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CHULABHORN ROYAL ACADEMY

ALTERNATIVE FUNDING MODELS FOR HIGH-COST INNOVATIVE DRUGS IN THAILAND

A Roadmap towards an Implementation

Ipsos

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This whitepaper is sponsored and commissioned by Roche Thailand

This whitepaper was assisted by Ipsos PTE. LTD

Alternative Funding Models for High-Cost Innovative Drugs in Thailand – A Roadmap towards Implementation

EXECUTIVE SUMMARY

Despite the exemplary achievement of universal health coverage for its citizens, patient access to innovative medicines, including oncology treatments remains a challenge in Thailand, especially given the rapid pace of scientific development and the high associated costs. Cancer is responsible for one-third of all premature non-communicable disease-related deaths in Thailand, and will become critical as Thailand becomes an aged population by 2025.[1,2]

While regulatory approval when benchmarked to the World Health Organization Essential Medicines List (WHO-EML) and National Comprehensive Cancer Network (NCCN) recommended drug lists is 97.5% and 78% respectively, reimbursable access is considerably lower within the current health technology assessment (HTA) consideration pathway.[3] Along with the variations of patient access to newer oncology drugs that exist across the three healthcare insurance schemes with high mortality rate among NCDs with the enormous cost containment concern, there is a need for Thailand to find a sustainable solution in healthcare funding and equitable access of high-cost drugs.[3,4]

A research program was therefore initiated in two phases to explore both potential solutions and implementation issues to address the current challenge in Thailand related to limited and delayed access to high-cost innovative medicines including oncology treatments.

1. A paper capturing the first phase which included a workshop in 2021 convened by Chulabhorn Royal Academy (CRA) with a panel of Thai policymakers, clinicians, health economists and patient organizations,

"Modernization of Thai Health Technology Assessment: Identifying Alternative Approaches in Thai Health Technology Assessment to Improve Cancer Patient Outcomes"

explored and presented a consensus on funding methodologies that are most likely to improve patient access in Thailand.[4]

Conclusions: Managed entry agreements (MEAs) and a Cancer Drug Fund (CDF) were recognised as simple and appropriate solutions for Thailand. Participants from the workshop expressed confidence that this approach would provide an environment where manufacturers are competitive in pricing, access is rapid, and Thai-specific evidence generation occurs.[3]

2. The second phase of the research program and the focus of this paper consider issues and opportunities related to the implementation of the identified mechanism(s) for improving patient access in Thailand. The multi-faceted approach included a targeted literature review, a workshop with key stakeholders

"Alternative financing solution and managed entry agreement: Unleashing access to unattainable medicines workshop"

a review of international experience through a survey mechanism, and in-depth interviews with senior Thai healthcare decision-makers and stakeholders. Through each component of the research program, the implementation of MEAs and a CDF were considered for Thailand.

The final goal was to identify a potential framework, pilot, and implementation scheme based on rigorously researched and numerous sources of information that are applicable to the Thai context.

Key findings from literature suggested high prevalence of MEAs

- **MEAs are a widely used instrument**, not only in Organization for Economic Cooperation and Development (OECD) countries (used by >66% of members) but in Central and Eastern Europe, with increasing use in the Middle East/North Africa, Sub-Saharan Africa, with sporadic use in Asia – particularly in South Korea and Taiwan.[5-8]

- There is **almost no uptake of MEAs in the Association of Southeast Asian Nations (ASEAN)**, with only South Korea and Taiwan as key Asian high-income countries (HIC) implemented MEAs.[7-8] Thailand will be placed in a pioneer position given that there are no appropriate comparators among upper middle-income countries (UMIC) in exploring MEA implementation in this region.

- **Well-implemented MEAs may serve as a tool to improve patient access to high-cost drugs while reducing payer and societal cost uncertainties, broader coverage, adherence to guidelines, improved patient outcomes and reducing time to access.**[5-7] In Taiwan during 2018-2021, 100% of all oncology drugs being evaluated went through risk-sharing agreements; MEAs saved Taiwan more than 10 million NTD since 2018.[9] In South Korea, deployment of MEAs has benefitted at least 15,000 patients with early access to new drugs especially for oncology and rare diseases, resulting in a comparable drug coverage level to that of the UK and higher than Australia.[6] A considerable body of literature indicates that similar schemes have achieved their objectives in a number of geographies[10-11]

Results from the various components of this research phase were synthesized into a possible MEA framework for Thailand with a series of recommendations

- **Prioritization and criteria setting** is considered as the first step to identify and prioritize eligibility of therapeutic areas and medicines. This includes **high-cost innovative medicines for oncology and rare diseases with no alternative treatments** that can bring clinically meaningful effectiveness or improvements to patients, where majority of stakeholders agreed due to the public health needs and treatment access challenges through the current HTA pathway. This is similar to South Korea wherein the criteria are strictly confined to these two therapeutic areas, while other countries such as UK and Italy are not limited in eligible diseases.[12-13]

- **The integration of MEA utilization into Thai HTA process under the National List of Essential Medicines (NLEM) governance body was recommended** to achieve a rapid adoption of the MEA framework and proper oversight of the reimbursement landscape. However, another option of a new committee that is specialized in MEA with greater capability to accelerate the assessment process without having to increase the workload burden currently undertaken by NLEM was also mentioned.

- Considering the potential for MEA in Thailand's framework, **an introduction of MEAs and ring-fenced fund for innovative medicines globally with the core HTA skeleton from South Korea's innovative medicines evaluation was considered and adapted.**[12, 13-14, 45]

    - Conventional CEA is challenging for such class of assets – the need for expedited regulatory/fast-tracking, lack of mature data, trial design, lack of local data, etc.

- Many countries set their own specific decision-making criteria and threshold suiting the local context and values.
- Most Thai key respondents suggested that **CEA should not be the sole criterion**. As an alternative, **simplified economic evaluation (EE) should be considered for eligible drugs, with exemptions for exceptional cases.**

- Consensus on **financial-based agreements for the initial phases of MEA implementation** because of its simple mechanism and minimal infrastructure and resources for implementation requirements than the outcome-based agreement where the establishment of registry and monitoring outcomes are more complex.

Recommendations for Thailand

1. **Incorporation of an MEA Framework into the NLEM evaluation/HTA process** – this may consist of a dedicated subcommittee, or an external advisory body for consideration.
2. Requirements for country MEA implementation
    a. **Thailand's definition of innovative medicines that are applicable/eligible for MEA**
    b. **Infrastructure supporting collection of data pertaining to cost and clinical outcomes and evaluation**
    c. **Resources, capabilities-building and educational support for implementation**
    d. **Legislative and regulatory amendments related to drug procurement** to accommodate the MEA framework
3. **Focus on financial-based MEAs with simple financial mechanisms** for ease of implementation
4. **Establish a new, separate innovative medicine fund to supplement the MEA, for the most-costly drugs for diseases with low-prevalence (i.e. rare diseases) that are not affordable through other channels**
5. **Pilot the MEA Framework with multiple indications on a nationwide scale to ensure equity.** Keep the approach simple and consider efficiencies with sustainability

Conclusions

A MEA Framework for innovative medicines may be a promising solution to address the inherent challenges of limited and delayed access to high-cost innovative treatments in Thailand and broaden coverage of medicines to vulnerable populations. This research program represents the first consolidation of the most relevant stakeholders' views on how to customize the Thailand MEA framework approach for implementation. It includes specific criterion and how MEA utilization requires collaboration among the appropriate government decision-makers to establish a Thailand MEA roadmap starting from the definition of innovative medicines eligibility to the prioritization and decision-making criteria for preferred MEA mechanisms, until the re-evaluation after MEA outcomes assessment. With this movement, Thailand becomes a leader within ASEAN, and to foster innovation and competition as well as addressing patient and healthcare concerns. Ultimately, the positive impact of introducing this solution will manage healthcare expenditures and improve health outcomes for Thai citizens.

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ACRONYMS

ACRONYM	DESCRIPTION
ASEAN	Association of Southeast Asian Nations
BIA	Budget impact analysis
CADTH	Canadian Agency for Drugs and Technologies in Health
CDF	Cancer Drug Fund
CEA	Cost-effectiveness analysis
CED	Coverage with evidence development
CRA	Chulabhorn Royal Academy
CSMBS	Civil Servant Medical Benefit Scheme
DREC	Drug Reimbursement and Evaluation Committee
EE	Economic Evaluation
EMA	European Medicines Agency
EU	European Union
GDP	Gross Domestic Product
HIC	High Income Countries
HIRA	Health Insurance and Review Assessment
HITAP	Health Intervention and Technology Assessment Program
HST	Highly specialized technologies
HTA	Health Technology Assessment
HTAi	Health Technology Assessment International
ICER	Incremental cost-effectiveness ratio
INAHTA	International Network of Agencies for Health Technology Assessment
ISPOR	International Society for Health Economics and Outcomes Research
LMIC	Lower-middle income countries
MEA	Managed entry agreements
MOF	Ministry of Finance
MOL	Ministry of Labor
MOPH	Ministry of Public Health
NCCN	National Comprehensive Cancer Network
NCD	Non-communicable disease
NHSO	National Health Security Office
NICE	National Institute for Health and Care Excellence
NLEM	National List of Essential Medicines
NLEM E2	NLEM high-cost medicines that are reimbursed for particular condition
OECD	Organization for Economic Cooperation and Development
QALY	Quality-adjusted life year
RSA	Risk sharing agreement
SSS	Social Security Scheme
UCBP	Universal Coverage Benefit Package
UCS	Universal Coverage Scheme
UHC	Universal health coverage
UK	United Kingdom
UMIC	Upper-middle income countries
WHO	World Health Organization
WHO-EML	World Health Organization Essential Medicine List
WTP	Willingness-to-pay

1. THAILAND HEALTHCARE ENVIRONMENT: An overview of Thailand's healthcare system and current reimbursement status for innovative medicines

1.1 Oncology treatment access in Asian countries; access variation and inequity issues among challenges for Thailand

Thailand is a country with an upper middle-income economy as defined by the World Bank[15] with a policy on universal health coverage (UHC) since 2002 offering every Thai citizen access to essential healthcare including preventive, curative and palliative health services.[16] There are three healthcare schemes including the Universal Coverage Scheme (UCS) (under which 75% of citizens are covered); the Civil Servants Medical Benefits Scheme (CSMBS); and the Social Security Scheme (SSS).[16]

Despite achieving UHC, patient access to innovative medicines including oncology treatments remains a challenge in Thailand, especially given the rapid pace of scientific development and the high associated costs. While the National Health Security Office (NHSO) reimbursed USD 297 million for cancer care in 2018, with expenditure expected to increase in line with the increasing costs of innovative medicines[3], Thailand's healthcare expenditure accounted for approximately 3.8% of GDP. This is lower than the average spent by other upper-middle-income countries (5.8% in 2018) and countries in the region such as China spending approximately 6.5% of healthcare expenditure on cancer care in 2015.[13-15]

Figure 1: Variation of Access to New Cancer Drugs in Thailand [3,4]

There is a variation in access to new cancer drugs among Thai healthcare schemes, where CSMBS has the highest access to new medicines while UCS and SSS face extremely low coverage in some cases, which results in high cancer mortality rate and prevalence in Thailand.

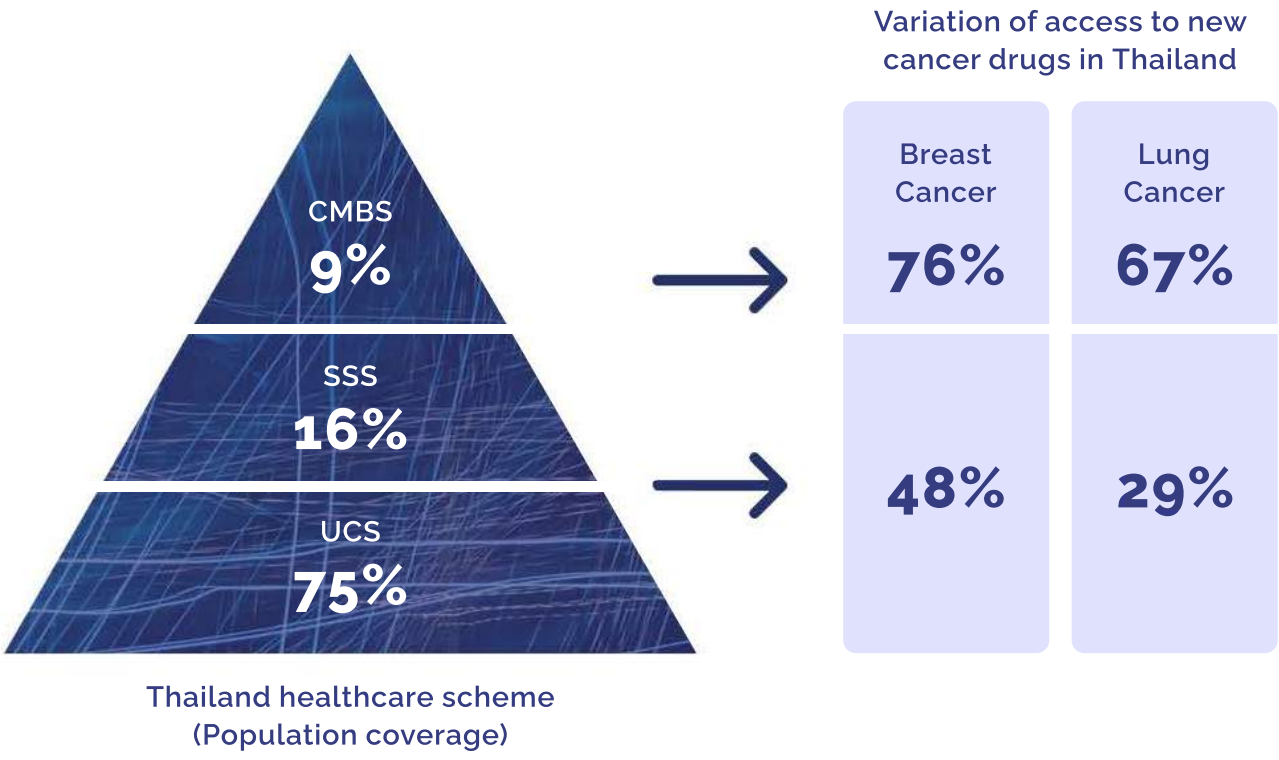
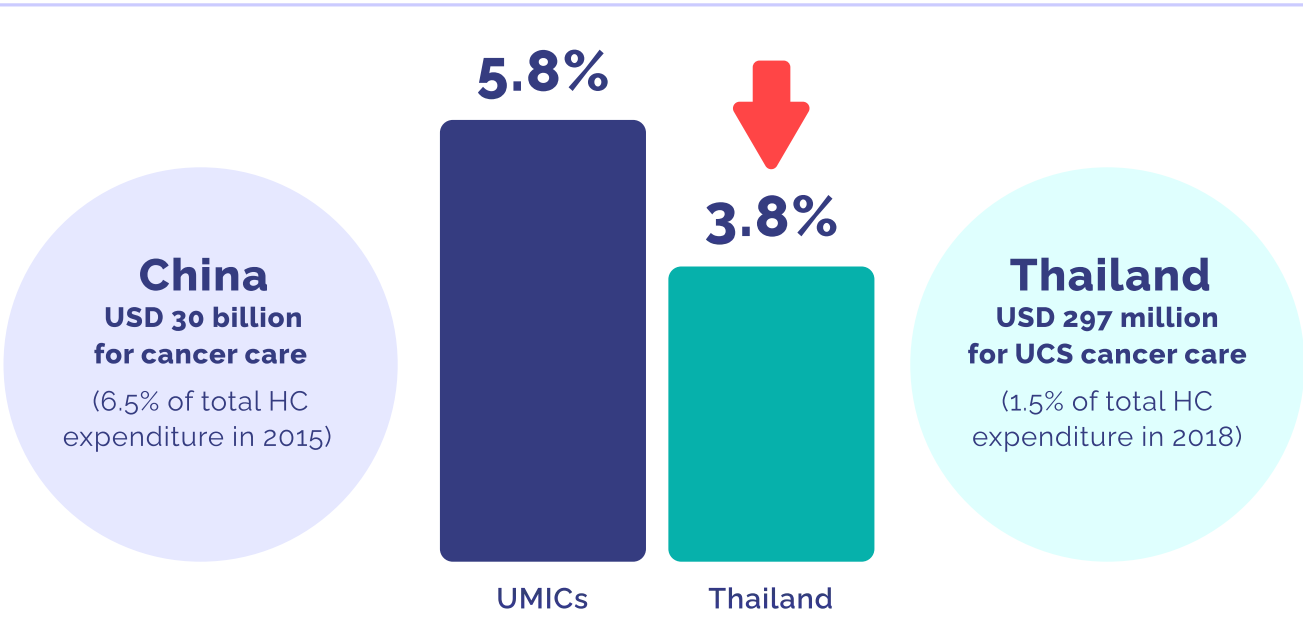


Figure 2: Thailand Cancer Care Spending[16-18]



Thailand's healthcare expenditure (3.8%) and proportion of cancer care of the healthcare budget (1.5%) is considerably low comparing with other upper-middle-income countries at 5.8% and 6.5%, respectively.

Average spending of healthcare expenditure of country GDP in 2018

1.2 Existing burden of cancer in Thailand – Cancer is a top 3 cause of non-communicable disease related premature death with continued increase as a significant future problem in an aging society

Cancer mortality rates in Thailand are higher than heart disease, metabolic disorders and HIV/AIDS with distinct inequities in access to treatments across the Thai population.[19] In 2016, over one-third of all non-communicable disease-related (NCD) pre-mature deaths in Thailand were due to cancer, and quality of life for Thai citizens is a continuing concern due to NCDs and modifiable adverse behaviour factors.[20] With the country's population of over 60 years of age increasing, Thailand will be considered an aged population by 2025, which will further contribute to increasing healthcare costs.[16] With these challenges confronting Thailand's healthcare system, health policies and initiatives will have to focus on efficient healthcare resource utilization with appropriate and sustainable healthcare spending.

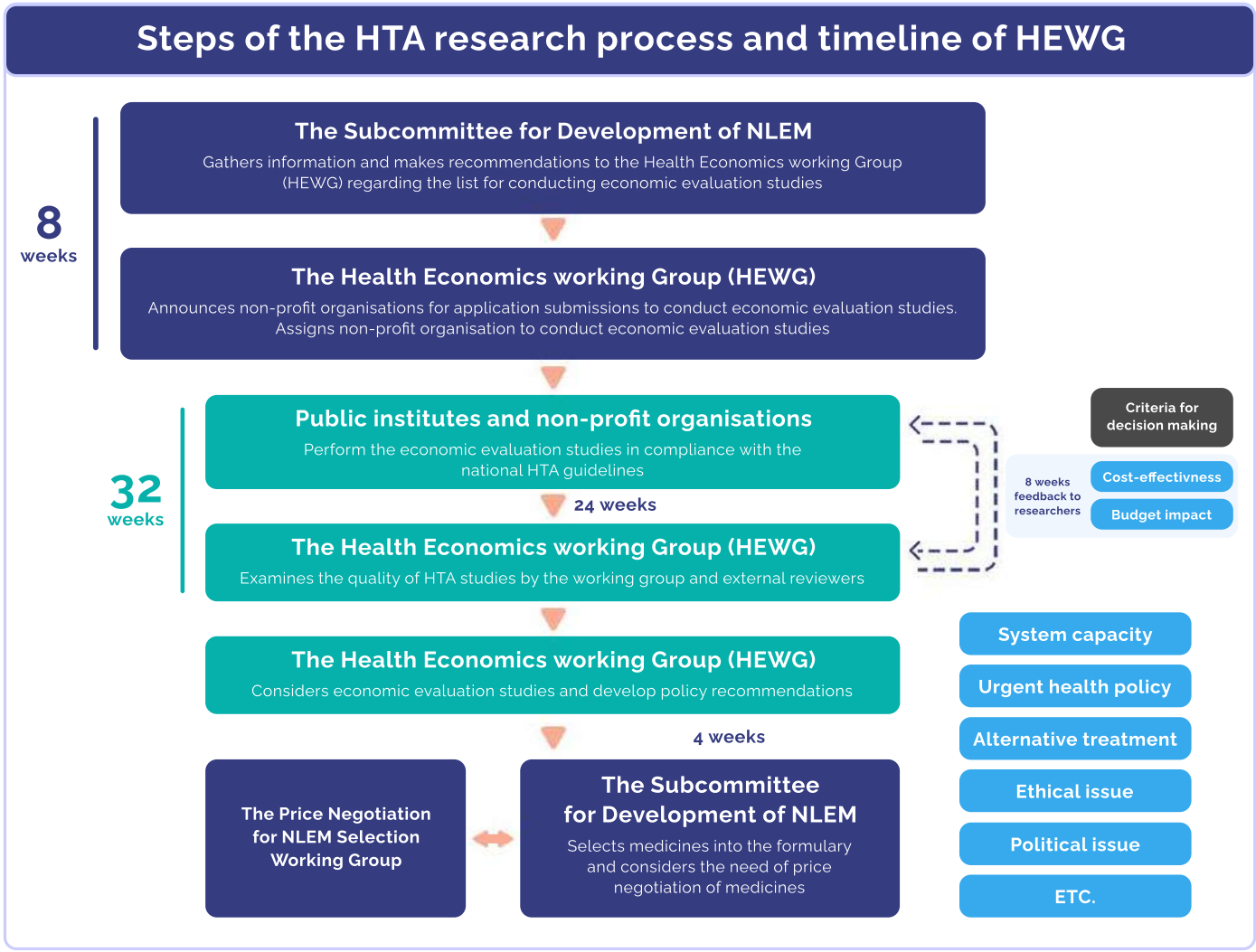
1/3 Cause of NCDs death by cancer

1.1% HC spending in cancer less than CVD, diabetes or COPD

1.3 HTA evaluation and funding landscape in Thailand – amenable to change?

The Health Intervention and Technology Assessment Program (HITAP) was established in 2007 as a semi-autonomous research arm of the Ministry of Public Health with well-established processes and methods for priority setting.[21] HTA has been formally integrated into coverage decisions, including in the development of the National List of Essential Medicines (NLEM) and the Universal Coverage Benefits Package (UCBP).[22] A key driver for HTA processes is to attain information about the cost-effectiveness and budget impact of new high-cost interventions to inform decisions about health policy and planning.[21]

Figure 3: HTA Research Process in Thailand which may usually take much longer than the expected timeframe [22]



Even with Thailand's formalized HTA methods that consider budget impact and cost-effectiveness as primary deciding factors, new cancer drugs with numerous high-efficacy, high-cost, high therapeutic breakthrough as well as rare diseases face challenges navigating reimbursement and access under current HTA processes because of its immature evidence, cost-effectiveness results and affordability issues.[23]

In reality, the actual timeframe required to conduct the CEA study and HTA assessment processes may take much longer than the expected timeline (Figure 3). The rapid pace of high-cost innovation in oncology is a global issue, requiring healthcare systems around the world to balance sustainability and patient access.[24]

Cost-effectiveness thresholds (CETs) or other methods to determine the best use of healthcare resources remain a barrier for Thailand and other comparable upper-middle-income countries with similar HTA foundations.[21] Notably, many countries do not typically utilize the arbitrary CETs range set by the World Health Organization (WHO)[24] or do not have an explicit CETs. Various criterions including elasticity of country income, value of heath, and past HTA experiences are used to inform the drug cost-effectiveness decision-making.[25-26] Thailand is one of the few countries to have an explicit threshold, currently set as US$ 5250/QALY since 2013 that is relatively lower than current 1 GDP leading to significant challenge for most of high-cost drugs being cost-effective and listing.[21]

Numerous healthcare systems within Asia and globally have reckoned with the challenge of novel oncology drugs and multiple HTA/methodological and funding mechanisms have been implemented. Examples include the use of end-of-life criteria and the cancer drug fund under the auspices of NICE, as well as extensive histories of managed entry agreements (MEA) and risk-sharing agreements (RSA) in Taiwan and South Korea. [5-6, 8-10] Addressing these challenges and exploring the alternative solutions are essential to ensuring equitable access to medicines and improved health outcomes for the Thai population.[27]

1.4 Targeted Literature Review: Understanding Experiences with MEAs integrated into the HTA process

A targeted literature review of publicly available information was undertaken to extract experiences of other countries with innovative funding solutions where formal and rigorous HTA processes are a cornerstone of healthcare decision-making. Identified countries include Australia, Bulgaria, Canada, Italy, South Korea, and the United Kingdom (UK). Innovative funding solutions such as MEA and Cancer Drug Funds (CDFs) are considered for their potential relevance and viability in the Thai context, where interesting commonalities exist among the countries studied.[28]

Two-thirds of OECD (Organization for Economic Cooperation and Development) and EU (European Union) countries use MEAs, of which the vast majority are financial agreements and mainly for therapies in oncology and rare diseases.[28] Among the countries examined more closely, including Australia, Bulgaria, Canada, Italy, South Korea and the United Kingdom (UK) all incorporate MEAs during the HTA process to improve patient access to higher-costing innovative treatment, while reducing uncertainty around comparative effectiveness, cost-effectiveness, and to manage budget impact.[6,28-29]

MEAs were incorporated to reduce the uncertainty around the clinical, cost, and especially cost-effectiveness of a particular drug, a critical aspect of the drug review process in all countries considered which contributes to efficiencies in healthcare resource use.[28] While MEAs are most widely used in higher-income settings, it is likely that LMICs and UMICs with more limited resources could benefit more from applying them.[8,28,36-37] Given the lack of ASEAN comparators and low prevalence of MEAs outside of the high-income countries, Thailand potentially sits in a pioneer position within ASEAN in terms of consideration the use of MEAs as a method of improving access while reducing clinical, cost, utilization, or cost-effectiveness uncertainties. There is negligible adoption in the ASEAN region aside from Singapore's nascent value-based pricing requirements under ACE's guidelines and ad-hoc use in Thailand.[38]

Fundamentally, the criteria for consideration of an MEA for a medicine were shared among countries and included[6,29,39]

- Highly unmet clinical need
- High-cost
- Medicines for cancer and rare diseases
- No alternative treatments.

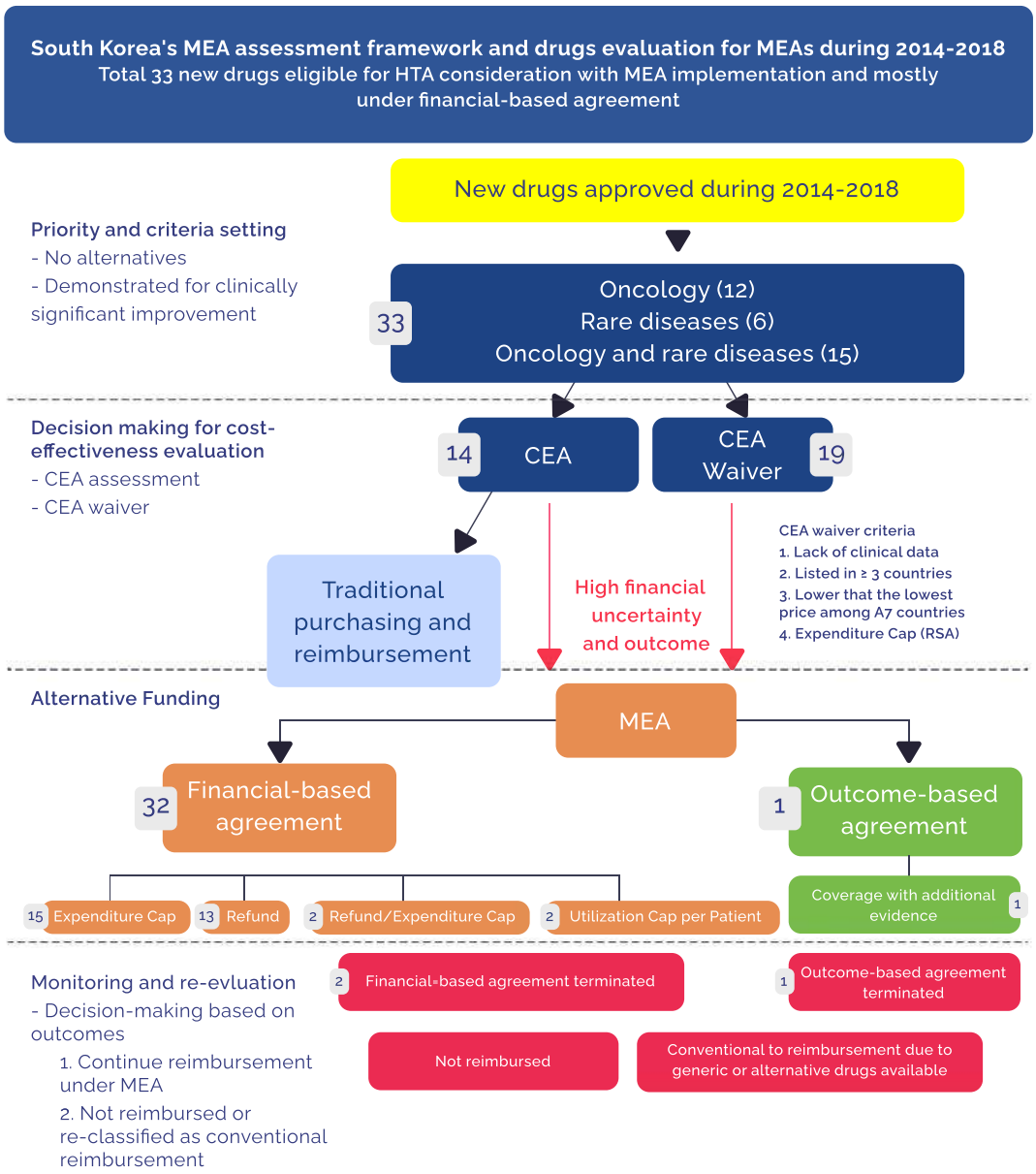
Variations of these criteria involved processes wherein countries utilized MEAs more broadly in their entire HTA process (e.g. Bulgaria).[31] In Australia, the UK and Italy, comprehensive MEA frameworks are incorporated into HTA processes with well-funded and complex data registries in place to support performance-based MEAs, though financial MEAs (most often simple discounts) are most common.[40-42]

Figure 4: Example of alternative mechanisms for high-cost drugs consideration [21, 40, 43-47]

South Korea	RSA and CEA waiver for oncology and rare diseases
Taiwan	MEA and no mandate required CEA evaluation
UK	MEA, CDF, end of life criteria and flexible ICER threshold
Australia	MEA and CDF
Canada	MEA and soft WTP approach

- In South Korea, a waiver of cost-effectiveness analysis is granted, or flexibility is permitted for novel oncology drugs or orphan drugs based on satisfying the strict criteria. Such drugs are considered where there are significant challenges in evidence generation of cost-effectiveness (e.g. novel drugs, rare disease) but clinically essential with no alternative intervention, are reimbursed in at least three A7 nations and are subject to an expenditure cap RSA under the cost-effectiveness waiver system.[10,43]

Figure 5: South Korea's MEA Framework 2014-2018 significantly increasing new cancer drugs listing rate from 43% (2008-2013) to 57% (2014-2016) of total drug submissions[10]



- Similarly in the UK, an explicit ICER threshold ranging from £30,000 to £50,000 per QALY is used based on the QALY shortfall method based on the severity of a disease as the future health lost, even increasing the range to £100,000 - £300,000 per QALY for orphan drugs considered via highly specialized technologies (HST) program that offers significant health benefits.[44]

- In Australia where there is no explicit ICER threshold, new medications are typically approved with thresholds ranging from AUD45,000 to AUD60,000 per QALY. [47]

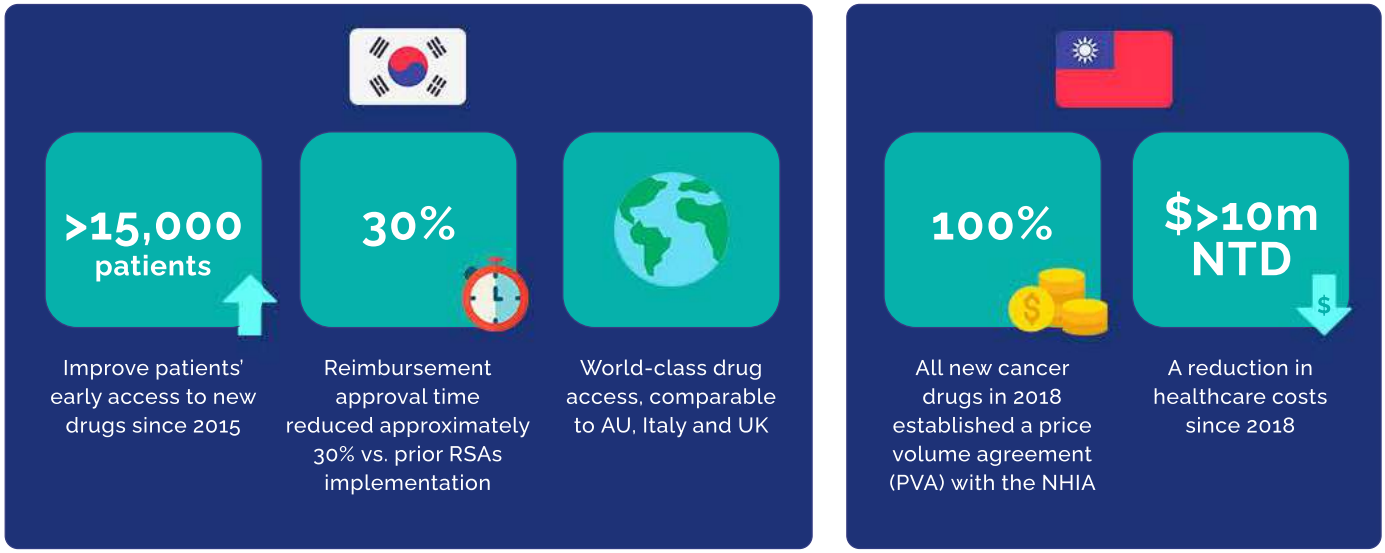
- In the Canadian example where there is no explicit ICER threshold, a "soft" WTP approach may be used as part of a contextual decision-making process, whereby drugs with wide-ranging ICERs are accepted for reimbursement with measures such as MEAs to control budgets.[10]

Reimbursement with MEAs has shown substantial improvements in patient access to cancer medicines, with reimbursement being dependent on MEA availability in 20% and 60% of cases in Finland and South Korea, respectively. Australia uses MEAs as part of its plan to help achieve coverage for up to 33% of new medicine-indication pairing. Finally, the use of financial-based MEAs in particular is associated with increased speed of access.[5]

In addition to increasing patient access and reducing uncertainty regarding cost-effectiveness, MEAs are applied for a number of other reasons specific to the healthcare system's desired policy objectives. MEAs may serve simply as a cost-containment tool for payers, may improve access, guideline and reward innovation, and serve as a check against clinical, cost, or utilization uncertainty.[5]

Within experienced APAC markets, the use of MEAs has been successful. South Korea's deployment of MEAs has enhanced patient access to new drugs, reduce patient out-of-pocket spending, and expand drug coverage to levels comparable to that of the UK and higher than Australia.[6] In Taiwan, formal cost-effectiveness evaluation is often not a consideration for reimbursement with <20% of oncology drugs requiring a CEA – however, 100% of new oncology drugs will pass straight to MEA negotiations some years. From 2018-2021, these were estimated to result in savings of over 10 million NTD.[7]

Figure 6: Benefits of MEAs implementation in Asia[7,10]



Challenges do exist even with the perceived benefits of MEAs in improving patient access to high-cost drugs given its clinical and operational complexity.[44-46] Methodological problems around model design, administration costs and logistical delays persists, with the need for continuous validation of the models and assumptions. Even so, real-world data from later stages of clinical trials for certain drugs may not necessarily address nor improve the degree of cost and clinical uncertainty,[48-49] which highlights a potential limitation but still a viable mechanism to provide patients with the opportunity more options to treatment without burdening the payer in the longer term.

Apart from MEA implementation challenges, the evaluation of MEA outcomes informing decision-making for the drug listing or delisting is important. MEAs give opportunities to gather additional evidence to reduce clinical or cost uncertainties. However, the clear data collection objectives and measurable indicators within the conditional period addressing the original uncertainties in the appraisals for a final decision are required. [50-51]

Furthermore, there is always a need to find a balance between cost containment and the expansion of coverage. Cost-effectiveness thresholds and budget impact analysis concerns are often challenged by the nature of the disease areas (i.e., low number of patients, severity of disease) and the limited healthcare funding. Notably from the earlier workshops, there was an acknowledgement among Thai stakeholders that innovative medicines for specific disease categories (e.g. oncology, rare/orphan diseases) should be accorded a higher ICER threshold given the likelihood of a higher willingness-to-pay (WTP), but should also consider avoiding catastrophic overspending in the healthcare system.

2. STUDY METHODOLOGY

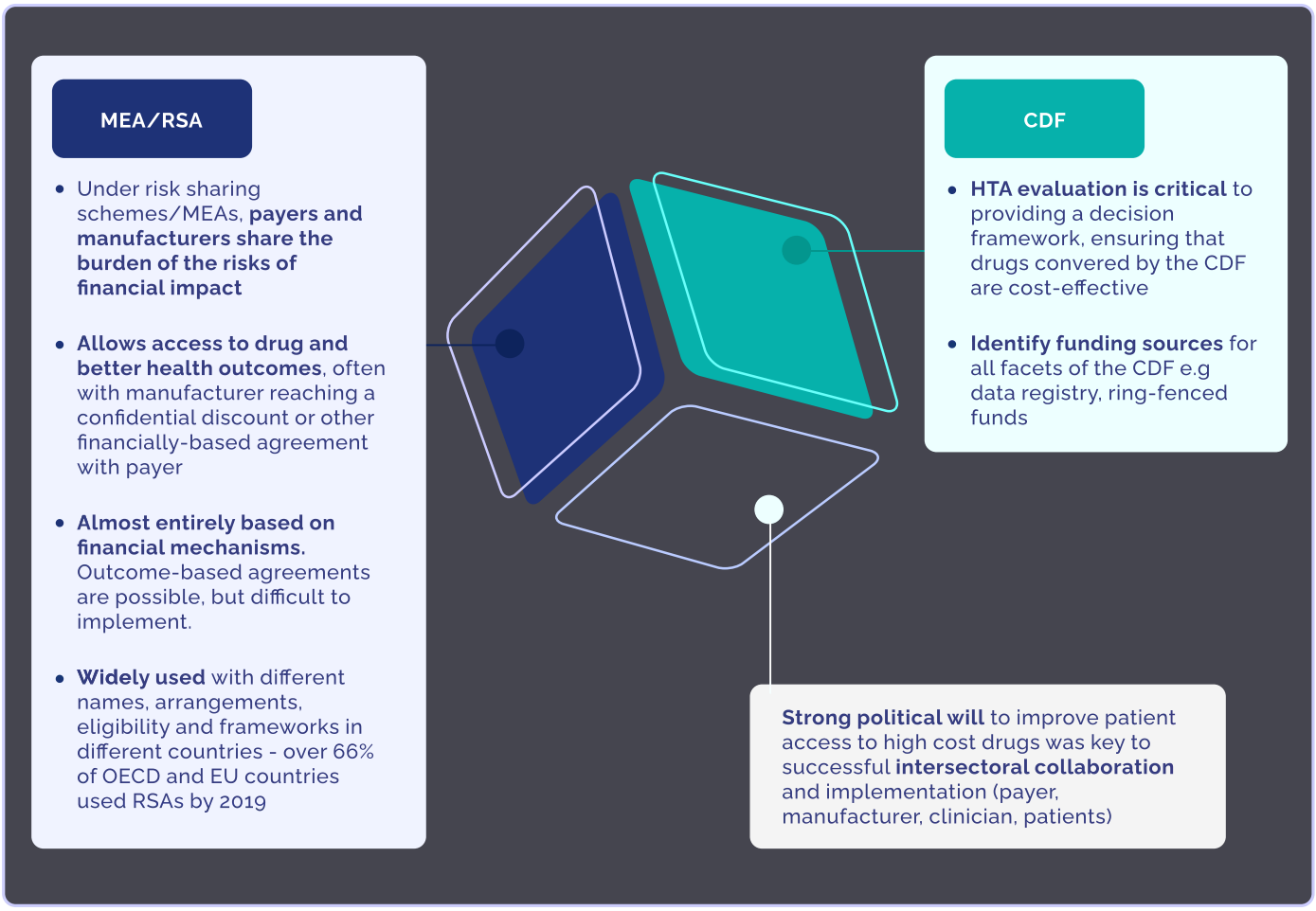
2.1 Research Program: Use of Modern Evaluation and Funding Mechanisms in Thailand–Solution Identification and Implementation Considerations

A research program was initiated in two phases to explore both solutions and implementation issues to address the current challenges in Thailand related to limited and delayed access to high-cost innovative medicines (including oncology treatments). A paper capturing the first phase which included a workshop in 2021 convened by Chulabhorn Royal Academy (CRA) with 21 panel lists of Thai policymakers, clinicians, health economists and patient organizations,

"Modernization of Thai Health Technology Assessment: Identifying Alternative Approaches in Thai Health Technology Assessment to Improve Cancer Patient Outcomes"

explored and presented a consensus on funding methodologies most likely to improve patient access in Thailand.[4] Conclusions from this phase of the program identified financial mechanisms, specifically managed entry agreements (MEAs) and a Cancer Drug Fund (CDF) as being the most appropriate solution and simplest approach for Thailand.

Figure 7: Considerations for Implementing Managed Entry Agreements[29, 45]



Participants from the workshop expressed confidence that this approach would provide an environment where manufacturers are competitive in pricing, access is rapid, and Thai-specific evidence generation occurs.[3] Preferences for these approaches underly the appreciation for the provision of an acceptable split of risk between payer and manufacturer, which allows for faster access to high-cost drugs without massively inflating healthcare budgets. Through understanding the experience of other comparable countries and the sound HTA infrastructure in Thailand, participants expressed enthusiasm for mapping out implementation pathways.

The second phase of the research program and the focus of this paper, consider issues and opportunities related to the implementation of the identified mechanism(s) for improving patient access in Thailand. The approach was multi-faceted and included a targeted literature review, a workshop held in Apr 2022 with key Thai stakeholders including payers (NHSO and CGD), clinicians (in oncology and rare diseases), academics and policy makers,

"Alternative financing solution and managed entry agreement: Unleashing access to unattainable medicines",

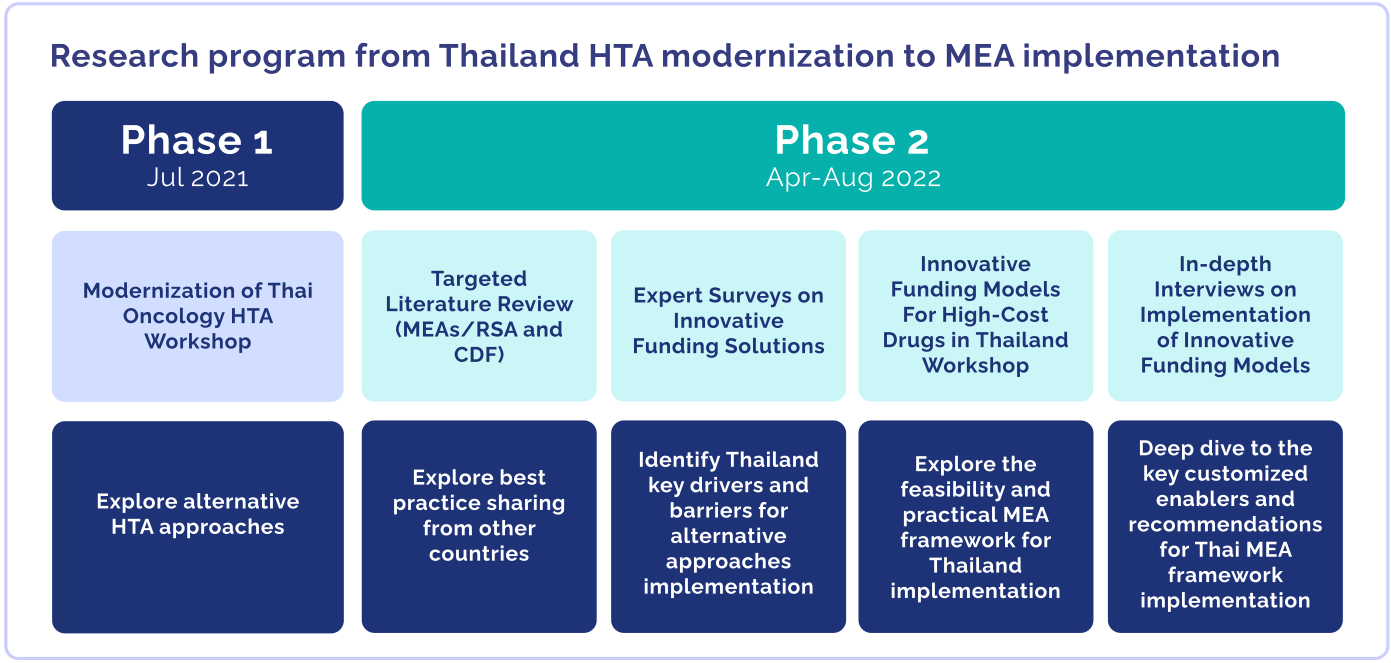
2.2 Objectives: Implementation Consideration Research

To explore the intricacies of developing an RSA/MEA framework that is relevant and viable for Thailand's healthcare system, the research approach to consider the implementation approach included the following objectives:

1. To gain perspectives from key Thai stakeholders including policy makers, clinicians, payers, academics and international experts on the issues and opportunities involved in the implementation of alternative funding solutions for high-cost drugs in Thailand.

2. To determine a customized MEA framework for Thailand as a payer tool for the initiation and implementation of a pathway towards providing access to high-cost drugs and pilot implementation as an expansion to the current HTA framework.

Figure 8: Research program components



2.3 Expert Insights Survey

Eight experts who are payers and policy-makers from six countries including Italy, UK, Australia, Hong-Kong, Taiwan and South Korea were surveyed to gain insights related to drivers and barriers faced during the implementation of innovative funding models in their respective countries.

Pertinent factors that could guide Thailand's implementation approach were collected and summarized for presentation during a subsequent workshop.

2.4 Alternative financing solution and managed entry agreement: Unleashing access to unattainable medicines workshop

A workshop was convened in April 2022 with ten Thai participants including payers (NHSO, CGD), clinicians (in oncology and rare diseases), academics and policymakers to educate and seek learnings on the practical implementation of innovative funding models for high-cost cancer and rare diseases drugs in Thailand including RSAs/MEAs and CDFs. Three expert speakers from Italy, South Korea and Singapore shared their insights and experience to guide discussions on the implementation of an innovative medicines funding framework in Thailand.

2.5 In-depth Interviews on Implementation of Innovative Funding Models in Thailand

In-depth interviews, each one hour in length, were initially invited to nine key opinion leaders with significant involvement in the previous workshop, HTA policy and reimbursement decision-making process. It was finally conducted with seven senior Thai payers and clinical stakeholders from NHSO, NLEM, HITAP and CRA to obtain detailed insights into the practicalities of implementing an innovative medicines MEA framework specific to the Thai environment. Perspectives from the leading organizations involved in the current HTA and NLEM pathway together with clinical perspectives were gained from these discussions.

3. RESULTS

3.1 Results of Initial Pre-Workshop Implementation Experience Interviews

Building on the understanding of international experience with MEAs, a consideration of how these innovative models were implemented was explored through surveys with eight health policy experts who were recruited from six mature global markets with extensive experience developing, implementing, and sustaining innovative medicine funding models. The countries represented (Italy, Hong Kong, Taiwan, South Korea, UK and Australia)[10] have HTA evaluation as part of their formal healthcare decision-making process, have experience with MEAs and all except Taiwan and South Korea have experience with ring-fenced funds such as CDF.

Each contributing expert was asked nine questions (Appendix Table 2: Survey Questions – Expert Insights into Drivers and Barriers in the Implementation of an Innovative Funding Model) that explored their insights regarding drivers and barriers faced during the implementation of innovative funding models in their country.

3.1.1 Insights from Survey Responses: collaboration, political will, practical approach

Responses to the survey questions confirmed the findings from the literature that MEAs, typically financial-based, are a common tool used successfully by other countries to manage budget concerns related to high-cost medicines, often including CDF or innovative medicine fund through ring-fenced fund mechanism.

Collaboration among all stakeholders (i.e., payers, manufacturers, clinicians, patients) was identified as a key factor in successful implementation, with an understanding that strong political will to improve patient access to high-cost medicines is fundamental. Targeted stakeholder consultations (e.g., public hearing for risk-sharing type models, drug advisory committees for performance-based models) are suggested as a means to ensure collaboration and buy-in. It is noted that key stakeholders such as clinicians, payers and decision makers are already involved in the current Thai HTA framework, which would not differ significantly if MEAs are introduced. However, ensuring all stakeholders' views are incorporated at the final decision is crucial.

Barriers pertaining to financial-based MEAs versus outcome-based MEAs are different. For the latter, data infrastructure to include patient-level and real-world data collection is a significant undertaking with practical capacity concerns for all stakeholders involved in data generation (e.g., pharmacists, physicians, social workers, etc.). Additionally, the mechanism of gathering treatment information from clinicians and patients and caregivers must be strictly managed. Keeping the MEA approach as simple as possible is recommended, with a budget-capping approach suggested as easy to understand and implement.

Figure 9: Key success factors for MEA implementation in Thailand

3.1.2 Regional stewardship from an expert advisory committee

For both financial-based and outcome-based MEAs, a comprehensive understanding of alternative funding mechanisms together with costs and consequences is necessary. This implementation requires a HTA infrastructure with greater intersectoral collaboration, robust HTA decision-makers and clear policy direction. A drug advisory committee consisting of domain experts to provide regional stewardship of evidence-based practice and provide a framework to guide the clinical priorities and implementation of innovative funding models is recommended, which would likely be an extension of responsibilities for payers and clinicians in the respective therapeutic area under the existing HTA framework.

To manage expectations from the public and to maintain budgets, formal MEA appraisal mechanisms should be in place for each agreement made. Re-evaluation may be introduced as part of these mechanisms to determine if an agreement should be continued, amended or terminated.

3.2 Results from Workshop: Alternative financing solution and managed entry agreement: Unleashing access to unattainable medicines

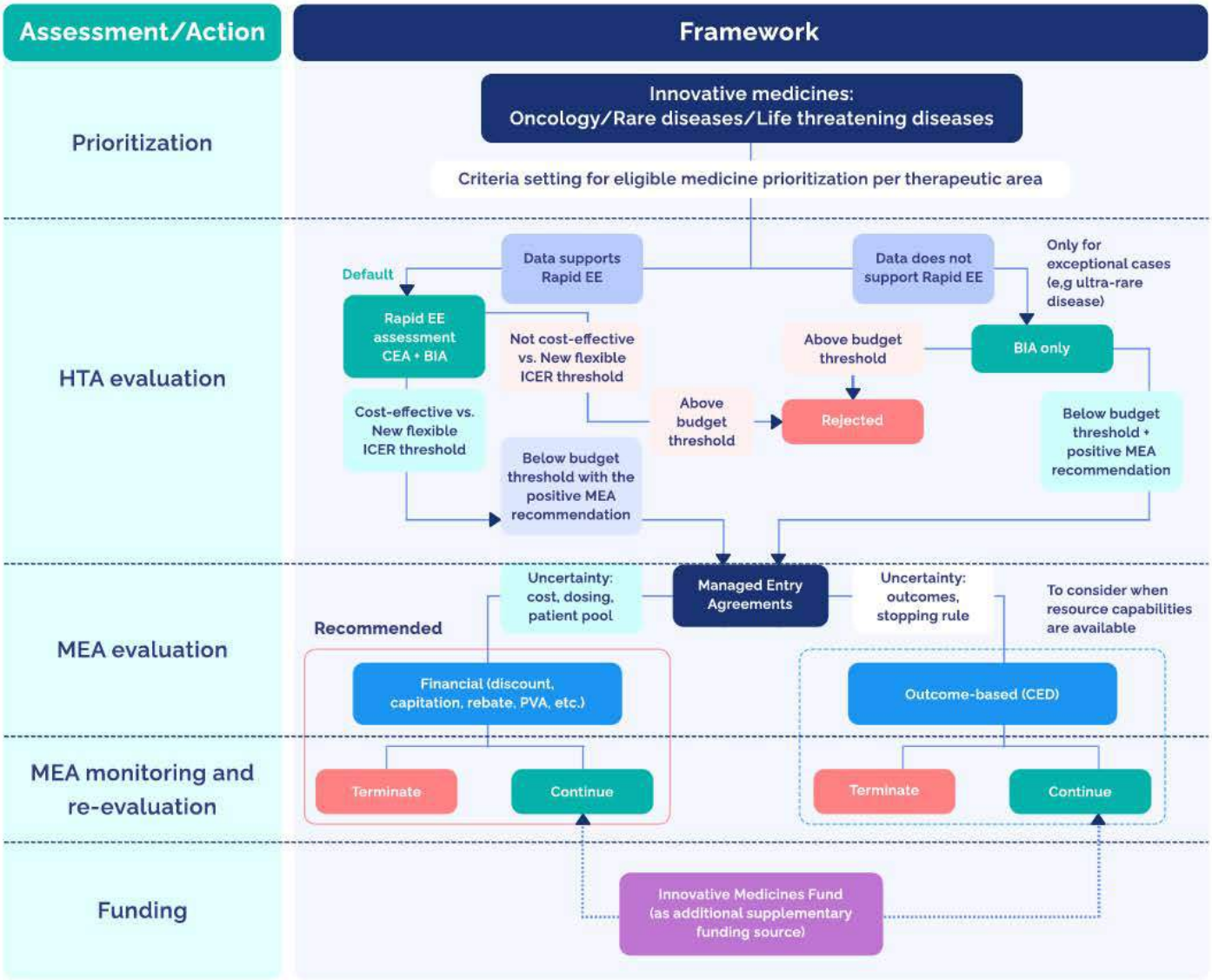
The innovative funding models workshop in Apr 2022 contributed learnings and initial views on the implementation of an innovative medicine funding solution from a Thai perspective. Majority of the participants (n = 6) generally agreed that oncology, rare diseases and life-threatening diseases were the recommended therapeutic areas of focus for innovative funding through the new MEAs and ring-fenced fund mechanism. Even though the current NLEM process may be the effective pathway in this decision-making process, the need for extensive research and consultancy with relevant stakeholders for the policy proposal development are recommended. Caution was urged in regard to resource needs and infrastructure, suggesting anew that the significant data infrastructure required for outcome-based MEAs may only be appropriate for a later stage of implementation. Furthermore, a clear definition of medicines fall under the innovative funding category will need to be established to distinguish such medicines from mainstream HTA evaluation.

Piloting a series of MEAs, with different indications and pharmaceutical company partners was recommended for Thailand. This would permit meaningful comparison and process adjustments as well as a formal evaluation of an initial framework.

3.3 Results from In-Depth Stakeholder Interviews on Implementation of Innovative Medicines Funding Model in Thailand

The insights gathered following the 2nd workshop with in-depth interviews with seven Thai key stakeholders including 4 participants from the workshop and 3 new relevant policy stakeholders formed the foundation for the development of a draft MEA framework (Figure 10). Senior representatives from NHSO, HITAP, NLEM Committee, and CRA provided context and practical information to consider how an MEA framework may be incorporated into the current HTA process in Thailand with reference to South Korean drug evaluation and decision-making process as the core framework for Thailand customization.10 (See Appendix, Table 3: Key Steps – Proposed MEA Framework).

Figure 10: Proposed MEA Implementation Framework



3.3.1 Requirement for clarity of definition of "innovative medicines" and the call for an expert committee

In the Thai context, all interviewees opined that specific eligibility criteria are required to identify appropriate diseases and treatments with clear definition of the term "innovative medicines" to provide clarity on the interpretation of this term. The majority of respondents agreed to consider current NLEM committee principles of safety, efficacy, cost-effectiveness and acceptable budget impact when aligning on the scope of definition of "innovative medicines".

One interviewee commented that a duration of treatment should be considered as a rare disease may require life-time duration of treatment where there is a need to ensure sustainable long-term funding to avoid the situation of patients discontinuing treatment due to disruption in funding. Another interviewee commented that drugs for life-threatening conditions will need to consider whether the impact is immediate or long-term. Regardless of variations in perspectives, interviewees recommended that terms and definitions of these priorities should be set to provide clarity on the appropriate submission process for which channel/track and evidence requirements can be prepared and proposed through either the UCBP or NLEM listing submission process.

The call for a committee to assess the current public health needs, access challenges and priorities was corroborated and further refined the eligibility of innovative medicines applicable for MEA to include:

i. National Drug committee as policy governance
ii. Payers
iii. Providers
iv. Patients – Patient group representative or NGO
v. Academia or Medical Association
vi. MOPH as regulator
vii. Pharmaceutical representatives

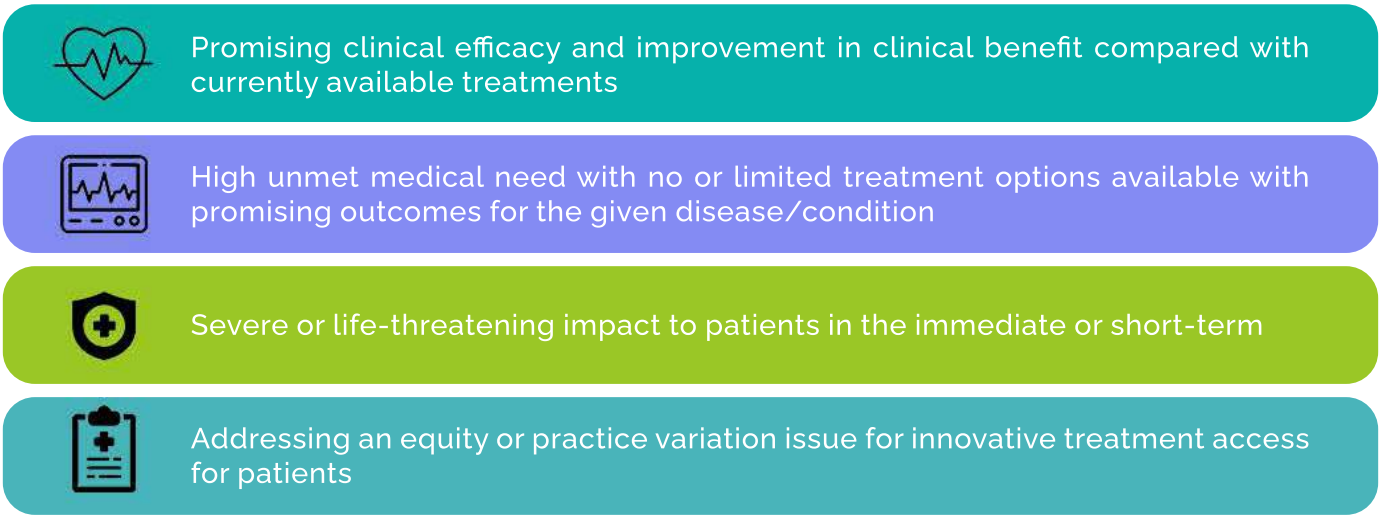
While stakeholders did not have a clear consensus on how the adoption of MEA can be incorporated into Thai HTA process, there were two suggested approaches that can be considered: (1) integrating into the current NLEM processes, or (2) having a newly appointed committee working separately in coordination with NLEM processes.

The first option may be achieved through an appropriate sub-committee or expert working group under the NLEM committee, as the NLEM has oversight on the drug reimbursement landscape in Thailand. While this option may be desirable, expertise in MEAs is required and it may increase the workload burden and slow the evaluation process. Most countries with MEA implementation such as South Korea, Australia, UK, Italy, proposed MEA as a tool for the innovative medicine reimbursement assessment leading to more rapid access and efficient time in reviews.[5-6] The initial period may require guidance from an international advisory panel – within APAC supporting NLEM committee for the framework establishment. This can be done similar to NICE-CADTH scientific advice framework where HITAP can rely on international experts to provide scientific advice pertaining to planned evidence generation.

The second option offers a new committee that is specialises in MEA with more capability to accelerate the assessment process without having to increase the workload burden currently undertaken by NLEM. The challenge with this option is the significant time commitment required to set up a committee and to align on the framework that will establish roles and responsibilities with the current committee. Furthermore, there will be a need for this separate committee to liaise with NLEM to ensure consistency in the alignment of reimbursement decisions as seen in Canada experience that having a separated HTA agencies for oncology and non-oncology evaluation led to delaying in the drug access.[58] As such, the majority preferred the former option, contingent on adequate resources being made available to support this initiative.

3.3.2 Innovative Medicines Criteria Setting: A customized criteria adapted from South Korea

The recommended criteria for eligible innovative medicines include:



These criteria should be considered during assessment by the committee with the understanding that general characteristics of innovative medicines (particularly in the case of rare disease) include limited information with a lower strength of evidence and marginal incremental clinical benefit. One interviewee opined that the scope of having no alternative treatment available when comparing against current standard of care treatment for a particular disease will have to be defined in manner that is not too narrow nor too broad to be considered for prioritisation under this evaluation track. As such, the recommended criteria proposed based on the outputs of the research considers

3.3.3 Cost Effectiveness and Budget impact Criteria Setting

In terms of cost-effectiveness and budget impact approaches, recommendations of setting a higher flexible ICER threshold and budget impact thresholds were raised. These thresholds could be potentially established based on referencing available global data with consideration of adjustments made in respect of Thailand's GDP, healthcare budget and disease burden.

However, there was no concrete opinion on the values to be set for a revised cost-effectiveness threshold and an explicit budget impact, although one interviewee suggested that the value of cost-effectiveness compared exceeding the current Thai threshold should not be the definite exclusion for reimbursement decision-making while another interviewee recommended the budget impact for innovative medicine at THB 50 – 100 million per drug per year.

In terms of the HTA assessment pathway of eligible innovative medicines, majority of interviewees suggested a separate track from the traditional full HTA review given the limited availability of Thai clinical data and the necessity to ensure timely equitable access of innovative medicines to patients in Thailand. Two possible pathways analogous to the South Korean framework were suggested for the Thai MEA framework: a default pathway and an exceptional pathway. Interviewees agreed that HITAP is the appropriate stakeholder for leading the assessment and economic evaluation with consideration for capabilities and capacity improvement whereas one interviewee argued that HITAP has the largest resources for health economics and policy research in this region and recommended to refine the appropriate decision-making criteria than an arbitrary CET adjustment.

3.3.3.1 Default pathway

The default pathway involving a simplified economic evaluation (EE) with budget impact analysis (BIA) is intended for most cases to introduce more efficiencies and shorten the timeline to evaluation and ultimately patient access to innovative medicines.

Unlike traditional CEA evaluation process requiring extensive resources and a long time to generate Thai clinical data. This new "default" pathway for innovative medicines which fulfil the criteria to be evaluated under the MEA framework requires only a previously conducted CEA where the drug was approved for reimbursement by an established HTA agency (e.g. CADTH, NICE) or simplified CEA alongside with a BIA with potential adaptation of Thai parameters. This applies where there is a lack of certainty in the collection of Thai data (e.g., costs, clinical efficacy) with a reduced requirement of clinical efficacy data obtained from phase 2/3 randomized clinical trials. This proposed approach 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 of innovative medicines.

3.3.3.2 Exceptional pathway

The exceptional pathway is intended only for very challenging cases (e.g., ultra-rare disease) will require a BIA only given the small patient pool and the lack of substantive clinical data available to be able to be subject to evaluation under the default pathway.

Under this route, the recommended criteria included a drug that is intended for treatment for 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 available efficacious

3.3.4 Feasibility of Pilot MEA Implementation in Thailand

As the implementation of the MEA framework is a huge endeavour, the majority of interviewees recommended that pilot projects shall be undertaken to ensure the feasibility of such a framework on a nationwide scale in Thailand. Key areas that are relevant were considered and recommended among interviewees, which include the scale of the pilot implementation, agreement terms, data system for tracking and drug procurement processes.

Pilot implementation feasibility among stakeholders' views

Scale of pilot implementation: Nationwide scale to ensure patient access equity. Healthcare resources and capability building would need to be sufficiently adequate to ensure proper testing nationwide

Agreements should be for 2 – 5 years with annual MEA outcomes evaluation to assess on the effectiveness of the MEA framework for a particular drug. Even though one interviewee opined the price transparency, majority aligned on prices of these drugs remained confidential among the relevant stakeholders under these agreements as this is the general rule implemented globally.

Drug procurement process: Innovative medicines can be procured through existing E2 category of the NLEM process. Requires legislative amendments to cater to the multi-year procurement per MEA condition, with an annual review process could be considered contingent on having sufficient resources to support.

Data System: E2 category database can be potentially leveraged for financial based agreement, however, the outcome-based agreement requires the new specific patients' data collection system

Post-MEA evaluation process: Straightforward approach of either continuation of listing or delisting of innovative medicine from the NLEM, which is dependent on

A financial-based agreement was consensus recommended for the first pilot MEA implementation within the near term due to minimal new requirements and adaptation of existing resources while the outcome-based agreement shall be planned as the long-term solution as the centralized clinical data infrastructure needs to be in place prior to implementation.

Short term goal
Financial based agreement

Long term goal
Outcome based agreement

4. CONCLUSIONS AND RECOMMENDATIONS

The information gathered, corroborated, and expanded upon through the various stages of this review of the implementation of MEAs for innovative, high-cost drugs in the Thailand healthcare setting has culminated in practical recommendations and approaches. Multiple stakeholders have expressed positive perceptions towards the benefits of implementing MEAs in Thailand based on global examples, and agreed on prioritising MEA for oncology and rare diseases innovative medicines to improve patient access. The proposed MEA framework consolidated throughout this research program have highlighted the most plausible MEA pathway. However, alignment on priorities, criterions and decision-making criteria for official Thailand MEA framework establishment requires a call for action among the relevant stakeholders to ensure benefits to the healthcare system. Key challenges for implementation were highlighted among stakeholders including:

1. Lack of political will to support the right governance body and relevant stakeholders required for collaboration

2. Lack of clarity in terms of the decision-making criteria and integrating the MEA framework to current NLEM process

3. Specific areas of MEA implementation such as legislative and regulatory amendments, confidential agreements and procurement process, building infrastructure and capabilities supporting applicable type of MEAs in pilot implementation are required

Countries around the world are implementing MEAs with varied processes, but each with positive budget impact, improved patient outcomes (i.e., quality of life, survival) and improved access to treatment for patients. Their experiences are considered and reflected in the recommendations for the Thailand approach.

One of the most crucial factors for an MEA implementation framework in Thailand is to establish sustainability for the entire healthcare ecosystem to ensure the best health outcomes for patients possible. The framework must not contribute to a situation of overspending on the healthcare budget or challenges to the stakeholders delivering the medicine to the patients, each of which would impact patients with the discontinuation of treatment with no alternative. Specific eligibility criteria for innovative medicines under the efficient HTA assessment pathway are required to identify and recommend appropriate disease and treatment under this MEA framework.

Recommendations

Financial-based MEAs should be the focus in Thailand in part because current processes may be exploited to maximize implementation efficiency (i.e., the current NLEM E2 drug listing category pathway)

Outcome-based MEAs should be considered for development in later stages when resource capabilities and data infrastructure are available.

Collaborate and co-create with all relevant stakeholders including payers, HTA leaders, pharmaceutical companies, medical associations, academia, patient groups and specialist experts to improve the HTA system and provide patient access to innovative medicines.

Investigate legislative interventions required to facilitate MEAs with a duration of 2-5 years (with annual evaluation of progress) for Thai procurement law.[52] As this could potentially be a time-consuming process, an annual review process can be considered contingent on having sufficient resources to support.

Build capability among healthcare practitioners regarding the implementation of MEAs. (e.g., pharmacists, who will be MEA implementors at the hospital level, must understand the MEA definition and the framework process.)

Establish a new ring-fenced innovative medicine fund to increase the current payer healthcare budget and **sustain the long-run healthcare financing.**

Pilot the MEA Framework through a national program with consideration of current processes integration could potentially support the first phase launch of financial-based agreement model while new requirements i.e. data infrastructure and capabilities for outcome-based agreement model being

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APPENDICES

Definition of Terms

Risk Sharing Agreements/Managed Entry Agreements (RSAs/MEAs)

RSA, as defined by HTAi[35] as 'an agreement between the producer/manufacturer and the payer/provider that allows access (coverage/reimbursement) of a health technology under certain conditions. These agreements may use a variety of mechanisms to address uncertainty about technology performance or to manage technology adoption to maximize their effective use or to limit their budgetary impact'. RSAs are largely based on financial agreements adopted by over two-thirds of the Organization for Economic Co-operation and Development and European Union countries, often with manufacturer reaching a confidential discount or other financial-based agreements with the payer. Agreements based on clinical results which include the collection of real-world data and payment is based on observed results are possible but often difficult to implement.[49]

Cancer Drug Funds (CDF)

A CDF is an approach where a separate source of funding is intended to improve access to promising new treatments through MEA while collecting further clinical evidence. It is intended to be interim in nature, with the evidence appraisal beginning much sooner in the drug approval process. A CDF will have financial certainty with a fixed budget and a mechanism to control expenditure.[45] In the United Kingdom (UK), through a partnership with the payer and HTA body, greater flexibility is afforded to the National Healthcare Service (NHS) in its negotiations with pharmaceutical companies to encourage appropriate pricing of cancer drugs.[45]

APPENDICES

Table 1: International Experiences with MEAs

 **Australia**	• Between 2010 and 2017, 11 medicines were considered for MEAs, 75% of these were oncology drugs with the main uncertainty being overall survival[46] • Manufacturers made 50% of proposals for MEAs. • Three schemes were implemented (6 others received coverage after reduced prices).
	• Ultimately, financial risk to the payer was reduced. • Effectiveness on health outcomes (survival) studied in one of the three schemes supported the cost-effectiveness claim, though due to limitations on data this was deemed inconclusive[25]
	• Payer will consider outcomes-based MEA if: there is a high unmet clinical need; new clinical data will resolve uncertainty, and price confidentiality is maintained. • Financial MEAs dominate the landscape in Australia[36] • MEAs reduce uncertainty around comparative effectiveness, cost-effectiveness and manage budget impact[24]
 **Bulgaria**	• MEAs are considered essential for reimbursement to be maintained • If negotiations are unsuccessful, funding for medicines is phased out.
	• Models include financial instruments including discounts, price/volume, and coverage with evidence development[28] • Agreements are valid for one year with an annual renegotiation of discounts. If no discount is provided, funding for the medicine stops[47]
	• MEAs are required for all new medicines covered since 2015 and for patented medicines already covered before 2015 to maintain coverage[47]
 **Canada**	• One province (Ontario) established Bill 102, the Transparent Drug System for Patients Act in 2006. This legislation granted the ability to negotiate MEAs with manufacturers, including confidential financial terms, to achieve better value for the publicly funded system • A pan-Canadian Pharmaceutical Alliance (pCPA) process to collectively negotiate with manufacturers has completed hundreds of negotiations, though there is acknowledgement that patient outcomes data is an ongoing challenge[36]
	• There is an assumption that financial agreements are most common though details of negotiations are confidential. • Investigation underway to determine the approach to rare disease drugs that may include MEA.[36]

- Unofficial range of incremental cost per quality-adjusted life-year values, which, when considered in the context of a decision maker's priorities and the interventions' place in therapy, may be considered acceptable (versus cost-effectiveness threshold)[48]
- MEAs reduce uncertainty around comparative effectiveness, cost-effectiveness and manage budget impact[24]
- Unofficial budget threshold: €20million and €50million[42]

Italy

- Italy is the most active practitioner of MEA in Europe.[36]
- Two types of MEAs are most often implemented: risk sharing and payment by results[36]

- The focus for MEAs is on high-cost medicines with uncertainty as to safety, appropriateness of use in routine practice, effectiveness, cost-effectiveness and/or budget impact[35]
- MEAs reduce uncertainty around comparative effectiveness, cost-effectiveness and manage budget impact[24]

- Registries set up by the Italian Medicines Agency (AIFA) are specifically established for data collection, which represents a significant administrative burden. Clinical data is shared between clinicians and pharmacists and the regulatory agency[37].
- Data contributes to comprehensive evaluations and full understanding of the MEA experience.[38]
- The registries are well-established (and considered a leading (best-practice) infrastructure world-wide), however it remains a challenge in terms of capacity[38]

- MEAs contributed substantially to an improvement in the access of cancer medicines for Italian patients[45]
- In 2021, Italy had over 20 MEAs in place. Repayments from manufacturers under the terms of these deals were €344.2 million.[49]
- A funding mechanism with €500 million for oncology drugs and another €500 million for non-oncology drugs is in place. If spending surpasses these funds, industry must pay back the surplus.[42]
- Italy does not consider affordability or cost-effectiveness in drug coverage decisions but relies on price negotiations, capping on specific expenditures and performance-based schemes.[42]

South Korea

- Eligibility for Korean RSAs: drugs for cancer and rare diseases and not having other alternative treatments
- Extensive experience since 2013 with mostly financial agreements (largely refund and expenditure cap)[6]

	• Implemented exemption for economic evaluation (EEE) in 2015 for drugs with very strict criteria: only cancer drugs or orphan drugs can receive a waiver of economic evaluation when: (1) the condition is so severe that patients' lives are threatened and there is no alternative intervention; (2) the number of patients is too small to generate evidence; and (3) the drug is reimbursed in at least three of the seven countries including: UK, Italy, France, Germany, Switzerland, the US, and Japan[10] • Implementation of RSAs succeeded in containing pharmaceutical expenditure and improving access to new drugs[6] • Korea does not have an explicit ICER threshold, however per capita GDP level is considered in the deliberation process. Flexibility is allowed for cases of oncology drugs or orphan drugs, wherein ICER exceeds per capita GDP.[39]
 **United Kingdom**	• MEAs are referred to as Patient Access Schemes (PASs) • An entire unit of NICE is responsible for coordination of the MEA negotiations.
	• In 2018, there were 184 active PASs, with 72% in place as simple discounts[36] • The CDF includes a fixed budget and a mechanism to control expenditure.41 Through a partnership with the payer and HTA body, greater flexibility in negotiations with pharmaceutical companies is realized.[41] • The CDF contributes increased access and process efficiencies.[41]
	• In the UK, there is an increasing capacity for registries and data management and more complex access arrangements.[36] • MEAs reduce uncertainty around comparative effectiveness, cost-effectiveness and manage budget impact[24]
	• Cost effectiveness threshold: £20,000 to £30,000 per QALY[50] • Flexibility in ICER threshold is allowed for rare or ultra-rare disease. Above a most plausible ICER of £100,000-£300,000 per QALY gained, judgements about the acceptability of the highly specialised technology as an effective use of resources must take consider the incremental therapeutic improvement (i.e., additional QALY's gained).[51]

Table 2: Survey Questions – Expert Insights into Drivers and Barriers in the Implementation of Innovative Funding Models

SURVEY QUESTIONS	
1	What were the main drivers in implementing RSA/ MEA/CDF in your country/ region, and what were the main barriers? How will these barriers apply to upper-middle income Asian economies such as Thailand?
2	How were funding sources, processes and governance for new access models considered, designed and implemented by all stakeholders?
3	How did payers/ policy makers overcome the implementation barriers?
4	For time-limited schemes (e.g., 5-year contracts), what approaches exist to ensure continued patient access beyond the initial agreed duration? What approaches should exist in theory? What happens in cases where evidence supports continued benefit, or otherwise?
5	If your health system undertakes periodic reviews of the schemes, how frequently are they reviewed and which aspects of the schemes are reviewed (e.g. financial, coverage, external reference, outcomes, others)?
6	Based on post-implementation experience of the schemes available in your country/ region, what are payer's attitudes towards RSA/MEA/CDF, and what improvements would they recommend in the future?
7	What sort of access solutions do you think best address Thailand's situation?
8	For countries like Thailand, what do you think is the best model to increase patient access to new cancer drugs, and which should be considered as priority? Which aspects of the scheme will present the most challenges to implementation?
9	What are the local evidence requirements and infrastructure for implementing new funding mechanisms such as RSA, MEA, CDF, for new cancer drugs in Thailand

Participants in expert survey

Eight experts from six countries included an HEOR professor and former member of the regional HTA Committee and a member of the National Centre for HTA from Italy; a Medical Director, former HTA Chief Manager from Hong Kong; a member of the ISPOR Board of Directors, former director at the CDE from Taiwan; a HEOR professor, advisory to the NECA, HITA and KCDC from South Korea; an HTA professor, former advisory to NICE and a health economist, former advisory to NICE, SMC and other HTA bodies from the UK; and an HTA professor, current member of the VCCC Alliance from Australia.

Implementation of Innovative Funding Models for High-cost Drugs in Thailand Workshop

Expert panellists

1. Prof. Fabrizio Gianfrate, Health Economics and Outcome Research, University of Ferrara and LUISS, Business School Rome, Italy

2. Prof. Jeonghoon Ahn, Department of Health Convergence, Ewha Womans University, South Korea

3. Omar Akhtar, HEOR Director, Ipsos Singapore.

Table 3: Key Steps – Proposed MEA Framework

Goal and Priority setting	
To target the disease area with higher unmet need and public health burden, and with stronger or increasing political will and direction.	
Activities	Set up a committee to assess the current public health needs, access challenges and priorities endorsed by the country's political will
Stakeholders	MOPH Payers - NHSO/SSO/CGD NLEM Committee Medical Association
Criteria setting	
To define the specific disease or severity of diseases and treatment assessment criteria including alternative existence or benefit scale assessment.	
Activities	Establish the metric for evaluation and prioritization of specific diseases and innovative products - oncology and rare diseases
Stakeholders	MOPH Payers - NHSO/SSO/CGD NLEM Committee Medical Association
Cost-effectiveness and budget impact criteria setting	
To define the appropriate economic assessment criteria for eligible innovative medicines within the process of MEA model feasibility.	
Activities	Establish the economic assessment metric for innovative medicines eligible for MEA model feasibility
Stakeholders	MOPH Payers - NHSO/SSO/CGD NLEM Committee HITAP/Academic Society
Define MEA model for implementation	
To define the set of practical MEAs for implementation considering the uncertainties, model feasibility including the legal, resources and capabilities requirement in Thailand and to define appropriate performance metrics for MEAs.	
Activities	Engage payers, clinicians, patients, and industry stakeholders to understand needs, uncertainties around clinical benefits and financial impact. Select preferred MEA models, identify required resources and capacities, stakeholders, estimated timeline, and policy endorsement for implementation planning.
Stakeholders	MOF MOPH Payers - NHSO/SSO/CGD Pharmaceutical representatives

Monitoring and data collection

To monitor the benefit and impact on the healthcare system, and reevaluate the uncertainty for decision-making regarding the MEA

Activities	Define MEA performance metrics and timeline. Set up a centralized expert committee to develop, negotiate pricing and assess the performance/outcomes of MEAs.
Stakeholders	MOPH Payers - NHSO/SSO/CGD Pharmaceutical representatives

Re-evaluation

To redefine the uncertainty and benefit of the product and expected impact for further decision-making.

Activities	Define the decision-making criteria and pathway of MEA performance outcomes evaluation.
Stakeholders	MOPH Payers - NHSO/SSO/CGD NLEM Committee

Establish innovative medicine fund supporting MEAs

To explore and establish an alternative source of healthcare funding mechanism i.e. innovative medicine fund or CDF supporting sustainable MEAs implementation for innovative medicines or cancer drugs in the long run.

Activities	Explore alternative healthcare funding among all Thai healthcare schemes by payers, respective budget holders and high-level policy makers in order to obtain political will endorsement and define the appropriate additional source of funding pathway i.e. increasing healthcare global budget allocation, sin-tax, or other private funding etc.
Stakeholders	Budget holders – MOPH/MOL/MOF Payers - NHSO/SSO/CGD

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Stakeholders	Budget holders – MOPH/MOL/MOF Payers - NHSO/SSO/CGD

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สำนักงานปลัดกระทรวงสาธารณสุข
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เรื่อง ขอประชาสัมพันธ์เผยแพร่ Alternative Funding Models for High-Cost Innovative Drugs in Thailand: A Roadmap Towards an Implementation

เรียน หัวหน้าศูนย์ปฏิบัติการต่อต้านการทุจริต

ตามที่ราชวิทยาลัยจุฬาภรณ์ ได้เผยแพร่รายงานการศึกษาวิจัย เรื่อง “Alternative Funding Models for High-Cost Innovative Drugs in Thailand: A Roadmap Towards an Implementation ” เพื่อเผยแพร่ให้กับผู้ที่เกี่ยวข้องหรือผู้สนใจนำไปใช้เพื่อให้เกิดประโยชน์ต่อไป นั้น

ในการนี้ สำนักงานปลัดกระทรวงสาธารณสุข โดย สำนักวิชาการสาธารณสุข ขอประชาสัมพันธ์เชิญชวนให้บุคลากรในหน่วยงานของท่าน ที่สนใจงานวิจัย เรื่อง “Alternative Funding Models for High-Cost Innovative Drugs in Thailand: A Roadmap Towards an Implementation” เพื่อนำไปใช้ให้เกิดประโยชน์ต่อไป รายละเอียดสิ่งที่ส่งมาด้วย ตาม QR code ที่ปรากฏด้านล่างนี้ ทั้งนี้ หากท่านมีข้อสงสัยเพิ่มเติมสามารถติดต่อได้ที่ งานพัฒนาเครือข่ายและบริหารจัดการโครงการพิเศษ หมายเลขโทรศัพท์ ๐ ๒๕๗๖ ๖๑๐๐ ต่อ ๘๔๒๕ ๘๔๒๙ ไปรษณีย์อิเล็กทรอนิกส์ arpaporn.arn@cra.ac.th

จึงเรียนมาเพื่อโปรดประชาสัมพันธ์ให้บุคลากรในหน่วยงานของท่านทราบต่อไปด้วย จะเป็นพระคุณ

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- [x] กลุ่มงานป้องกันฯ
- [ ] กลุ่มงานจริยธรรม

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สิ่งที่ส่งมาด้วย

สำนักวิชาการสาธารณสุข
โทรศัพท์ ๐ ๒๕๙๑ ๘๕๖๖
โทรสาร ๐ ๒๕๙๐ ๑๗๑๘

แบบฟอร์มการขอเผยแพร่ข้อมูลผ่านเว็บไซต์ของหน่วยงานในราชการบริหารส่วนกลาง
สำนักงานปลัดกระทรวงสาธารณสุข
ตามประกาศสำนักงานปลัดกระทรวงสาธารณสุข
เรื่อง แนวทางการเผยแพร่ข้อมูลต่อสาธารณะผ่านเว็บไซต์ของหน่วยงาน พ.ศ. ๒๕๖๑
สำหรับหน่วยงานในราชการบริหารส่วนกลางสำนักงานปลัดกระทรวงสาธารณสุข

แบบฟอร์มการขอเผยแพร่ข้อมูลผ่านเว็บไซต์ของหน่วยงานในสังกัดสำนักงานปลัดกระทรวงสาธารณสุข

ชื่อหน่วยงาน : ศูนย์ปฏิบัติการต่อต้านการทุจริต กระทรวงสาธารณสุข
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หัวข้อ: รายงานการศึกษาวิจัย เรื่อง “Alternative Funding Models for High-Cost Innovative Drugs in Thailand : A Roadmap Towards an Implementation” ของราชวิทยาลัยจุฬาภรณ์ และเอกสารที่เกี่ยวข้อง

รายละเอียดข้อมูล (โดยสรุปหรือเอกสารแนบ)
รายงานการศึกษาวิจัย เรื่อง “Alternative Funding Models for High-Cost Innovative Drugs in Thailand : A Roadmap Towards an Implementation” ของราชวิทยาลัยจุฬาภรณ์ และเอกสารที่เกี่ยวข้อง

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