiveness of the MEA framework for a particular drug was suggested by all interviewees. Most stakeholders agreed that the prices or terms of such drugs should remain confidential among the relevant parties, in line with global practices. Nonetheless, they strongly supported transparency in the decision-making process, suggesting anonymous or aggregate data disclosures as a reasonable compro-

mise. Those engaged in the drug reimbursement process insisted that, to establish a sustainable approach to innovative drug access, all stakeholders must benefit from new financing strategies, creating a win-win-win outcome for payer, patient and pharmaceutical industry. In terms of type of MEAs to be tested in the pilots, a possible approach is to adopt financial-based MEAs for innovative medicines intended for a wide pool of patients (e.g. oncology) and outcomes-based MEAs for innovative medicines for rare disease indications due to small pool of patients which makes it easier for data collection purposes. This allows both types of MEAs to be tested to best assess the feasibility of implementation in the wider scale.

Drug procurement process A suggestion was to procure innovative medicines through the existing E2 category, which covers high-cost medicines that are critical for certain patient groups under the NLEM process. However, legislative amendments would be necessary to cater for multi-year procurement. Financial mechanisms such as rebates or free drugs offered as part of MEA contracts, with an annual review process to be considered contingent on having sufficient resources to support.

Data system The existing E2 category database can be potentially leveraged for financial-based agreement since the E2 category is catered for high-cost drugs claims and utilizations. Patient level data collection system, healthcare professionals' capabilities and investment are required for outcome-based agreement implementation.

Post-MEA evaluation process Stakeholders opined a straightforward approach of either continuation of listing or delisting of innovative medicine from the NLEM depending on the level of acceptable achievement (i.e., clinical, cost-effectiveness, budget impact outcomes) of clinical and economic certainties collected from the MEAs similar to regular drugs that are evaluated under the existing traditional pathway.

Discussion

Establishing a balance between enabling the earliest appropriate patient access, equipping payers with tools to negotiate prices, and ensuring the sustainability of the healthcare system are key towards evaluating and reimbursing novel high-cost innovative medicines. Alternative financing mechanisms such as MEAs provide an opportunity for oncologists to prescribe, and for their patients to receive, treatments that would otherwise see very limited use in Thailand. MEAs are an important tool for managing healthcare budgets and ensuring patients have access to necessary treatments. By negotiating pricing and reimbursement terms in advance, and setting conditions for the use of new drugs, MEAs can help make healthcare budgets more sustainable and ensure that patients get access to the best possible care.

The multi-stakeholder workshops and interviews made clear that strong support exists from all stakeholder types for modernizing the current practice of HTA evaluation and funding for innovative medicines in Thailand. The adaptation of South Korea's MEA framework with use of simple financial MEA mechanisms was perceived to be feasible for implementation in Thailand to improve access of innovative medicines to patients as some existing drug utilization system at national level (i.e., E2 category of the NLEM process) can be adopted for financial-based agreement monitoring and evaluation. While outcome-based MEAs may have potential, it requires the development of infrastructure and resources to generate Thai-specific evidence, including capabilities for data collection and evaluation. Outcome-based MEAs requires more expertise, multi-stakeholder engagement, data infrastructure than financial-based MEAs. Similar to other countries, financial-based MEAs are more easily assessed and implemented as part of cost-effectiveness and budget impact analyses, and therefore accelerate the access of drugs with relatively low additional strain on HTA reviewers [8, 10]. This can be achieved by integrating this new MEA framework pathway under the NLEM committee as their current role is to oversee the drug reimbursement landscape and to ensure the evaluation process for innovative medicines streamlines with the existing drug reimbursement processes and core principles. However, this may create the burden of current NLEM committee workloads and slow the entire evaluation processes for innovative medicines. A new separate committee with expertise in MEAs was brought into consideration as a suggested approach by some participants that it can speed up the drug evaluation process. However, concerns were raised on having two separate committees to work closely to ensure consistency and coordination of reimbursement decisions.

A recent study by Butani et al. investigated the possibility of broadening access to expensive medicines under Thailand's UCS using methods similar to this study [17]. The authors proposed the E3 framework, which focuses on reimbursing high-cost medicines that may not be cost-effective but are lifesaving and without alternatives. However, the framework's strict clinical criteria, such as the requirement for the drug to extend life by at least a year, prevent severe co-morbidities, and significantly improve the quality of life, are highly restrictive. This may limit the number of high-cost medicines that meet these requirements, given that patient's prognosis and outcomes can greatly differ based on the disease's nature and spectrum. The same study also suggested a budget cap of THB 500 million (approximately USD 14.3 million) per year for the initial three years, which might

not be sufficient considering the UCS covers over 70% of the Thai population and may not be adequate to provide access to high-cost drugs under the scheme. Moreover, the E3 framework remains a policy proposal that does not consider the operational aspects of the MEA framework. Our proposed approach operationalizes the framework by identifying and addressing priority therapeutic areas with some flexibility, allowing more therapies to be considered and evaluated. This way, our proposed approach would also allow greater flexibility to consider and allocate budgets for specific therapeutic areas with significant clinical need. A budget al.location limit can be established for each therapeutic area, with periodic use of real-world data to analyze burden of illness to revise the cap and maintain sustainable healthcare spending. Alongside the use of financial-based MEAs and flexibility on the use of economic assessments, we can undertake evidence generation activities through a pilot program to better assess a drug's cost-effectiveness and/or budget impact before deciding to continue or discontinue reimbursement. Despite the differences in approach, the proposed E3 framework attempts for a single-track streamlined approach with the common goal of providing patient access to effective high-cost treatments and contribute towards financial sustainability.

HTA is the core principle for innovative medicines evaluation similar with Korean framework, Thailand's ICER threshold was suggested to increase with potential flexibilities to allow greater access of high-cost innovative medicines while balancing overall affordability. Several drugs which Health Intervention and Technology Assessment Program (HITAP) previously evaluated were rejected as their ICERs far exceeded the current ICER threshold (approximately 5,000 USD/QALY) [23]. Internationally, the UK's NICE adopts a flexible ICER threshold of about 1–1.5 times of GDP per capita (£30,000 – £50,000 (USD 37,850 – USD 63,090) per QALY) for drugs that treat life-threatening conditions or about 3 times of GDP per capita (up to £100,000 (USD 126,700) per QALY) with the specific criteria for weighted QALY adjustment for highly specialized technologies [12]. South Korea also uses a flexible ICER threshold (2 times of GDP per capita or South Korean won (KRW) 5,000,000 per QALY) for a limited number of anti-cancer drugs or apply a CEA waiver to drugs that fulfils the exemption criteria (e.g., drugs for rare diseases with life-threatening and no alternative treatment) [8]. Since several HTA agencies have established ICER thresholds with some special exemptions or flexibilities for high-cost innovative medicines such as cancer drugs [24], Thailand may also consider these international methodologies and adopting similar approaches. However, it remains critical to strike a balance between budget controls and access to innovative medicines.

It is critical for Thailand to pilot MEAs to generate data and demonstrate improvements in patient access and outcomes as policy recommendations are being refined. Various steps to formulate national pilot projects were highlighted in the section above. Key considerations such as criteria development, having both funding and healthcare resource capacities to initiate pilots in healthcare institutions nationwide, legislative amendments to accommodate drug procurement, infrastructure to track MEA outcomes will require initial investment in time, and operational capabilities. Additionally, potential challenges in model design, administrative cost and logistic delays may necessitate continuous validation of the framework and assumptions.

Given the lack of exploration of alternative financing options for innovative medicines in the Southeast Asian region, this is the first study gathering key Thai stakeholders' views towards the modernization of HTA and alternative financing mechanisms in Thailand. Noting the demonstrable benefits of MEAs which have supported patient early access to drugs and potential reduction in healthcare costs globally [8, 10, 11, 25], Thailand can benefit substantially from the implementation of MEAs given concerns of tight healthcare budgets and early equitable access of high-cost innovative drugs. If successful, Thailand will become the pioneer of MEA in the region which could become a model for implementation which other ASEAN countries can reference. A key strength of this study is the extensive stakeholder engagement process, which included two multi-stakeholder workshops and in-depth interviews with senior policymakers, academics, clinicians, and patient advocates. This approach ensured that diverse perspectives were incorporated into the development of the proposed MEA framework tailored to the Thai context. Additionally, this research incorporated international experiences from countries to guide the customization of the MEA framework for Thailand. The comparison with the South Korean MEA framework supported in the identification of areas for adaptation while maintaining consistency with core HTA principles.

This study underscores the importance of adopting multiple solutions to support access to high-cost treatments for patients. It is worth noting that this new MEA framework was developed by synthesizing the views of all stakeholders, incorporating the majority consensus, differing suggestions, and identifying areas that require further exploration to find the best fit within the Thai context. Actioning this change will require the following: (1) a political will to support governance and relevant multi-stakeholder collaboration to modernize HTA evaluation in practice, especially with respect to funding mechanisms and HTA guidelines; (2) a concrete and realistic roadmap to implement change (goals and KPIs, timelines, and a stakeholder engagement plan); (3) an

evidence generation plan to support implementation and evaluation for a streamline MEA framework in the long term.

This study carries several limitations. The workshop sessions and in-depth interviews were designed to qualitatively explore individual opinions of a targeted set of stakeholders and may not fully capture the views of all parties involved in Thailand's broader healthcare ecosystem. Although patient advocates were included, they were fewer in number compared to other stakeholder groups. Despite this, the inputs obtained from the in-depth interviews to guide the development of an appropriate MEA framework reflected the majority perspectives of stakeholders relevant to the Thai context. Although variations in stakeholders' perspectives were expected, common aggregated views were explored and considered to minimize gaps and overlaps within the proposed framework. Further studies or formal policy discussions should be conducted to gather further opinions from Thai key stakeholders to better understand the practicalities of implementing MEAs into policy.

Despite these limitations, this study represents a significant step forward in exploring alternative financing mechanisms for innovative medicines in Thailand. The proposed MEA framework, informed by extensive stakeholder engagement and international experiences, provides a solid foundation for policymakers to pilot and scale up MEAs to improve patient access to high-cost cancer and rare disease drugs while ensuring financial sustainability.

Additional studies investigating the local environment, burden of illness associated societal perspective and assessing the benefits of MEA in terms of achieving patient access to innovative medicines and ensuring equitable healthcare budget allocation may also help further refine policy changes, ensuring suitability to the Thai context. In addition, further studies on the collaborative management of MEAs across the three public health insurance schemes are essential to ensure that all Thai citizens, regardless of their insurance scheme, have equitable access to innovative medicines.

Conclusions

The information obtained through the various stages of this study led to the culmination of practical recommendations and approaches in developing the recommendations for alternative financing mechanisms framework in Thailand. Thailand has an opportunity to implement several initiatives under the current HTA pathway to improve patient access to innovative medicines. The proposed MEA framework represents an important foundation to address inherent challenges of limited and delayed access to high-cost innovative treatments. It promotes broadening of medicine coverage for vulnerable populations whilst imposing reliable expenditures control mechanisms. Ultimately, this creates a solution to improve health outcomes for Thai citizens in a financially sustainable and predictable manner that will pave a leading position within ASEAN.

Supplementary Information

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Supplementary Material 1

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Author contributions

T.U, J.S., P.A., J.A., N.M., C.A., O.A. and A.G. contributed to study concept and design; interpretation of data and critical revision of the manuscript. O.A., P.S. and M.K. contributed to the acquisition, analysis, and interpretation of data; drafting and critical revision of the manuscript. All authors read and approved the final manuscript.

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Data availability

The data that support the findings of this study are not openly available due to reasons of sensitivity and are available from the corresponding author upon reasonable request.

Declarations

Ethics approval and consent to participate

Ethical approval for this study was received from the Human Research Ethics Committee, Chulabhorn Royal Academy (Certificate of Approval Number: EC 081/2566). All methods in relation to this study were conducted in accordance with the ESOMAR guidelines and the Declaration of Helsinki (1964). Informed consent was obtained from all survey participants for anonymized data to be included in publications.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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