DRIVING EVIDENCE-INFORMED HEALTHCARE DECISION-MAKING: INTRODUCING THE HTA FRAMEWORK AND SENSITISING STAKEHOLDERS ON HTA IN BHUTAN: 29 MAY – 2 JUNE 2023

PREPARED BY: HEALTH INTERVENTION AND TECHNOLOGY ASSESSMENT PROGRAM (HITAP)

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List of acronyms

ADP	Access and Deliver Partnership
ASEAN	Association of Southeast Asian Nation
BHTF	Bhutan Health Trust Fund
CBS	Center for Bhutan Studies
CSO	Civil Society Organizations
DHS	Department of Health Services
GNHI	Gross National Happiness Index
EMTD	Essential Medicine and Technology Assessment Division
HFD	Health Financing Division
HITAD	Health Intervention and Technology Assessment Division
HITAP	Health Intervention and Technology Assessment Program
HLC-HS	High-Level Committee for Health Sector
HRO	Human Resource Officers
HTA	Health Technology Assessment
KGUMSB	Khesar Gyalpo University of Medical Sciences of Bhutan
MoF	Ministry of Finance
MoH	Ministry of Health
NMS	National Medical Service
RUB	Royal University of Bhutan
UHC	Universal Health Coverage
UNDP	United Nations Development Programme
WHA	World Health Assembly
WHO	World Health Organization

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This report provides an overview of the stakeholder consultation workshop conducted with the aim of sensitising stakeholders on Health Technology Assessment (HTA) and to receive feedback from those stakeholders on the national HTA framework for Bhutan. This collaborative event, held from 29th May to 2nd June 2023, was organised by the Health Intervention and Technology Assessment Division (HITAD), Ministry of Health, Bhutan and the Health Intervention and Technology Assessment Program (HITAP), Ministry of Public Health, Thailand, under the aegis of the Access and Delivery Partnership (ADP), hosted by the United Nations Development Programme (UNDP).

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The findings, interpretations, and conclusions presented in this report do not necessarily reflect the views of the funding or participating agencies.

Executive summary

The Health Intervention and Technology Assessment Division (HITAD) under the Ministry of Health, Bhutan, has been leading the efforts to institutionalise Health Technology Assessment (HTA) in Bhutan. Towards this goal, HITAD and the Health Intervention and Technology Assessment Program (HITAP), Ministry of Public Health, Thailand, with support from the Access and Delivery Partnership (ADP), have been working towards developing the national HTA framework for Bhutan. To ensure the framework is fit-for-purpose to the Bhutanese context and to increase ownership, a five-day stakeholder consultation workshop was held between 29 May to 2 June 2023, to solicit inputs and revise the framework.

Following a series of deliberations, the framework was revised and presented to all participating stakeholders on the final day of the workshop. This was then presented to the High-Level Committee for Health Sector (HLC-HC) on the 5th of June 2023. Further revisions were made to the framework based on suggestions from the HLC-HC before being officially endorsed on 29 June 2023.

This report provides a summary of the key activities, discussions, and outcomes of the stakeholder consultation. It serves as evidence for Bhutan's continued commitment to institutionalising HTA as one of the priority setting tools in the health sector. With the convergence of strong political commitment, partnerships, and stakeholder driven policies, Bhutan is now working towards implementing the framework. However, several bottlenecks have been identified which may hinder realisation of this objective including the lack of technical capacity in the country to produce and use evidence from HTA. HITAD, HITAP, and ADP are devising strategies to address such issues and welcome support and collaboration from the international HTA community including research and developmental partners.

Introduction

Bhutan's constitution mandates the provision of free healthcare to all its citizen. However, despite being grounded in the renowned Gross National Happiness Index (GNHI), this provision of free healthcare has resulted in notably elevated health expenditures that may not be sustainable in the long term. Thus, Bhutan has been working to institutionalise Health Technology Assessment (HTA) as one of the tools to drive efficient and equitable allocation of healthcare resources.

Bhutan started its HTA journey in the 2000s with the Essential Drug Program. Subsequently, in alignment with the World Health Organization's (WHO) resolution during the 67th World Health Assembly (WHA) advocating the use of HTA for achieving Universal Health Coverage (UHC), the then government approved Bhutan's first HTA agency, the Essential Medicines and Technology Division (EMTD).

Thus, HTA is not new to Bhutan and their commitment is reflected in their collaboration with international partners at HTAsiaLink, development of the HTA process guideline in 2018, and several HTA studies including on pneumococcal and rotavirus vaccines which informed policies. These studies not only marked significant milestones in using evidence for informed healthcare decision-making, but also played a vital role in fostering HTA capacity development in Bhutan.

Furthermore, the healthcare system in Bhutan is currently experiencing notable changes through reforms within the Ministry of Health (MoH). As part of these reforms, the previously known as EMTD has undergone a transformation and is now recognised as the Health Intervention and Technology Assessment Division (HITAD). These reforms present a valuable opportunity to propel the 6institutionalisation of HTA in Bhutan.

The Health Intervention and Technology Assessment Program (HITAP), Ministry of Public Health, Thailand, has been working with the HITAD to develop the national HTA framework for Bhutan, with the support of the Access and Delivery Partnership (ADP). The process of developing of this framework involved review of similar documents from other countries followed by extensive deliberation. However, for the framework to be context specific and to ensure buy-in from relevant stakeholders, a stakeholder consultation was deemed necessary. Thus, HITAP and HITAD organised a stakeholder consultation workshop in Bhutan from 29th May 203 to 2nd June 2023. The main objectives of this consultation were:

- To introduce the concepts and value of HTA.
- To present the draft HTA framework, solicit feedback from relevant stakeholders, and to revise the framework.
- To get the framework endorsed by the stakeholders and the High-Level Committee for Health Sector (HLC-HS).

This report provides a summary of the five-day event, the key stakeholder engagement activities, crucial discussion points and the next steps forward. Additional supporting documents are provided in the Annexures.

Stakeholder engagement activities

Multiple methods were employed to ensure active participation from the stakeholders during this five-day event. These methods included:

- Interactive talks/presentations: Engaging talks were conducted to foster interaction and exchange of ideas between the presenters and the stakeholders.
- Group exercise: A group exercise was organised to provide a deeper understanding of the complex nature of priority-setting in relation to investment and divestment decisions concerning health technologies.
- Group discussions: Several structured group discussions were held to allow stakeholders to deliberate on the draft HTA framework.

The following section of the report will delve into each of these methods, highlighting their significance and the key outcomes achieved during each of the events.

1. Exploring HTA through interactive talks

Given the recent reforms within the Ministry of Health (MOH) in Bhutan, introducing the concepts of HTA, highlighting the processes and stakeholders involved, and communicating its value in optimising healthcare decisions to relevant stakeholders was considered timely.

The introductory session by Mr. Sarin K C from HITAP on the first day set the stage for the subsequent four days of discussions. He posed the question, 'how should we prioritise an organ between a 20-year-old and a 60-year-old?', to which stakeholders gave a wide range of responses. In doing so, he exemplified the need to (i) identify what matters to the stakeholders and people of Bhutan, (ii) understand the underlying trade-offs and evaluate the costs and benefits surrounding decisions, and (iii) engage with a diverse group of stakeholders to understand priorities, perspectives, gather information, and arrive at acceptable decisions. He then introduced the principles and methodological concepts of HTA. Examples of HTA in action across several countries were shared including a case study from Thailand. Cases of enormous savings to health systems by following the recommendations from HTA evidence were emphasised to communicate the impact and potential value of HTA. Stakeholders were particularly intrigued by these real-world case studies and spurred discussions around their generalisability to Bhutanese context. The session closed with key lessons and opportunities for Bhutan. The session not only provided an overview of HTA but also equipped the stakeholders to engage more constructively in the discussions to follow on the HTA framework.

ADP's continued support and existing relationship with Bhutan MOH through UNDP has been instrumental in Bhutan's HTA journey. Ms. Ngawang Dema from UNDP led the subsequent session on the opportunities to further advance HTA in Bhutan. She began by highlighting some of the past engagements and achievements resulting from the partnership between UNDP, ADP, HITAD, and HITAP. She then noted key challenges (for e.g., lack of capacity) and potential solutions (through trainings and collaboration) towards the goals of institutionalising HTA in Bhutan, as identified during the stakeholder consultation in June 2022. Furthermore, using Mentimeter, the audience where then asked to rank the areas that Bhutan is doing well in the context of HTA. With a staggeringly high proportion of consensus, 'collaboration and knowledge sharing' was the area that was ranked the

first. This was followed by 'cost-effectiveness' and 'policy& regulation'. The area that was ranked the last was 'future planning'. This session along with the results from the stakeholders gave crucial insights into the possible opportunities that can be leveraged and the areas that needs to be addressed for effective implementation of HTA in Bhutan.

Lastly, the talk by Ms. Saudamini Dabak from HITAP on stakeholder involvement in the HTA process on the second day introduced participants to various types of stakeholders who are involved in the HTA process in Thailand and their expected roles and responsibilities in that process. Notably, the session also drew the participants' attention to some of the key points to be considered during stakeholder involvement, drawing on the HTA process guideline in Thailand. In addition to Thailand, the stakeholders involved in different steps of the HTA process in the Association of Southeast Asian Nations (ASEAN) region were also highlighted during this session. This session gave a foundation for the participants for their follow up discussion on potential stakeholders for Bhutan's HTA process.

2. Group exercise on HTA

Stakeholders were divided into four groups to engage in a group exercise aimed at introducing the complex decision-making process in healthcare. The groups were tasked with brainstorming and discussing various aspects related to health technology investment and disinvestment. The questions they addressed were:

1. What health technologies/interventions should be invested/disinvested in your country?
2. In your context, what are the main barriers to investing/disinvesting in those health technologies/interventions?
3. List of criteria used in prioritising investment/disinvestment in health technologies/interventions.
4. Who should be involved in this decision-making (person/organisation)?
5. Who should inform/nominate topics of health interventions/technologies for this investment/disinvestment decision?

The first two groups focused on discussing technologies that Bhutan should invested in, while the latter two groups focused on technologies that would benefit from disinvestment. After a 70-minute discussion, each group was instructed to present the output of their discussion as a 5-minute PowerPoint presentation to the larger audience.

The exercise's main outcome was to enable the participating stakeholders to experience the multifaceted nature of priority setting in healthcare. While the specific technologies for investment and disinvestment suggested varied across the groups, common elements and themes emerged during the discussions on barriers, criteria, and stakeholder involvement.

Both investment-focused groups identified a lack of local experts or specialists to deliver the services as a potential barrier to investing in the suggested technologies. They also highlighted insufficient or absent local data for evidence generation, policy restrictions, and sustainability issues associated with donated technologies as common barriers.

Regarding criteria for investment and stakeholder involvement, there was no common suggestion from either of the groups. However, both groups suggested that Civil Society Organizations (CSOs) and clinical end users should have the eligibility to nominate potential technologies for investment.

Moving on to the disinvestment-focused groups, political backlash emerged as a common barrier to disinvestment. Additionally, in line with the investment-focused groups' observation of the lack of specialists as a key barrier, both disinvestment groups suggested that the availability of specialists should be a criterion for disinvestment. Interestingly, echoing the concerns raised by the investment-focused group on the heavy reliance on donated technologies, one of the disinvestment-focused groups suggested the use of donated limited-edition technology as a potential criterion for selecting the health technologies for disinvestment. Lastly, both the disinvestment-focused groups unanimously recommended involvement from the department within the MOH in both the nomination and decision-making stages.

In conclusion, while different stakeholders presented different perspectives, the lack of adequate human resources, both for service provision and evidence generation, emerged as a prominent concern throughout the discussions.

Table 1 summarises the responses from the different groups participating in the exercise.

Groups/Questions	Main barriers to investing/disinvesting	Criteria used in prioritising investment/disinvestment	Stakeholders in decision-making process	Stakeholders in nomination process
Group 1 (Investment)	• Policy restrictions • Lack of expertise • Inadequate local evidence • Donor-driven technology leading to sustainability issues of the technology • Lack of high-level commitment • Financial constrains	• Financial viability • Adequate evidence • Adequate human resource • Adequate infrastructure	• High-Level Committee for Health Sector (HLC-HS)	• CSOs • Government agencies • Relevant agencies and programs • End users
Group 2 (Investment)	• Policy restrictions • Lack of expertise • Inadequate local evidence to establish cost-effectiveness • Reliance on the export/donor driven technologies • Lack of adequate resources allocation • Lack of standard or uniform process systems	• Disease burden • Cost of referral/out of pocket expenditure • National priority • Preventative service/technology • Access to delivery of equitable health care services	• Clinical end users • Relevant CSOs • Public feedback • MoH • Ministry of Finance • Cabinet	• Clinical end users • CSOs • Private sectors • Patient party • Retired health professionals

Groups/Questions	Main barriers to investing/disinvesting	Criteria used in prioritising investment/disinvestment	Stakeholders in decision-making process	Stakeholders in nomination process
Group 3 (Disinvestment)	• Public backlash • Political backlash • Physicians' resistance • NGOs/ Patient group resistance	• Long term sustainability • Uptake of technology/ coverage • Lack of specialist • No evidence on efficacy • Not a significant impact on quality of life • No clear evidence/ implication • Cost-effectiveness • Burden of disease	• Departments from MoH • Physicians • Developmental partners	• All health care workers • Departments from MoH
Group 4 (Disinvestment)	• Policy makers (interest barriers) • Manufacturers interest • Lack of human resource • Lack of evidence sharing among the stakeholders	• Quality evidence • Limited edition technology/devices • User-friendliness of technologies • Lack of specialists	• Policy makers • Departments from MoH • Subject experts • HLC-HS • Service users • Service providers/ healthcare professionals • Human Resource Officers (HROs) • CSOs	• Service user • Subject expert • Researchers • Departments from MoH • CSOs

Table 1: Key responses from group exercise discussions

3. Group discussions on HTA framework for Bhutan

Context is a significant determinant for the uptake and effective use of HTA framework for any setting. Hence, an extensive deliberation with the Bhutanese stakeholders was warranted. To facilitate this discussion, Mr. Pempa from HITAD, presented the sequence of steps involved in the HTA decision-making process, the duration for each step, and the stakeholders involved at each stage of the proposed framework on 30 June 2023 (refer to **Annex 4** for the proposed HTA framework). The participants were subsequently divided into four groups to discuss and review the proposed framework.

However, the team believed that presenting the different aspects of the HTA framework predisposed the participants to a limited perspective. Owing to this framing effect, the team decided to adopt an alternative strategy. The team facilitated a discussion on the criteria that can govern each step of the HTA process before sharing those outlined in the proposed framework. Consequently, on the third day, stakeholders engaged in discussions and developed potential criteria to be used at different stages of the HTA process, including topic nomination, topic selection, evidence generation, and

decision-making. Notably, the criteria developed collaboratively by HITAD and HITAP team were not disclosed to the stakeholders in advance.

Lastly, at the end of the day, each group was instructed to present their discussion points in a 5-minute PowerPoint presentation to the larger audience.

Key points raised by the stakeholders and common themes that emerged during the discussions were considered while revising the HTA framework.

The following section summarises key findings from the group discussions pertaining to different components of the HTA framework, namely,

- the HTA process
- key stakeholders and their roles
- the criteria to be considered at each stage of the HTA process

3.1 HTA process in Bhutan

This was the first of the group exercises where participants were asked to review the HTA process for Bhutan including the timelines for each steps within that process and ensure fitness-for-purpose to Bhutan's context.

The proposed HTA framework comprised of the following steps: the first step would entail nominating topics to consider in the Bhutan universal health benefits package. This would be followed by prioritisation, where topics submitted would be prioritised for assessment, based on certain criteria. This would be followed by evidence generation, where the topics selected for assessment would undergo either a rapid assessment or a full HTA. The next step would entail critically appraising the evidence and making a recommendation; feedback from the appraisal committee would be sent to the research team for further revisions when necessary before making final recommendations. Once a recommendation is established, price negotiation may occur using results from the threshold analysis (the price at which an intervention becomes cost-effective for a given willingness-to-pay threshold). Then, a final decision regarding the inclusion of the proposed health intervention. The next steps would be to procure the technology, disseminate information (that the technology has been included), and implement the technology into service. A simplified version of the process is shown in **Figure 1**.

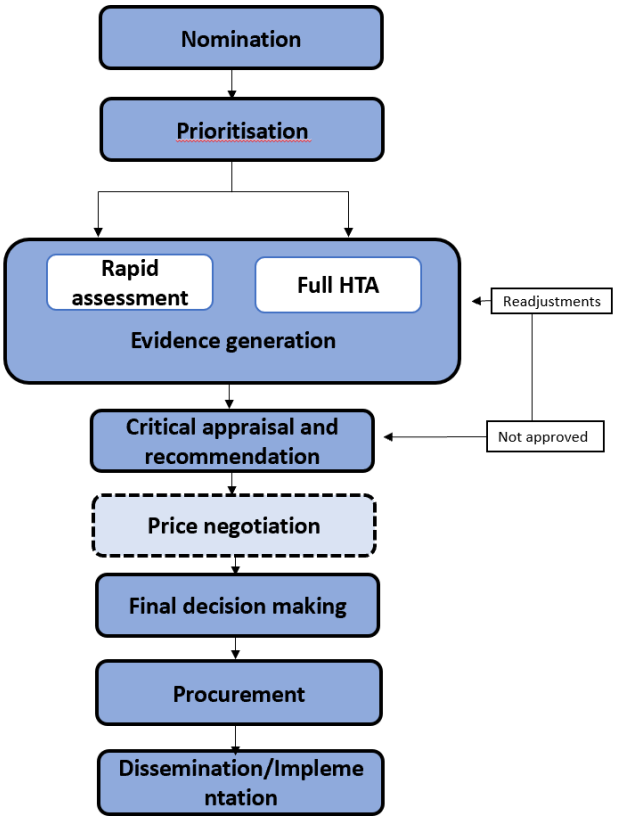

Figure 1: Proposed process for HTA (simplified)

The discussions were rich, and the key points are summarised below.

For the first step, the term “proposal” was suggested instead of nomination, given the familiarity with the term in Bhutan. It was suggested that there be a “screening” step between the “proposal” and “prioritisation” steps to increase efficiency (by excluding irrelevant proposals) of the process. It was also suggested that once the topics are selected, they are announced publicly to ensure transparency. For the next step, the term “assessment” was suggested, instead of “evidence generation”. Stakeholders unanimously agreed on conducting rapid assessment/HTA during emergencies and full HTA during routine periods.

The inclusion of price negotiation in the HTA process spurred debate among stakeholders. Certain stakeholders suggested either completely removing this step from the process or including it under procurement. Stakeholders indicated their preferences to adhere to the current procurement practices in the country. However, they noted the importance of conducting price negotiation before making a decision, to ensure the price reflects the value of the intervention. The term “cost benchmarking” was also suggested instead of price negotiation, again due to stakeholder’s familiarity with the term. Procurement processes might need to be updated to reflect the use of evidence. Teams proposed separating out the dissemination and implementation steps and linking the latter to procurement. To ensure accountability in the system, a monitoring and evaluation (M&E) step was also proposed.

Stakeholders suggested linking the HTA process to Bhutan’s fiscal and procurement cycle to ensure budgets are released to relevant departments such that HTA can be operationalised and decisions can be implemented. Suggestions were made to limit the time period for proposal submission (unlike the current system of accepting topics on a rolling basis throughout the year) to allow relevant departments to plan their course of actions. A feasible and realistic timeline to complete rapid assessments was suggested to be between 3-6 months.

The updated version of the flow diagram presented on the final day of the consultation is presented in **Figure 2.**

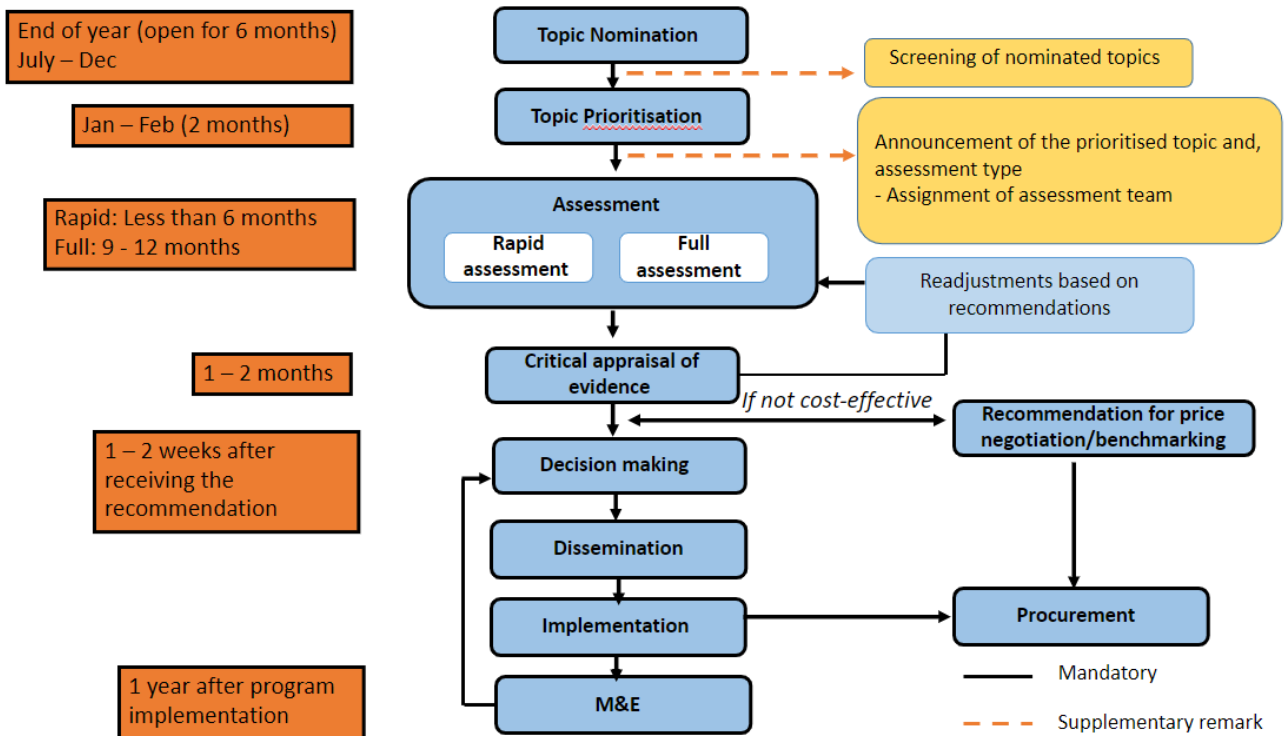

Figure 2: Updated version of HTA process, based on stakeholder consultation.

3.2 Stakeholders involved in HTA process in Bhutan

The objective of this session was to identify relevant stakeholders and their responsibilities for each of the steps defined under the Bhutan HTA process under 3.1. Before the group discussion, the significance of stakeholder engagement, examples from Thailand and ASEAN, and key considerations for nominating stakeholders and sustaining such deliberative process were shared with the participants.

For the purpose of this group discussion, the steps were categorised into topic nomination, topic prioritisation, evidence generation, critical appraisal and recommendation, price negotiation, final decision-making, procurement, implementation and dissemination, and monitoring and evaluation.

For the topic nomination step, all three groups identified a wide range of stakeholders including the MOH, healthcare professionals, patient groups, civil society, private sector, academia, other ministries, and donors. The primary reason for including these stakeholders was to ensure equity - health issues faced by all segments of the population are heard and considered by decision-makers. Their roles would include nominating the topics and providing supporting evidence to the Secretariat (HITAD) as per policy.

For the topic prioritisation step, two groups proposed similar blend of stakeholders such as policymakers, technical committee comprising health professionals, academics, researchers, ethicists, and regulators. This was proposed to ensure there is adequate knowledge among the stakeholders on the topics and the impact they may have on the population as well as to reduce the monopoly on decision-making by a single stakeholder. Their roles would include reviewing supporting data and providing additional information before prioritising topics. However, concerns related to conflict of interests were raised given the majority of nominated stakeholders would be

represented in other steps including topic nomination, critical appraisal, and recommendation. On the other hand, one group proposed HITAD as the sole stakeholder. This was proposed to address the concerns over conflict of interest as HITAD, as the Secretariat, would only facilitate other steps and not actively participate in them. The group further emphasised that the role of any stakeholder at this step would be to strictly follow the topic prioritisation criteria which would be co-created by stakeholders, invalidating the issue of representation.

For the evidence generation step, all groups nominated HITAD to commission the research to researchers and academics who would gather inputs from other stakeholders including subject experts, civil society, etc. The primary role of this group would be to convene stakeholder consultation to identify key parameters, assumptions, and data sources, collect data, conduct research, and present findings to stakeholders and the critical appraisal committee.

For the critical appraisal and recommendation step, two groups nominated subject experts, regulators, policymakers, ethicists, and legal representatives. However, the other group highlighted the issues of conflict of interest, relevance, and capacity, if broader groups are involved. Instead, the third group proposed creating a technical working group comprising health economists (permanent) and including subject experts from NITAG, NMC, and BMED as appropriate. Their roles would entail critically reviewing the evidence using a pre-defined checklist to ensure quality and comprehensiveness, provide feedback to the evidence generation team, and share recommendation to the price negotiation team.

For the price negotiation step, all groups nominated the procurement team, planning and financing team, HITAD, industry, and implementation team. Their role would include using recommendation from the critical appraisal committee to negotiate price that is considered cost-effective in Bhutanese context and inform the Secretariat and the research team if a new price needs to be reflected in the analysis.

For the decision-making step, participants nominated the HLC-HS to make final decisions after evaluating all available evidence and seek budget approval from the Cabinet and the Ministry of Finance. Participants raised concerns over politicisation of decision-making and suggested that HLC strongly follow the recommendations from the critical appraisal committee unless valid reasons hold.

For the procurement step, all groups nominated the procurement agency with inputs from the price negotiation team. Their role would be to carry out procurement as per their policies and ensure standards of quality are maintained.

For the implementation and dissemination, all groups recognised that stakeholders may vary depending on the topic under consideration. Therefore, relevant divisions under MOH, the procurement team, and healthcare professionals were nominated. Their role would be to inform the beneficiaries about available services and to provide services as per guidelines.

Finally, for the M&E step, Bhutan Food and Drug Administration (BFDA), district health authorities, HITAD, and other end users such as healthcare professionals and patients were nominated. Their role would include monitoring relevant outcomes such as service utilisation, clinical benefits, adverse events, etc., providing feedback and sharing data with HITAD and the research team when re-assessments are required.

The list of stakeholders presented on the final day of the consultation is provided in **Table 2.**

Stages	Stakeholders	Roles and responsibilities	Remarks
Nomination	• Departments from MoH • Any departments under NMS • Any health facility • Civil Society Organization (CSO) • Manufacturers • Research institutes • Any other public agencies	• Nominate topics • Submit supporting evidence as per the submission form	These nominations can only be made through their respective organisations and not individually.
Prioritisation	• HITAD	• Use the pre-defined criteria to prioritise the topics	Priotitisaton criteria will be strictly adhered by HITAP while scoring and the result would be publicised to ensure transparency
Assessment	• KGUMSB • Royal University of Bhutan • Centre for Bhutan Studies • Independent researchers, • National or international research agencies	• HITAD as the secretariat will be commissioning the group for evidence generation	
Critical appraisal and recommendation	• The National Health Technology Appraisal Committee (NAC) consisting of: o Epidemiologist (permanent member) o Health economist (permanent member) o Public health specialist (permanent members) o Clinical experts (recruited based on the topic) o Ethical experts	• NAC will be nominated on the basis of the topic of appraisal	

Stages	Stakeholders	Roles and responsibilities	Remarks
Price negotiation	• Bhutan Food and Drug Authority (FDA) • Bhutan Health Trust Fund (BHTF) • Health Financing Division (HFD) • Department of Health Services • Procurement team • HITAD	• To use the results from the cost-effectiveness and budget impact analysis to negotiate a price that is closer to the cost-effective price	
Final decision making	• High level committee for health sector (HLC-HS)	• To use the following to deliberate and make a final decision: o pre-defined criteria for decision-making o presented evidence to deliberate • To take forward the decision proposal to the Ministry of Finance	
Procurement	• Department of Medical Product • Tender Committee	• Procurement committee will refer to the HTA results	
Dissemination	• HITAD	• Publish cost-effectiveness/budget impact analysis results • Announce the final decision to the public	
implementation	• National Medical Service (NMS) • MOH	• To provide the included services to the public	
Monitoring and evaluation	• Monitoring team: o Department of Health Service (DHS) o National Medical Service (NMS) o Planning and Policy Divison	• Collect data on programme implementation and share the stat with the evalution team	

Stages	Stakeholders	Roles and responsibilities	Remarks
	○ BFDA • Evaluating team: ○ HLC-HS ○ HITAD	• Evaluation of the implemented services and make a decision whether a re-evaluation should inform new decisions	

Table 2: Stakeholder at each stage of the HTA process, based on stakeholder consultation

3.3 Criteria used at each stage of the HTA process

To ensure a transparent and publicly acceptable decision-making process, explicit criteria governing different stages of the HTA process are crucial. The objective of this group discussion was for the stakeholders to identify criteria or considerations which would be used at each step of the process.

Initial discussions revolved around the screening criteria which may be used to eliminate irrelevant proposals from further consideration in the HTA process. Some of the screening criteria raised by all the groups were:

1. Incomplete submission
2. Technology is already included in the benefits package in Bhutan
3. Technology is currently banned in Bhutan

In addition, other relevant context specific items like technologies not approved by Bhutan Food & Drug Administration (BFDA), technologies in the early phases of clinical trials and those countering the national priorities were raised by different groups and invited debate among the stakeholders.

The subsequent discussion focused on developing the prioritisation criteria and determining its implementation for topic selection. Although both participating groups proposed a scoring system for topic selection, there were variations in the scoring approach and the components of the criteria among the teams. The first group devised 3-point scoring criteria with 13 components, which could be scored from 1 to 3, and were divided across three categories with varying weights corresponding to their relevance. The first and the most relevant category with a weight of three category encompassed five elements. The second category consisted of three components each assigned a weight of two. The final category, comprising five dimensions, had a weight of one. The intervention that gained the highest score was then proposed to be prioritised.

The other group of participating stakeholders devised a scoring system that had a qualitative and quantitative part. The qualitative part comprised of eight components and was assessed on a dichotomous scale. Additionally, the quantitative criteria consisted of three components rated on a 5-point scale. The group proposed that any technology with a score exceeding 75% in the qualitative scale or 80% in the quantitative scale should be given priority for further evidence generation in the prioritisation process.

While the groups drafted a diverse list of indicators and scoring methods, there were common indicators that resonated strongly with all stakeholders. These were:

1. Burden of disease
2. Disease severity
3. Safety of the health technology
4. Health technology with multiple indications
5. Health systems readiness in terms of both human resource and infrastructure
6. Alignment with national priorities

Another group proposed additional indicators that were in line with the constraints of the healthcare system in Bhutan. They recommended including the impact on referral and the infectiousness of the disease as potential criteria for prioritisation. These indicators hold particular relevance within the Bhutanese health system context. The stakeholders highlighted the concerning rise in expenditure on referrals in Bhutan, emphasising the need for prioritising relevant health technologies and interventions. Furthermore, they underscored that although conditions like multi-drug resistant tuberculosis might not be highly prevalent at present, they have the potential to impose a burden on the healthcare system if not given due priority.

Finally, the stakeholders unanimously agreed against using a rigid set of criteria for making a final decision-making. Instead, they suggested a list of considerations to inform decisions. Some of the commonly identified considerations included value for money, readiness of the health system, equity implications, budget implications, and the safety profile of the health technology being evaluated.

The following table highlights the scoring criteria for proposal selection presented on the last day after addressing the comment by the stakeholders.

S.no	Criteria	Indicators	1	2	3
1	Burden of disease	Prevalence	0-10%	>10 – 20%	>20%
2	Infectiousness of the disease	Use the National Early Warning, Alert Response Surveillance (NEWAR) system	Mild	Moderate	Severe
3	Disease Severity	Mortality (% of total number of cases)	0-1%	>1-2%	>2%
4	Safety profile of proposed health intervention or technologies*	No. of adverse events resulting from the interventions	1/10	1/100	1/1000
5	Efficacy profile of proposed health intervention or technologies*	Percentage	0-30%	30% - <=80%	>80%

6	Health impact of the proposed health technology	Improvement in life expectancy and QoL	Prolong life & no improvement in QoL	Prolong life & improvement in Quality of Life (QoL)	Cure (back to normal condition)
7	Impact on referral	Proportion of referral in last five year	5-15%	15-30%	>30%
8	Aligning with National Goals	Either it is mentioned in the national plans document	Not included in any national strategy or plan	Complements a national strategy or plan	Yes, included in any national strategy or plan

Table 3: Proposed scoring criteria. **which is as safe or better compared to existing*

The final segment of the discussion revolved around the necessity of establishing scoring criteria to facilitate final decision-making. Consensus was reached among all stakeholders that an overly rigid scoring framework was unnecessary. Nonetheless, they put forth their respective suggestions for criteria worthy of deliberation, which could contribute to the decision-making process. These suggested criteria were:

- Value for money - cost-effective
- Budget implication
- Health system readiness
- Equity implications
- Clinical effectiveness
- Safety
- Sustainability
- Equity
- Ethical concern
- Social Benefits
- Cost effectiveness

Upon further deliberation and addressing the comments by the stakeholders, the final list of considerations proposed on the last day is highlighted in **Table 4.**

S.no.	Criteria
1	All of the criteria listed in the prioritisation criteria
2	Value for money: cost-effectiveness
3	Budget impact
4	Feasibility for the health system (human resources, infrastructure, other)
5	Ethical, legal social implications

Table 4: Consideration for final decision making, presented after the stakeholder consultation

Outcomes of the stakeholder consultation

Revised HTA Framework for Bhutan

After the stakeholder consultation on the second and third day of the workshop, feedback and comments provided by the stakeholders were collected and carefully considered while revising the framework. Inputs from stakeholders were compared with the proposed HTA framework, and a deliberate assessment was made regarding the relevance of incorporating or omitting each stakeholder suggestion in order to enhance fitness and implementation of the HTA process.

A revised framework was then presented to the stakeholders on the last day of the workshop, seeking their further comments and feedback. This step ensured that the stakeholders had the opportunity to review and contribute to the final version of the framework, fostering a sense of ownership and inclusivity in the HTA process.

On 5th June 2023, HITAD presented the revised framework to the HLC-HS for further consultation (**Figure 2**). The framework was officially endorsed on 29th June 2023. To ensure rigor and comprehensiveness, the framework is now undergoing external review by the international HTA community until 23rd August 2023. Once the review and revision is complete, the final version of the framework will be published on Bhutan MoH website and on Guide to Economic Analysis and Research (GEAR) – a repository of all national HTA guidelines, to ensure access.

HITAP team's reflection

Following the stakeholder consultation, an After-Action Review (AAR) was conducted by the HITAP team to reflect on the visit and evaluate what went well and what could have been improved (refer to **Annex 3** for the AAR template).

Overall, the organising team had a positive feedback on the outcomes of the visit. The team successfully achieved the objective of raising awareness about HTA and effectively engaged with the stakeholders, facilitating productive discussions that led to the development of the latest HTA framework for Bhutan. The need to engage with youth for the furtherance of HTA in the country was also identified as part of the AAR. While there were time constraints in planning the visit, the organising team appreciated the flexibility in the agenda, which allowed them to maximise the inputs from the stakeholders. Despite the challenges, the team was able to identify tangible next steps and areas for future collaboration.

Future directions

After the event, both teams identified priority areas for future collaboration. HITAP will continue to provide support to HITAD in endorsing the HTA process guideline. The event highlighted the ongoing need for further technical capacity building, as it is an integral part of institutionalising HTA.

With the objectives of understanding and improving procurement policies in Bhutan and of building technical capacity of researchers, the team will conduct a review on pooled procurement strategies, globally. This endeavor will involve researchers from both HITAD and KGUMSB, providing an opportunity not only to enhance research methodology capacity but also to offer integral policy recommendations to address issues arising from lower purchasing power in Bhutan.

Enhancing technical capacity and fostering routine use of evidence among stakeholders are crucial factors for institutionalising HTA in any setting. Hence, HITAD and HITAP team have identified potential strategies for building and strengthening capacity. These include:

Short-term strategies	➢ Conducting regular stakeholder sensitisation sessions ➢ Organising HTA roadshows
Intermediate-term strategies	➢ Providing technical training for the critical appraisal committee ➢ Providing university based structured introductory and advanced courses on HTA
Long-term strategies	➢ Professional development activities in the form of internships at HITAP ➢ Supporting advanced degrees on HTA and health economics

Table 5:Capacity development strategies identified by HITAD and HITAP team

Annexures

Annex 1: Agenda

Driving Evidence-Informed Healthcare Decision-Making: Introducing the HTA Framework and Sensitizing Stakeholders on HTA in Bhutan

Date: 29th May – 2nd June 2023
Location: Dusit, Thimphu, Bhutan
Format: In-person

Objectives:

- To raise awareness on Health Technology Assessment (HTA) in Bhutan
- To present the draft framework for HTA in Bhutan and receive feedback from relevant stakeholders
- To finalize the framework for endorsement and use in Bhutan

List of participants for the stakeholder consultation:

Tentative list of participants for stakeholder consultation meeting:

- Members of the National Medicines Committee
- Members of the National Immunization Technical Advisory Group (NITAG)
- Drug Technical Advisory Committee, MOH
- HODs for surgery, Medicines and diagnostic department, JDWNRH
- Non-Communicable Disease Division, Department of Public Health
- Communicable Disease Division, Department of Public Health
- Royal Center for Disease Control (RCDC)
- Bhutan Food and Drug Authority (FDA)
- Bhutan Health Trust Fund
- Dept. of Clinical Service, National Medical Services (NMS)
- Dept. of Medical Product, NMS
- Dept. of Biomedical Engineering, NMS
- Khesar Gyalpo University of Medical Sciences of Bhutan (KGUMSB)
- Traditional Medicine Division, Department of Health Services
- Health Financing Division, Department of Health Services
- Civil Society Organization
    - Bhutan Kidney Foundation (BKF)
    - Bhutan Cancer Society (BCS)

- Policy and Planning Division (PPD)

Outputs:

1. Meeting slides
2. Mission report
3. Revised HTA framework for Bhutan

Outcomes:

1. Increased awareness of HTA in Bhutan
2. Provisional endorsement of the HTA framework for Bhutan
3. Launch and implementation of the HTA framework in Bhutan

Agenda:

Time	Agenda	Objective	Description	Format	Session lead	List of participants
Day 1 (29th May 2023)						
10.00 – 10.10	Welcome remarks		- Welcoming the attendees to the stakeholder consultation	Speech	Pempa, HITAD	o Members of the High-Level Committee for Health Sector (HLCHS) o Stakeholders *(please refer to the listabove)* o HITAD, DHS, Experts from HITAP, Thailand
10.10 – 10.20	Opening remarks		- Opening Remarks from the HLC-HS Chair (Hon'ble Secretary, MoH)	Speech	Tshering, HITAD	
10.20 – 10:25	Agenda overview		- Explanation of the key objectives of this stakeholder consultation - Overview of the agenda for each of the days	Speech	Chief, HITAD	
10.25 – 10.50	HTA in Bhutan: story thus far	To present Bhutan's HTA journey	- Historical development of HTA in Bhutan - HTA outputs and engagements (including impacts) - Status of HTA in Bhutan	15 min presentation with 10 min Q&A	Pempa, HITAD	

Time	Agenda	Objective	Description	Format	Session lead	List of participants
10.50 – 11.10	Group photo and break (20 min)					
11.10 – 12.10	What is HTA and how can it be used as a priority setting tool?	To introduce the HTA and to highlight the significance of evidence-informed decision making using real-world examples	- Introduction to HTA - What are the core principles of HTA and why are they important? - Application of HTA in policy andpractice in Thailand	25 min presentation with35 min Q&A	Sarin K C,HITAP	
12.10 – 12.30			- Remarks from the HLC-HS Chair (H.E Health Minister)	Speech	HLC-HS	
12.30 – 1.30	LUNCH (60 min)					
13.30 – 14.00	Challenges, Opportunities, and the Path Forward for Institutional	To review the challenges identified in the previous session	Presentation: - Recapping the challenges of HTA in advancing UHC in Bhutan Discussion	10 min presentation and 20 min discussion	Ms. Ngawang Dema, UNDP	o Stakeholders *(please refer to the listabove)* o HITAD, DHS, Experts from HITAP, Thailand

Time	Agenda	Objective	Description	Format	Session lead	List of participants
	izing HTA in Bhutan	and to identify feasible solutions to address those challenges	- Addressing the challenges in institutionalizing HTA in Bhutan - Discussing the possible goals and strategies for addressing the challenges			
14.00 – 15.30	Investment and Disinvestment of Health Technologies	To explore the main barriers, criteria, process for raising topics, decision-makers and who to communicate to on investment or disinvestment of health	Presentation - Introduction to the exercise Small group discussion - Discuss the health technologies that the stakeholders may consider investing in or from which the stakeholders would disinvest	10 min introductory presentation, 70 min discussion	HITAP	o Stakeholders *(please refer to the listabove)* o HITAD, DHS, Experts from HITAP, Thailand

Time	Agenda	Objective	Description	Format	Session lead	List of participants
		technologies.				
15.30 – 15.45	Break (15 min)					
15.45 – 16.00	Investment and Disinvestment of Health Technologies *(cont.)*		Presentation of the discussion point from the investment/disinvestment exercise	20 min for presentation and 20 min for discussion		o Stakeholders *(please refer to the listabove)* o HITAD, DHS, o Experts from HITAP, Thailand
16.00-16:30	Closing		- Summary of the day - Agenda for day 2 - Expectation from the attendees onday 2	Presentation	HITAD	
Day 2 (30th May 2023) – Stakeholder consultation on HTA process and the involved stakeholders						
10.00 – 10.10	Introduction		- Agenda for the day - Expected outputs and outcomes at the end of the day	Presentation	Pempa, HITAD	o Stakeholders *(please refer to the listabove)* o HITAD, DHS, o Experts from HITAP, Thailand
10. 10 – 10.40	Sequence of decision-making process under the new HTA framework including the	To introduce the latest proposed HTA process for Bhutan	Presentation - The new complete HTA framework in Bhutan Presentation - Timeline in Thailand	20 min presentation with Q&A	Pempa, HITAD	

Time	Agenda	Objective	Description	Format	Session lead	List of participants
	timeframe					
10.40 – 11.10	Sequence of decision-making process under the new HTA framework including the timeframe	To gather feedback from stakeholders about the suitability of steps and the timeline of the proposed HTA process for Bhutan	Small group discussion - Feedback on the entire sequential flow of the proposed HTA framework	30 min small group discussion	HITAD	
11.10 – 11.25	Break (15 min)					
11.25 – 12.00	Sequence of decision-making process under the new HTA framework including the timeframe	To gather feedback from stakeholders about the suitability of steps and the timeline of the	Presentation of the critiques of the proposed HTA process	20 min for group presentation and 15 min for discussion		o Stakeholders *(please refer to the listabove)* o HITAD, DHS, o Experts from HITAP, Thailand

Time	Agenda	Objective	Description	Format	Session lead	List of participants
		proposed HTA process for Bhutan				
12.00– 13.00	Lunch (60 min)					
13.00 – 13.30	Roles and responsibilities of key stakeholders in the Bhutan HTA process	To introduce the multitude of stakeholders involved in HTA process	Presentation - Stakeholders in priority setting (examples from other countries)	30 min presentation and Q&A	Saudamini Dabak, HITAP	o Stakeholders *(please refer to the listabove)* o HITAD, DHS, o Experts from HITAP, Thailand
13.30 – 14.00	Roles and responsibilities of key stakeholders in the Bhutan HTA process	To map the key stakeholders involved in each step of the HTA process in Bhutan	Presentation - Introduction to the exercise Small group discussion: Proposing the potential stakeholders at each stage of the HTA process in Bhutan	5 min presentation and 25 min discussion	HITAD	
14.00 – 14.30	Roles and responsibilities of key stakeholder	To map the key stakeholders involved	Presentation by each group	30 min		

Time	Agenda	Objective	Description	Format	Session lead	List of participants
	s in the Bhutan HTA process	in each step of the HTA process in Bhutan				
14.30 – 15.00	Roles and responsibilities of key stakeholders in the Bhutan HTA process	To introduce the multitude of stakeholders involved in HTA process involved in	- Proposed stakeholders and their role in current HTA framework for Bhutan	30 min presentation with Q&A	HITAD	
15.00 – 15.45	Roles and responsibilities of key stakeholders in the Bhutan HTA process	To review the suitability of the roles and responsibilities of the proposed stakeholders in each step of the HTA process	Small group discussion: - Adequacy of the proposed stakeholders at each step of the HTA process in Bhutan	30 min discussion		

Time	Agenda	Objective	Description	Format	Session lead	List of participants
15.45 – 16.00	Break (20 min)					
16.00 – 16.30	Roles and responsibilities of key stakeholders in the Bhutan HTA process	To review the suitability of the roles and responsibilities of the proposed stakeholders in each step of the HTA process	- Presentation by each group and summary	30 min		o Stakeholders *(please refer to the listabove)* o HITAD, DHS, o Experts from HITAP, Thailand
16.15 – 16.30	Discussion and summary		- Presentation by each group and summary	Presentation	HITAD	
Day 3 (31st May 2023) – Stakeholder consultation on the proposed prioritization criteria						
10.00 – 10.10	Introduction		- Agenda for the day - Expected outputs and outcomes at the end of the day	Presentation	HITAD	o Stakeholders *(please refer to the listabove)* o HITAD, DHS, o Experts from HITAP, Thailand
10.10 – 10.30	Criteria for topic nomination, selection, and	To review and update the proposed criteria for	Presentation - Why do we need explicit criteria at each stage of the HTA process?	10 min presentation	HITAP	

Time	Agenda	Objective	Description	Format	Session lead	List of participants
	decision-making	topic nomination, selection and decision-making				
10.30 – 11.00	Criteria for topic nomination, selection, and decision-making	To review and update the proposed criteria for topic nomination, selection and decision-making	<u>Small group discussion 1:</u> - Discuss the potential criteria that can be used for screening the nominated topics in Bhutan	30 min discussion		
11.00 – 11.15	Break (15 min)					
11.15 – 12.15	Criteria for topic nomination, selection, and decision-making	To review and update the proposed criteria for topic nomination,	<u>Small group discussion 2:</u> - Discuss and finalise a potential criterion that can be used for topic selection in Bhutan	60 min discussion		o Stakeholders *(please refer to the listabove)* o HITAD, DHS, o Experts from HITAP, Thailand

Time	Agenda	Objective	Description	Format	Session lead	List of participants
		selection and decision-making				
12.15 – 13.15	Lunch (60 min)					
13.15 –14.45	Criteria for topic nomination, selection, and decision-making	To review and update the proposed criteria for topic nomination, selection and decision-making	<u>Small group discussion 3:</u> - Discuss how to use the previously discussed prioritisation criteria for topic selection in Bhutan	90 min discussion		o Stakeholders *(please refer to the listabove)* o HITAD, DHS, o Experts from HITAP, Thailand
14.45 – 15.00	Break (15 min)					
15.00 – 15.40	Criteria for topic nomination, selection, and decision-making	To review and update the proposed criteria for topic nomination, selection	<u>Small group discussion 4:</u> Discuss the potential criteria that can be used for determining if a proposed topic should undergo full or rapid assessment	40 min discussion		o Stakeholders *(please refer to the listabove)* o HITAD, DHS, o Experts from HITAP, Thailand

Time	Agenda	Objective	Description	Format	Session lead	List of participants
		and decision-making				
15.40 – 15.45	Physical exercise (5 min)					
15.45 – 16.45	Criteria for topic nomination, selection, and decision-making	To review and update the proposed criteria for topic nomination, selection and decision-making	<u>Small group discussion 5:</u> Discuss the potential considerations for final decision making	60 min discussion		o Stakeholders *(please refer to the listabove)* o HITAD, DHS, o Experts from HITAP, Thailand
16.45 – 17.00	Criteria for topic nomination, selection, and decision-making	To review and update the proposed criteria for topic nomination, selection and decision-making	Participant presentation of the discussion point from all the discussions of the day	15 min presentation and Q&A		o Stakeholders *(please refer to the listabove)* o HITAD, DHS, o Experts from HITAP, Thailand

Time	Agenda	Objective	Description	Format	Session lead	List of participants
Day 4 (1st June 2023) – Finalisation of the proposed framework based on the consultation						
10.00 – 16.00	Finalization of the HTA framework		- HITAD, KSGUMSB, and HITAP to revise the HTA framework based on the inputs received from the stakeholder consultation		HITAD, KSGUMSB, HITAP	o HITAD, DHS, MOH o KSGUMSB o HITAP, MOPH, Thailand *(No stakeholders)*
Day 5 (2nd June 2023) – Presentation of the HTA framework for provisional endorsement						
9.00 – 9.10	Introduction		- Agenda for the day - Expected outcomes	Presentation	HITAD	o Stakeholders *(please refer to the listabove)* o HITAD, DHS o Experts from HITAP, Thailand
9.10 – 10.10	Revised HTA framework for Bhutan		Presentation of the revised HTA framework for Bhutan	Presentation	HITAD	
10.10 – 10. 30	Break (20 min)					
10.30 – 11.30	Discussion	Endorsement of the revised HTA framework	Discussion and feedback - Suitability of the new HTA frameworkfor Bhutan	Discussion	HITAD	o Stakeholders *(please refer to the listabove)* o HITAD, DHS o Experts from HITAP, Thailand
11.30 – 12.00	Summary and resolution		- Summary and resolution	Speech	HITAD	
12.00 – 12.15	Closing remarks		Closing - remarks	Speech	HITAD	
12.15 – 13.15	Lunch (60 min)					
13.15 – 15.00	Finalizatio		HITAD, KSGUMSB, and		HITAD, KSGUMSB	o HITAD, DHS,

Time	Agenda	Objective	Description	Format	Session lead	List of participants
	n of HTA framework and planning the next steps		HITAP to consider the comments on the framework and discuss next steps		, HITAP	MOH o KSGUMSB o HITAP, MOPH, Thailand (No stakeholders)

Annex 2: Participant feedback form

On the last day of this 5—day event, participants were invited to provide their valuable feedback by completing a brief Google form. The form ensured anonymity for the respondents. It consisted of the following questions:

1. Has your knowledge on HTA improved after participating in this stakeholder consultation?
2. As a stakeholder, were you able to voice your opinion throughout the meeting?
3. As a stakeholder, were you able to voice your opinion throughout the meeting?
4. Do you have any suggestions for the HITAD team on how they can effectively implement the HTA framework?
5. Is there anything the organizing team could have done differently?
6. Do you have any other suggestions or comments?

The feedback received was overwhelmingly positive, with participants expressing that the event significantly enhanced their understanding of HTA. They also acknowledged that their suggestions for revising the HTA framework were incorporated into the final version. When asked about effective implementation of the framework by the HITAD team, a large majority emphasized the significance of further sensitization and dissemination of information to stakeholders regarding HTA.

Annex 3: After Action Review template

HITAP team used the following framework to reflect upon the sessions.

	Planning (logistics)	**Planning (session planning)**	**Content (Content, time and flow of content)**	**Others (communication, internal capacity building)**
What went well?				
What didn't go well				
Why didn't it go well				
What would you do differently next time				

Annex 4: Proposed HTA framework

Figure 1 shows the HTA framework developed collaboratively by HITAD and HITAP team before the stakeholder consultation.

Note that this framework has undergone several rounds of revision to address the recommendations and suggestions by the stakeholders.

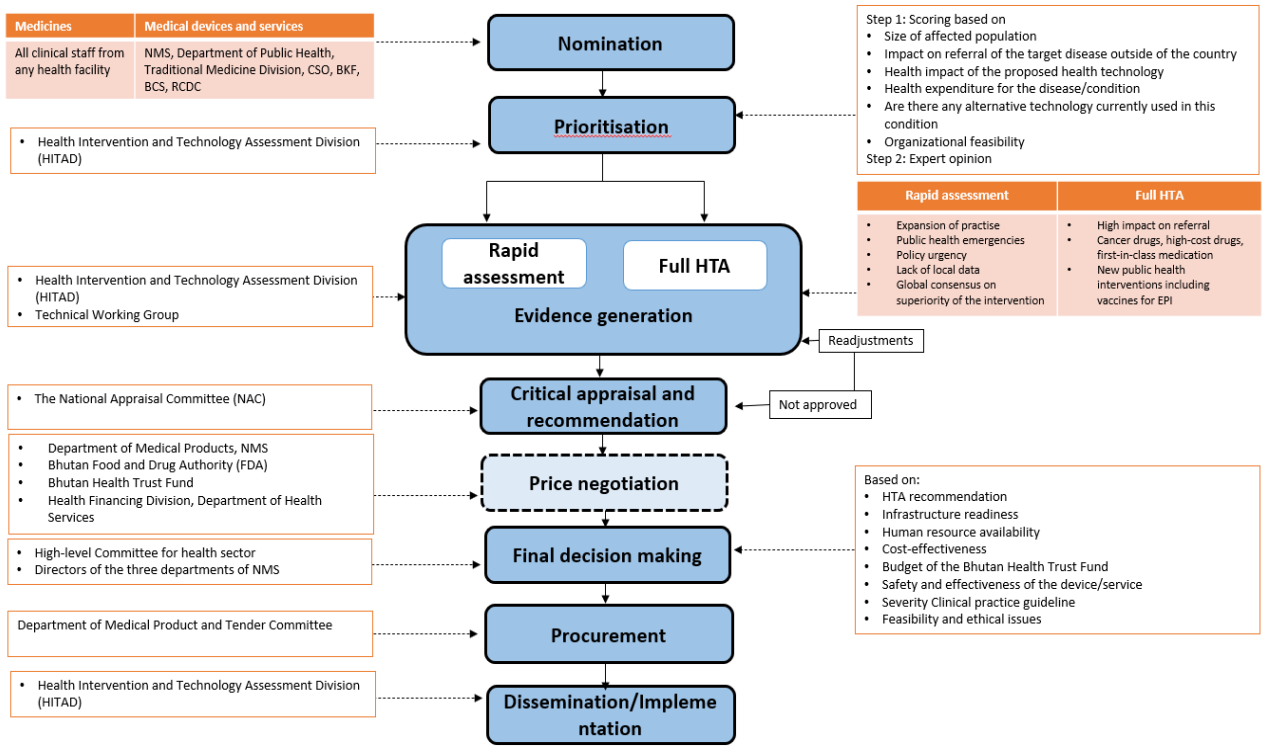

Figure 3: Proposed HTA framework for Bhutan