



Health intervention and Technology Assessment (HTA) process guideline,  
Essential Medicines and Technology Division (EMTD),  
Department of Medical Services,  
Ministry of Health.  
Kawangjangsa  
Thimphu 11001  
Bhutan

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This publication contains the collective view of various stakeholders from Ministry of Health and references of HTA guideline of other countries.

## FOREWORD

Essential Medicines and Technology Division (EMTD) was established in 2009 with the mandate to facilitate the introduction of new health interventions and technologies through evidence based research that guide policy decision making.

HTA process guideline shall facilitate collaboration among the members of health professionals and the guideline is to ensure that the introduction of any health interventions and technologies are evidence based and approved by the Health Intervention and Technology Assessment Panel (HTAP)

This HTA process guideline is in line with National Health Policy 2011 and the resolutions of World Health Assembly 2007 and 2014. And this 2nd edition HTA process guideline shall provide more holistic and comprehensive HTA process covering the areas that were not covered in the 1st edition.

This guideline shall play an important role in streamlining our health care system and thereby ensuring introduction of safe and reliable health interventions and technologies and at the same time ensure rational use of such health interventions and technologies for universal health coverage.



(Dr. Ugen Dophu)  
**Secretary**  
**Ministry of Health**

## **ACKNOWLEDGEMENTS**

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This guideline can be used as the reference for healthcare professionals for planning to introduce new Health intervention and Technology in the healthcare setting for successful Universal Health Coverage.

## EMTD PROGRAM PROFILE

### **Vision**

An organization that plays a key role in promoting safety, affordability and sustainability of health interventions and technologies in the delivery of health care services for universal health coverage.

### **Mission**

Ensuring the availability of safe and quality health interventions and technologies for health care services.

### **Mandates**

- Promote access to evidence-based health resource allocation and use of cost-effective interventions and technologies in health care services.
- Promote rational use of medicine, interventions and health technologies.
- Disseminate reliable information on matters related to pharmaceuticals, interventions and health technologies.
- Act as a nodal agency in MOH for matters related to medicines, interventions and health technologies.

### **Major Strategies**

- Conduct studies to generate information for adopting best practices for the sustainable and safe use of medicinal products and health technologies in health care.
- Formulate policies for the introduction and management of essential medicines and health technologies.
- Develop and publish documents and guidelines related to medicinal products and health technologies such as National Drug Policy, Essential Medicines List (EML), Essential Medicines Formulary, National Antibiotic Guidelines, Standard Treatment Guideline, HTA Guideline, Standard List of Services and Store Management Manual.
- Collaborate with regulatory bodies and agencies in monitoring the quality and utilization of health technologies.
- Disseminate evidenced-based information on matters related to pharmaceuticals and health technologies.

## **ACRONYMS**

**BHU** - Basic Health Unit

**DH** - District Hospital

**EMTD** - Essential Medicines and Technology Division

**HT** - Health intervention and Technology

**HTA** - Health intervention and Technology Assessment

**HTAP** - Health Technology Assessment Panel

**HR** - Human Resource

**MOH** - Ministry of Health

**NRH** - National Referral Hospital

**RRH** - Regional Referral Hospital

**Rx** - Prescription

**QASD** - Quality Assurance and Standardization Division

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## INTRODUCTION

Health Intervention and Technology Assessment (HTA) section under Essential Medicines and Technology Division, Department of Medical Services, Ministry of Health was established in 2008 following the approval from cabinet and in accord with 60<sup>th</sup> World Health Assembly 2007 resolution to establish HTA in its member states.

National Health Policy 2011 states the importance and need of HTA, in section 8.4, 9.8 & 9.9 as follows;

Section 8.4: Introduction of any new health technologies shall be allowed only after assessment and evaluation for its safety, efficacy, quality, indication and cost-effectiveness by the Health Intervention and Technology Assessment Panel.

Section 9.8: MOH shall ensure to prioritize investment in more cost effective and cost beneficial health care interventions.

Section 9.9: MOH shall explore and institute appropriate mechanisms suitable to Bhutanese context to ensure efficient utilization of health resources and maximize value for money.

Furthermore, 67<sup>th</sup> World Health Assembly 2014 resolution on HTA states;

- To assess the status of HITA in member states.
- To raise awareness, foster knowledge & encourage the practice of HITA & its uses in evidence-based decision making among national policy maker & other stakeholders.
- To support member state, especially low-income countries, in order to strengthen capacity for HITA to accelerate universal health coverage.

So the division has come up with new holistic HTA guideline which is adopted by referring HTA guidelines of Thailand (HiTAP), Canada (CADTH), United Kingdom (NICE), Malaysia (MaHATAs) and other international popular HTA guidelines.

## I. HEALTH TECHNOLOGY ASSESSMENT (HTA)

### I.1. Definition of Health Technology

A health technology is “any intervention that may be used to promote health, to prevent, diagnose or treat disease or for rehabilitation or long-term care”. It thus encompasses medical devices ranging from simple wooden tongue depressors and assistive devices, to the most sophisticated implants, medical imaging systems, drugs, medical and surgical procedures, and the organizational and supportive systems within which such care is provided.

### I.2. Definition of Health Technology Assessment (HTA)

HTA is “the systematic evaluation of properties, effects, and/or impacts of health-care technology. It may address the direct, intended consequences of technologies as well as their indirect, unintended consequences. Its main purpose is to inform technology-related policy-making in health care. HTA is conducted by interdisciplinary groups using explicit analytical frameworks drawing from a variety of methods”.

Depending on the issues involved, the time frame of decision-making, and the availability of resources, HTAs can take different forms such as a full-scale HTA report, contextualization of HTA reports produced elsewhere, rapid reviews, health technology information services or horizon scanning reports. HTA is always policy-oriented, context-embedded and methodologically sound.

In general HTA may include the assessment of:

- 1.2.1. Technical properties
- 1.2.2. Safety and efficacy
- 1.2.3. Economic evaluation
- 1.2.4. Impact and feasibility (social, ethical, political)

Its aim is to inform the formulation of safe, effective, efficient and evidence-based health policies that are patient focused and to achieve best value through research and scientific methods.

## 2. HTA WORKING PROCESS

HTA Phase	Approaches	Participants
<b>Topic selection</b>	<ul style="list-style-type: none"> <li>i. Consultation</li> <li>ii. Prioritization</li> </ul>	<ul style="list-style-type: none"> <li>i. HTA panel</li> <li>ii. Proponents</li> <li>iii. Expert members</li> <li>iv. EMTD researchers</li> </ul>
<b>Conducting HTA research</b>	<ul style="list-style-type: none"> <li>i. Consultation (to identify research questions&amp; methods)</li> <li>ii. Technical collaboration</li> <li>iii. Peer review</li> </ul>	<ul style="list-style-type: none"> <li>i. Expert members</li> <li>ii. Relevant stakeholders</li> <li>iii. EMTD researchers</li> </ul>
<b>Appraisal of results</b>	<ul style="list-style-type: none"> <li>i. Policy brief/Draft HTA report</li> <li>ii. Submission of comments</li> <li>iii. Discussion</li> <li>iv. Endorsement/approval</li> </ul>	<ul style="list-style-type: none"> <li>i. HTA panel</li> <li>ii. Expert members,</li> <li>iii. Beneficiaries</li> <li>iv. EMTD researchers</li> </ul>
<b>Dissemination of results and recommendation</b>	<ul style="list-style-type: none"> <li>i. Publications/HTA report</li> <li>ii. Presentations</li> <li>iii. Dialogues/feedbacks</li> </ul>	<ul style="list-style-type: none"> <li>i. Funding agencies,</li> <li>ii. Beneficiaries/users</li> <li>iii. NGOs and Media</li> <li>iv. EMTD researchers</li> </ul>
<b>M&amp;E of Health intervention and technology introduced</b>	<ul style="list-style-type: none"> <li>i. Utilization report</li> <li>ii. Feedback report</li> </ul>	<ul style="list-style-type: none"> <li>i. EMTD</li> <li>ii. Users</li> <li>iii. HTA panel</li> </ul>

### 3. STEPS OF HTA PROCESS

#### 3.1. Receipt of Proposals

EMTD receives proposals in the prescribed format (**Annexure I**: Application for Introduction of Health Intervention and Technology from any level of health facility in the country which must be routed through the relevant department under Ministry of Health. The **application form** can be downloaded from Ministry of Health's website [www.health.gov.bt/downloads/all-forms](http://www.health.gov.bt/downloads/all-forms). The deadline for proposal receipt is **1st week of January of a particular year**.

#### 3.2. Topic Selection (Screening & prioritization)

Upon the receipt of the proposals, HTA section will compile the entire proposals and screen for HTA eligibility as per the following steps. The screening will be conducted in February of the same year by EMTD and HTA expert Committee. The Proponent shall make presentation to HTA Expert committee and EMTD prior to topic selection.

##### 3.2.1. Steps for screening

- 3.2.1.1. Assign relative weights to **criteria (Annexure II**: Criteria used for screening)
- 3.2.1.2. For each criterion give a score
- 3.2.1.3. Review screened topics to ensure that assessment of these would be consistent with organizational goals
- 3.2.1.4. The topics shall be ranked based on the scores
- 3.2.1.5. EMTD shall present the selected proposal to the HTA panel for an endorsement of the HTA topic and inform proponent accordingly.

##### Note:

The topics shall be ranked based on the score and the topics for the particular fiscal period shall be endorsed by HTA Panel based on the ranking and other important factors for further assessment. However, an assessment of health technologies and interventions proposed for the purpose during the time of emergencies and disasters shall be fast-tracked.

### 3.3. Conduct of HTA

After an endorsement of the HTA topic from HTA panel, EMTD shall conduct HTA on the selected topics in the next fiscal year. The following HTA process shall be followed:

- 3.3.1. Drawing of HTA research protocol
- 3.3.2. Conduct HTA research (literature review/systematic review/economic evaluation/technical or clinical assessment )
- 3.3.3. Consultation with expert members and relevant stakeholders
- 3.3.4. Technical collaboration
- 3.3.5. Peer review
- 3.3.6. Produce HTA report/policy brief

### 3.4. HTA Report/Policy Brief

The HTA report shall be ready by the month of May of the particular fiscal year and the policy brief shall be as per the format given below:

- 3.4.1. Executive Summary
- 3.4.2. Introduction
- 3.4.3. Approach and Results
- 3.4.4. Conclusion
- 3.4.5. Policy Recommendations

### 3.5. HTAP meeting

The EMTD shall present the findings to HTA Panel for the endorsement and approval. The new health technology or intervention will either be accepted or rejected by the HTA panel based on the HTA findings and other factors. The HTA Panel meeting will be held as per the **Terms of Reference (Annexure III)**.

### 3.6. Dissemination of HTA report

The final HTA Report is printed and distributed to the proponent and relevant stakeholders (e.g. MSPD, HRD and Hospital Administration). The final report shall be uploaded to Ministry of Health website, [www.health.gov.bt](http://www.health.gov.bt). The dissemination of

HTA report will be done by June of the particular fiscal year. The report shall also be sent for international/external reviews.

### **3.7. Monitoring and Feedback**

The proponent, after getting approval from the HTA panel for the introduction of new Health Technology or Intervention, should inform EMTD in written of the installation/start of this new Health Intervention and Technology.

After 6-12 months of introduction of new Health Intervention and Technology, the proponent have to submit the **utilization reports** in the prescribed format (**Annexure IV**) on a monthly basis to the Health Intervention and Technology Assessment Section of EMTD. EMTD shall monitor periodically the utilization and functionality of the Health Technology or Intervention and present the report to HTA panel and provide feedback to the HTA expert committee for future necessary action. The proponent and other users of HTA report may give feedback through the **feedback forms (Annexure V)** to improve future assessments.

#### 4. TIMELINE FOR WORKING PROCESS

	ACTIVITIES	TIMELINE
1	Conduct HTA	July – April
2	Report on HTA	May
3	Dissemination of the HTA report	June
4	Deadline of proposal for HTA ( For next FY)	January
5	Topic screening and topic endorsement for HTA	February
6	Budget proposals on the endorsed HTA topics	March
7	Monitoring and evaluation for functionality and utilization of Health Intervention and Technology introduced in the healthcare centre	6-12 months of introduction

## Annexure I: APPLICATION FORM

Ministry of Health			
<b>I. Application Form for Health Intervention and Technology and Intervention Assessment</b>			
<p>The Health Intervention and Technology Assessment Panel (HTAP) decides at the Ministry of Health regarding the uptake, diffusion, and distribution of Health Interventions and Technologies, as well as removal of obsolete Health Interventions and Technologies, based on evidence of effectiveness, economic implication, human resource impact, societal impact, regulatory, ethical and utilization. EMTD provides HTAP with Health Technology Assessment (HTA) report and policy brief to facilitate the panel to make decision accordingly based on the available evidence.</p>			
<p><b>This Application is for Review of New or Updated Health Interventions and Technologies for use in healthcare centres of Bhutan. Please submit the executive summary of the proposal along with the duly filled application form and attach any relevant materials/documents to:</b></p>			
<p>Essential Medicines &amp; Technology Division (EMTD)            Department of Medical Services            Ministry of Health            Thimphu            Tel: +975 2 335722 (ext. 215)            Fax: + 975 2 335722            Email: <a href="mailto:emtd@health.gov.bt">emtd@health.gov.bt</a></p>			
<b>Proposal for:</b>			
For EMTD use only			
Approval for HTAP Review/Assessment?	<input type="checkbox"/>	Yes	<input type="checkbox"/> No
Date:			
Further assessment required?	<input type="checkbox"/>	Yes	<input type="checkbox"/> No
Date:			

**I.1. GENERAL INFORMATION**

<b>Application Date:</b>	Proposal number #: (Do not complete – for administrative purposes only)
<b>Proposing Department:</b>	Telephone #:
	Fax #:
	Email address:
<b>Affiliated healthcare facility (if applicable):</b>	
<b>Type of Health Intervention and Technology</b> (tick appropriate one) Medical Device/Equipment <input type="checkbox"/> Intervention <input type="checkbox"/> Treatment Purpose <input type="checkbox"/> Diagnostic purpose <input type="checkbox"/> Pharmaceuticals <input type="checkbox"/>	
<b>Name of the Proposed Health Intervention and Technology:</b>	
Disease / Condition in which the Health Intervention and Technology will benefit:	
Level of Health Facility till which the Health Intervention and Technology is to be made available :	
Till BHU <input type="checkbox"/> Till DH <input type="checkbox"/> Till RRH <input type="checkbox"/> Only NRH <input type="checkbox"/>	
<b>The executive summary must contain the following information ( a - g):</b>	<b>a) Prevalence of disease in a population for which Health Intervention and Technology is proposed</b>
<b>b) Efficacy of Health Intervention and Technology</b> (potential to cure/prevent/accuracy/sensitivity /specificity)	<b>c) Impact on referral outside the country</b>
<b>d) Impact on government health budget</b> (health expenditure and non-medical cost due to the target problem)	<b>e) Impact of human resource of health</b> (availability of competent human resource/need of training/up-gradation of skills etc.)
<b>f) Target population</b> (general population/adult/children/women/men etc.)	<b>g) Certification</b> ( if HT is a medical device)

## **I.2. EVIDENCE**

Please provide relevant evidences in support of propose Technology or Intervention

## **I.3. NOTE TO APPLICANT**

- I.4.1. The new Health Intervention and Technology proposed and deemed for review must improve the health outcome and generate efficiency.
- I.4.2. The new Health Intervention and Technology proposed must provide more benefits than the existing alternative health technologies.
- I.4.3. No information identifying individual patients is to form any part of this application.
- I.4.4. The applicant must make a detailed presentation to the HTA expert committee during screening process.
- I.4.5. Applicants must accept that by submitting the proposal the reviewers are permitted to discuss their proposal with key stakeholders.
- I.4.6. Only those proposals routed through the relevant department under Ministry of Health will be accepted by EMTD for the assessment.
- I.4.7. Application deadline: *1<sup>st</sup> week of January*

## **I.4. EMTD AND HTAP RESPONSIBILITIES**

- I.5.1. All reviews / assessments / evaluations will be evidence-based.
- I.5.2. Applicant names and affiliations will be kept confidential.
- I.5.3. Consultation from various experts may be sought as and when required.

**Applicant Signature**

**Date:**

## Annexure II: CRITERIA USED FOR TOPIC SCREENING/PRIORITIZATION

**I) Prioritization criteria for new services**

<b>Criteria/score</b>	<b>3</b>	<b>2</b>	<b>1</b>	<b>0</b>
Equity (target population)	For the whole population	For more than 50% of population	For 30% to 50% of population	For less than 30% of the population
Impact on referral of target disease outside the country	Contributes to more than 30% of total referral case	Contributes to more than 15% to 30% of total referral case	Contributes to more than 5% to 15% of total referral case	Contributes to less than 5% of total referral case
Efficacy of proposed Health Intervention (accuracy/sensitivity/specificity)	>90% and screened disease could be cured	81% to 90% and screened disease could be cured	>90% and screened disease could not be cured	81% to 90% and screened disease could not be cured
Impact on Health Budget	Accounts for >6% of annual health expenditure	Accounts for >3% to 6% of annual health expenditure	Accounts for 1% to 3% of annual health expenditure	Accounts for <1% of annual health expenditure
Impact of human resource of health	Competent HR is available for the proposed intervention	HR is available but need minor training for the proposed intervention	HR is available but need major training for the proposed intervention	HR is not available in the country for the proposed intervention

## 2) Prioritization criteria for new medical device

Criteria/score	3	2	1	0
Equity (target population)	For the whole population	For more than 50% of population	For 30% to 50% of population	For less than 30% of the population
Impact on referral of target disease outside the country	Contributes to more than 30% of total referral case	Contributes to more than 15% to 30% of total referral case	Contributes to more than 5% to 15% of total referral case	Contributes to less than 5% of total referral case
Efficacy of proposed Health Technology (accuracy/sensitivity /specificity)	>90% and screened disease could be cured	81% to 90% and screened disease could be cured	>90% and screened disease could not be cured	81% to 90% and screened disease could not be cured
Impact on Health budget	Accounts for >6% of annual health expenditure	Accounts for >3% to 6% of annual health expenditure	Accounts for 1% to 3% of annual health expenditure	Accounts for <1% of annual health expenditure
Impact of human resource of health	Competent HR is available for the proposed technology	HR is available but need minor training for the proposed technology	HR is available but need major training for the proposed technology	HR is not available in the country proposed technology
Certification	Certified by standardization organization of at least 3 countries of different region	Certified by standardization organization of at least 2 countries of different region	Certified by standardization organization of one country	Not certified by any standardization organization

### 3) Prioritization criteria for new medicine

Criteria/score	3	2	1	0
Equity (target population)	For the whole population	For more than 50% of population	For 30% to 50% of population	For less than 30% of the population
Prevalence of disease in a population for which Health Intervention and Technology is proposed	Affects more than 5% of the population	Affects from 1% to <5% of the population	Affects from 0.05% to <1% of the population	Affects < 0.05% of the population
Efficacy (clinical benefit of proposed Health Intervention and Technology)	Major clinical outcome (cure)	Moderate clinical outcome (Prolong life & major improvement of QOL)	Minor clinical outcome (minor improvement of QOL)	No expected change in clinical outcome
Impact on Health Budget	Accounts for >6% of annual health expenditure	Accounts for >3% to 6% of annual health expenditure	Accounts for 1% to 3% of annual health expenditure	Accounts for <1% of annual health expenditure
Impact of human resource of health	Competent human resource is available for the proposed Health Technology	Human resource is available but need minor training for the proposed Health Technology	Human resource is available but need major training for the proposed Health Technology	Human Resource is not available in the country proposed Health Technology

## Annexure III: TERMS OF REFERENCES

### **I. Health Technology Assessment Panel (HTAP)**

#### *I.1. Membership:*

I.1.1. All the members of High Level Committee of Ministry of Health

#### *I.2. Mandate:*

I.2.1. To endorse the topics selected by HTA expert committee for HTA.

I.2.2. To approve the intervention or technology based on the HTA report and other important factors.

I.2.3. To give direction/instruction/advice to HTA secretariat (EMTD) on the matter related to HTA.

I.2.4. To Review the utilization and functionality report and feedback of the interventions and technologies already approved and introduced.

#### *I.3. HTAP meeting:*

I.3.1. 1<sup>st</sup> meeting: For an endorsement of the selected topics for HTA

I.3.2. 2<sup>nd</sup> meeting: For an approval of the proposed Health Interventions and Technologies based on HTA report and other factors.

#### *I.4. Procedure of meeting:*

I.4.1. The EMTD shall prepare a HTA report on the proposed technology and present it to the committee. The Division shall also answer questions in relation to the review and evidence findings as required by the panel.

I.4.2. One of the following decision shall be made by the committee:

I.4.2.1. Approve the technology for introduction

I.4.2.2. Reject the proposal

I.4.2.3. Give further directives

## **2. HTA Core member**

### *2.1. Membership:*

#### *2.1.1. EMTD*

### *2.2. Mandate:*

#### *2.2.1. To receipt the proposals*

#### *2.2.2. Do topic selection*

#### *2.2.3. Conduct HTA*

#### *2.2.4. Produce HTA report/result*

#### *2.2.5. Present HTA report to HTAP*

## **3. HTA Expert Committee**

*3.1. Membership:* HTA Expert committee members will be nominated based on their expertise/relevancy to the HTA proposals

### *3.2. Mandate:*

*3.2.1. To screen and prioritized the HTA proposals based on the screening criteria.*

*3.2.2. To provide expert opinion/technical advice and technical support to HTA member secretariat (EMTD) on the topic of his/her expertise.*

*3.2.3. To provide recommendation to HTA panel through HTA report*

### *3.3. HTA Expert Committee meeting:*

*3.3.1. 1st expert committee meeting: For screening and prioritization of HTA proposals*

*3.3.2. 2nd expert committee meeting: Expert input on the endorsed topics*

*3.3.3. 3rd expert committee meeting: HTA report finalization and recommendation to the HTA panel for endorsement*

## Annexure IV: HEALTH TECHNOLOGY UTILIZATION REPORT FORM

<b>Name of the Health Intervention and Technology (HT)</b>		
<b>Name of Agency</b>		
<b>Date of Installation of the Health Intervention and Technology</b>		
<b>Utilization Report</b>		
<b>Date:</b>	<b>Month:</b>	<b>Year:</b>
<b>If the new HT is a Drug</b>		
No. of drugs dispensed monthly	Details, evidences (Stock Ledger) and monthly progress to be submitted to EMTD Office	
<b>If the new HT is a Biologic</b>		
No. of Biologics dispensed monthly	Details, evidences (Stock Ledger) and monthly progress to be submitted to EMTD Office	
<b>If the new HT is an Equipment/</b>		
No. of patients screened/treated monthly	Details, evidences (Rx & Logbook) and monthly progress to be submitted to EMTD Office	
<b>If the new HT is a kind of Supply</b>		
No. of patients screened/treated monthly	Details, evidences (Rx & Stock Ledger) and monthly progress to be submitted to EMTD Office	
<b>If the new HT is a Medical/Surgical Procedure/Service</b>		
No. of cases monthly	Details, evidences (Prescriptions) and monthly progress to be submitted to EMTD Office	
<b>If the new HT is a Support System</b>		
No. of cases monthly	Details, evidences (Rx & Stock Ledger) and monthly progress to be submitted to EMTD Office	

## Annexure V: HTA REPORT FEEDBACK FORM

Title of the Health Intervention and Technology Assessment/Technology Review:

.....

### 1.1. Contact information

Name:

Designation:

Organization:

Phone no:

Email Address:

### 1.2. How would you rate the report? Please tick ONE of the following:

Excellent        Good       Fair       Poor

### 1.3. How did you use this report? Please tick one of the following:

- 1.3.1. Influence or develop policy/decisions
- 1.3.2. Influence operational procedures/practices
- 1.3.3. Influence guideline formulation
- 1.3.4. Change awareness or increase understanding of the issue
- 1.3.5. Influence or make operational/capital funding decision
- 1.3.6. Other (please specify)

### 1.4. Regarding the technology how is it currently being used in your organization?

- 1.4.1. Not in use and not being considered
- 1.4.2. In use – full implementation
- 1.4.3. Not in use but under review
- 1.4.4. Other (please specify)

### 1.5. How well did the report meet your needs? Please tick one of the following

Really well       Well       Not so well       Not at all

For comments you may use separate sheets