FOREWORD

Health Technology refers not just to the equipments but is the set of services, drugs, equipment, techniques and procedure used by health care professionals in delivering medical care to individuals, and the system by which such care is delivered.

Assessment of such Health Technologies is a constraint for a country like ours where health care is provided free of cost to the public and the government makes huge expenditures in facilitating the various health centers in service delivery. The health care services provided to the public should be safe and reliable; this is where Essential Medicines and Technology Division (EMTD) come in the picture. EMTD is the gate keeper for the health system in ensuring the quality of drugs and other health technologies that enter our country, while at the same time monitoring cost-effectiveness as a measure to keep an eye on wastage and unnecessary excess expenditure.

EMTD was established and placed under the Department of Medical Services in the year 2008. Since then, EMTD has assessed few health technologies which have helped our Department and the Ministry as a whole in making rational decisions. These decisions guide the Ministry in making policies or bring about shifts in policies.

However, not many people including end users, clinical personnel, technical personnel, procurement personnel, administrative personnel and other personnel involved know much about the roles and responsibilities of EMTD or the procedures to be followed. Thus, this Health Technology Assessment Guideline has been developed in order to facilitate the understanding of the procedures of the Health Technology Assessment Cycle.

I am pleased that the staffs of EMTD have shown great interest and worked hard in developing the guideline. This guideline will play an important role in restructuring our health care system and thereby ensure introduction of safe and reliable health technologies and at the same time ensure rational use of such health technologies.

(Dr. Ugen Dophu)
Director General
Department of Medical Services

ACKNOWLEDGEMENT

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Abbreviations

EMTD – Essential Medicines and Technology Division
HT- Health Technology
HTA – Health Technology Assessment
HTAP – Health Technology Assessment Panel
Rx – Prescription
MoH – Ministry of Health
DVED – Drugs Vaccines and Equipments Division
QASD – Quality Assurance and Standards Division
HRD – Human Resource Division
JDWNRH – Jigme Dorji Wangchuk National Referral Hospital
RRH – Regional Referral Hospital
DH – District Hospital
BHU – Basic Health Unit

CONTENTS

INTRODUCTION

Essential Medicines and Technology Division

Essential Medicines and Technology Division (EMTD) is a Division under the Department of Medical Services, Ministry of Health. It was established under the approval from the Cabinet in the year 2008. It looks after the essential drugs and technologies that exists, and are to be introduced, in the country.

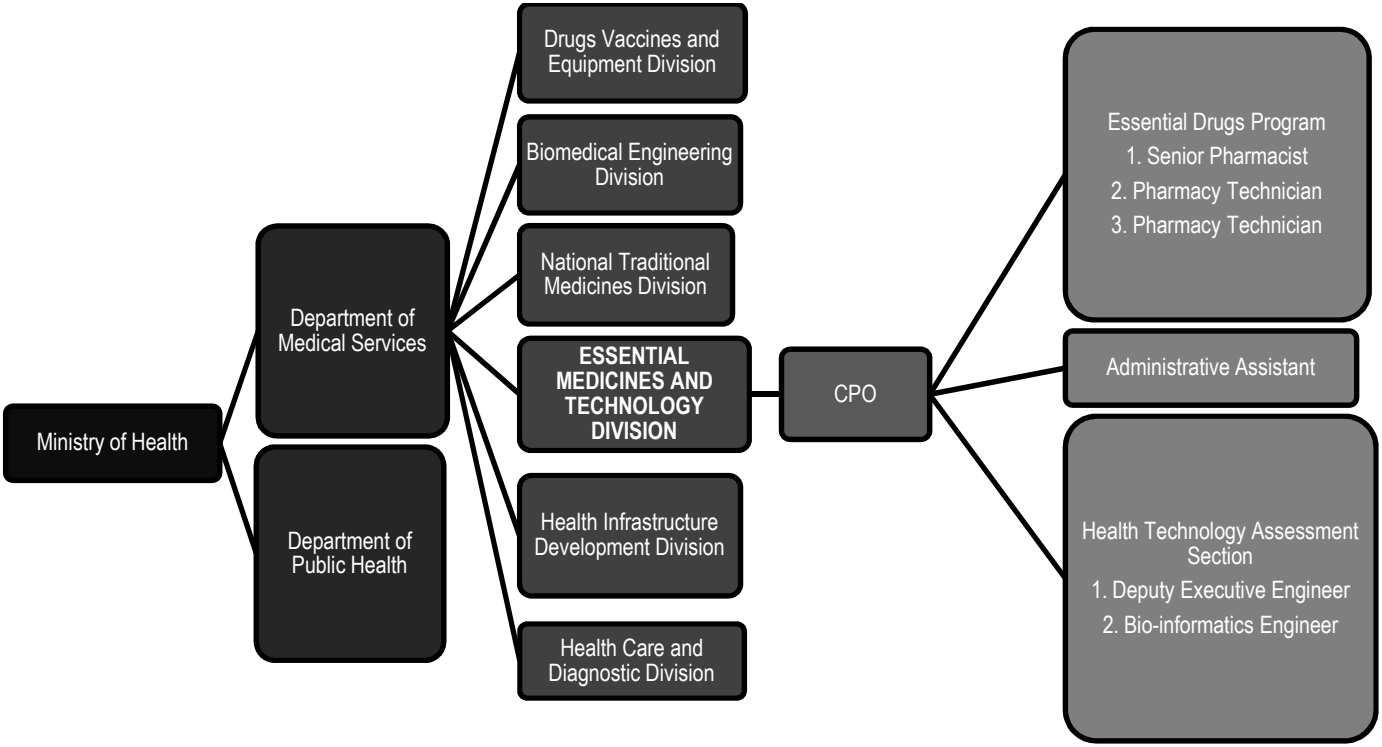
Mandates of EMTD

- To provide different sectors the support they require for adopting best practices for the sustainable and safe use of medicinal products and health technology and promoting access to health services;
- To introduce evidence-based medicines, treatment interventions and technologies that provide cost effective solutions to health problems through regular reviews and studies;
- To revise and publish Essential Drugs List, Bhutan National Formulary, Standard Treatment Guideline, National Antibiotics Guideline, Health Technology Assessment Guideline;
- To plan and conduct activities to upgrade knowledge on all matters related to pharmaceuticals and health technologies;
- To coordinate the monitoring and supervision of utilization of medical supplies at all levels at regular intervals;
- To study the impact, implication, development and use of health technology and to introduce policies based on social, ethical, economic and medical studies;
- Development of National Service Standards at different level of health facilities.

EMTD comprises of following two sections:

Sections	Essential Drugs Program	Health Technology Assessment Section
Functions	1. Essential Drugs List (every 2 years) 2. Bhutan National Drugs Formulary (every 2 years) 3. Standard Treatment Guideline (4-5 yearly) 4. National Antibiotic Guideline 5. Trainings (rational use of drugs, store in-charge)	1. Held 4 HTAP Meetings so far 2. Health Technology Assessment Guideline (every 3 years)
Committee	National Drug Committee (meets every 2 years)	Health Technology Assessment Panel meets twice in a year

MoH Organogram



HEALTH TECHNOLOGY ASSESSMENT (HTA)

Definitions

A. Health Technology

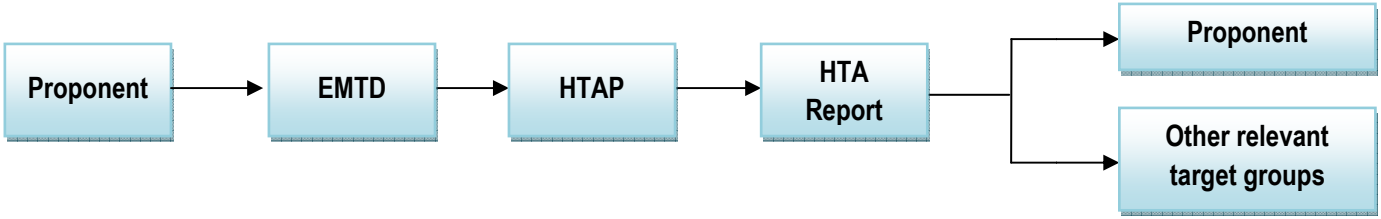
- Health Technology is the set of services, drugs, equipment, techniques and procedure used by health care professionals in delivering medical care to individuals, and the system by which such care is delivered.
- Broad categories of health technology include the following:
  - ***Drugs***: for example, NSAIDs, beta-blockers, antibiotics.
  - ***Biologics***: vaccines, blood products, cellular and gene therapies.
  - ***Devices, equipment and supplies***: for example, cardiac pacemakers, surgical gloves, CT-scanners, diagnostic test kits.
  - ***Medical and surgical procedures and services***: for example, psychotherapy, nutrition counseling, coronary angiography, gall bladder removal, mammography services, acupuncture.
  - ***Support system***: for example, electronic patient record system, telemedicine systems, drug formularies, blood banks, clinical laboratories.

B. Health Technology Assessment

- Health technology assessment is a multidisciplinary process that does systematic, transparent, unbiased and robust evaluation of properties, direct/indirect and/or intended/unintended effects or other impacts of health technology.
- In general HTA may include the assessment of:
  - Technical properties
  - Safety
  - Efficacy
  - Cost effectiveness
  - Feasibility
  - Impacts
    - Social
    - Legal
    - Ethical
    - Political
- Its aim is to inform the formulation of safe, effective, health policies that are patient focused and to achieve best value through research and scientific methods.

Source: Clifford S. Goodman. HTA 101 – Introduction on Health Technology Assessment. National Information Center on Health Services research and Health Care Technology. (NICHSR) 2004

HTA Work Process



The HTA Paradigm

1. **Step 1**: **Receipt of Proposals**

   EMTD receives proposals from any level of health facility in the country in the prescribed format (**Annexure I**: Application for Introduction of Health Technology).
   It is also found on Ministry of Health's website www.health.gov.bt/downloads
   We have 2 deadlines for receiving the proposals, which are as follows:

   - 4th week of August (for October HTAP Meeting)
   - 4th week of February (for April HTAP Meeting)

2. **Step 2: Prioritization**

   2.1 Reason for Priority setting

   - Number of assessment exceeds the capacity of HTA Staff.
   - Assessment needs to be in-line with policies/objectives of organization.
   - Need to study relevance/benefit.

   2.2 Steps for Systematic Priority Setting

   1. Select criteria to be used in priority setting
   2. Assign relative weights to criteria (**Annexure II:** Criteria used for Priority Setting)
   3. Preliminary search
   4. For each topic, assign a score for each criterion
   5. Calculate the priority score for each topic
   6. Rank topics according to priority scores
   7. Review priority topics to ensure that assessment of these would be consistent with organizational goals

   2.3 Other suggested Criteria for Prioritization of Health Technology Assessment

   - Number of people to whom it may be applied
   - Level of usage and potential for inappropriate use
   - Safety consideration
   - Whether assessment would be likely to influence future deployment and usage of technology
   - Training/accreditation/education issues
   - Implications if introduction is delayed
   - Whether the technology has already been adequately assessed by another organization

   Present priority setting exercise results to HTA Panel for approval and inform proponent accordingly.

3. **Step 3**: **HTA Protocol**

EMTD prepares a protocol for conducting the HTA which includes the following:

3.1 Protocol for: (Title of the Proposal)

1. Background information and search for scientific evidence
2. Report writing (Draft HTA Report)
3. Form an HTA Expert Division that comprises of technical, clinical and external reviewers.
4. Present preliminary HTA report to HTA Expert Committee
5. Present draft HTA report to the HTA Panel
6. Inform proponent and disseminate HTA Reports
7. Set timeline for the whole protocol

3.2 Search for scientific evidence comprises of the following:

- Name of the Technology
- Reason for request
- Requesting officer
- Technology description
- Cost/cost-effectiveness
- Effect on infrastructure
- Number of people whom applicable
- Availability of competing technology
- Level of usage
- Other related problems/issues

4. **Step 4**: **Draft HTA Report**

EMTD personnel does preliminary search for scientific evidences and consults the HTA Expert Committee and compiles a draft report.

The Draft report comprises of the following:

- Proposal Number:
- Title:
- Background:
- Findings/Evidences:
- Conclusion:
- Recommendations of HTA Expert Committee and EMTD:

- Dated Signature of the Chairman of the HTAP (only on the final report after endorsement)

5. **Step 5**: **HTA Expert Committee**
   - Preliminary HTA Report compiled by the EMTD personnel is presented to the HTA Expert Committee.
   - Each proposal should have a unique HTA Expert Committee.
   - This Committee comprises of the following Technical, Clinical and External Reviewers:
     1. One relevant Technical Personnel
     2. Three relevant Clinical Personnel
     3. External Reviewers include either (or a mixture) of the following based on content of the proposal:
        - A representative from Policy and Planning Division, MoH
        - A representative from the Administration and Finance Division, MoH
        - A representative from (relevant) Hospital Administration and Finance Division
   - Terms of Reference
     - To review the Preliminary HTA Report and come up with the Draft HTA Report to be presented to the HTA Panel;
     - Provide technical, clinical and other advices on effects and impacts due to the introduction of that particular health technology.
   - The quorum should comprise of at least one Technical, two Clinical and one External Reviewer
   - HTA Expert Committee Meetings will be held as per the timeline set in the HTA Protocol.

6. **Step 6: HTA Panel**
   The draft HTA report along with review and recommendation of HTA Expert Committee will be presented to the HTA Panel for their approval and endorsement.
   Inform Requestor: The decisions of the HTA Panel will be conveyed to the requestor.

7. **Step 7: Dissemination**
   - The final HTA Report is printed and distributed to relevant target groups (DVED, HRD, Hospital Administration) and also uploaded in full to Ministry of Health website, www.health.gov.bt

8. **Step 8: Monitoring and Feedback**

The proponent, after getting approval from the HTA Panel for the introduction of new health technology, should inform EMTD in written of the installation of this new health technology.

For 6 months after the installation of the new health technology, the proponent is to provide Utilization Reports in the prescribed format (**Annexure III**) on a monthly basis to the Health Technology Assessment Section of EMTD. Thereafter they should report to Quality Assurance and Standards Diviosn on an annual basis.

The proponent and other users of our HTA Report will also be given feedback forms (**Annexure IV**) so that we can improve our assessment or assessment procedures in the future. It will also be sent for international/external reviews.

Health Technology Assessment Panel

Health Technology Assessment Panel is an interdisciplinary and independent group of knowledgeable individuals willing to actively participate and make decisions based on the evidence and the best interest of the public. The HTAP will review the evidence related to proposed technologies and make decisions. HTAP will also look at issues such as patient safety, prevalence of condition, clinical effectiveness, health outcomes and cost. HTAP's reports provide consumers, legislators and the Ministry of Health with balanced, objective, and essential information prior to introduction of new technologies in our health care facilities.

Purpose

HTAP will function as an advisory body to the Ministry of Health. It will review the evidence and health technology assessment (HTA) reports prepared by EMTD and the HTA Expert Committee on new or existing technologies and make decisions on its introduction and use.

Scope

Health technology includes a wide range of procedures, devices and equipment applied to the maintenance, restoration and promotion of health. Technology encompasses interventions at any stage of health care including primary prevention, early detection of disease and risk factors, diagnosis, treatment, rehabilitation and palliative care.

HTA focuses on the effectiveness in improving patient outcomes of new and emerging health technologies that have a significant impact on the health care system including:

- Individual health technologies.
- Group of integrated health technologies that relate to specific disease states.
- Existing health technologies that have already diffused and are either related to a new or emerging technology under review or the health system regards a review of the technology as appropriate.

Mandates

1. Examine proposed health technologies in the context of existing clinical practice.
2. Provide advice and recommendations to MoH, practitioners and the broader health care system based on a systematic, objective, evidence based technology assessment and taking into account economic, human resource, regulatory and ethical considerations.

3. Create a forum to maximize opportunities and prioritize the uptake and diffusion of new/emerging health technologies deemed to significantly improve patient outcomes and/or system efficiencies relative to other existing or competing interventions.
4. Outline implications for implementing HTAP recommendations including the impact on the public, society, health care sectors and professions.
5. Provide transparency regarding its recommendations and the analyses upon which these recommendations are made to Bhutan's health care system.

Mission

1. To support collaboration between national and international organizations that brings added value to the Bhutanese health care system.
2. Facilitate, develop, implement and support efficient production and use of HTA in Bhutan.
3. Provide an access point for communication with stakeholders to promote transparency, objectivity, independence of expertise, fairness of procedure, and appropriate stakeholder consultation.
4. HTA to be based on research and best available scientific evidence.

Membership

HTAP members comprises of the following, nominated by the Ministry of Health:

1. Director General, Department of Public Health

He/She shall function as the Chairman of the Committee.

2. Three Medical Practitioners

- Diagnostic Services
- Surgical Services
- Medical Services

Introduction of new health technologies will mostly be in the hospitals, and as these representatives will be the ultimate service providers, their technical/clinical inputs are necessary in taking a rational decision.

3. Representative, Policy and Planning Division, MoH

He/she shall be required to have some level of knowledge on health economics so that he/she can guide the Committee and the Division on the cost-effectiveness/ economic evaluation issues.

4. ***Representative, Quality Assurance and Standards Division, MOH***

   He/she shall be required to have some level of knowledge on quality health care standards so that he/she can guide the Committee and the Division on the cost-effectiveness, efficiency and quality of health services and facilities.

5. ***Pharmacist, JDWNR Hospital***

   The proposed member shall be required to have professional experience in hospital/clinical pharmacy for at least 3-4 years. He/she shall provide expert advice on all matters related to pharmaceuticals.

6. ***EMTD (Member Secretary)***

   The Head of the Division shall function as the member-secretary to the Committee and maintain all records pertaining to the meeting and decisions made thereof.

Depending on the subject of discussion or area of expertise, relevant Specialist or Clinicians may be invited as **co-opted members** during any of the HTAP meetings.

Meetings

1. The HTAP will be conducted twice in a year to discuss and review health technologies and their impact on health care delivery.
2. The Chairman of the HTAP will chair all the meetings.
3. In order to hold the meeting, at least two-third of the members, i.e. 4 members, must be present.
4. All decisions taken by the Committee and signed by the Chairman shall be final and binding.
5. Co-opted members shall only be responsible for providing technical advice and guide the Committee. He/she shall not have the right to vote (***Voting*** is done on those cases where opinions of the members are contradicting and the panel is not able to come to a consensus decision).

Powers of the Chairman

The chairman shall have the power to:

1. Call for an emergency meeting as and when the need arises.
2. Cast a vote if there is tie in the decision taken by the members of the Committee.
3. Decided to hold a meeting even if the quorum is not met.

Procedures of the Meeting

1. All members of the HTAP shall be required to sign a declaration of "conflict of interest" at the beginning of each meeting. In case of conflict of interest arising, the said member shall be excluded for the proceedings and decisions of the Committee.
2. 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 requested by the HTAP.
3. If required, the applicant of the proposed technology may be invited to present the proposal before EMTD puts forward the evidence or findings.
4. Once the technologies to be discussed are introduced, the Committee shall deliberate the technology(s) topics under review.
5. One of the following decision shall be made by the Committee:
    a. ***Approve*** the technology for introduction
    b. ***Reject*** the proposal
    c. Request for ***additional information/justification/supporting evidence*** from the applicant
    d. Direct the Division to ***carry out further assessment*** on the concerned technology and keep the decision pending till next Committee meeting
6. All decisions made by the Committee supported by valid justification shall be signed by all Committee members present.
7. The Divisions shall inform the applicant and all concerned individuals/agencies on the Committee decision.
8. Any grievances or appeals on the Committee decisions shall be made in writing to the Division or the Chairman of the HTAP upon which the issue will be further deliberated at the next meeting.

Timeline for our work process

No.	Activities	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun
1	**Deadline for Receipt of Proposals**		4th week						4th week				
2	**Preparation for Next Meeting**												
3	**HTAP Meeting**				4th week						4th week		
4	**HTA Report Dissemination and Feedback on HTAP**					2nd week						2nd week	

HTA Products

1. **Health Technology Assessment Report (HTA Report)**
   - Comprehensive (social, ethical, clinical, economic) report
   - Developed from analysis, interpretation and synthesis of scientific research and/or technology assessment conducted by the organizations
   - Anticipating a future decision problem
   - Decision can wait (to some extent) based on evidence
   - Product should be out 1-2 weeks after approval by HTA Panel
   - ***Information Brief***: In those cases where HTA Report is requested in an urgent manner, an Information Brief will be produced which contains basic information on that particular health technology and not much study is done.
2. **Health Technology Assessment Guideline**
   - Detailed explanation of how HTA is conducted
   - Revised in every 3 years
3. To conduct **Health Technology Assessment Panel Meeting** to facilitate the introduction of the new technologies, make amendments (up-gradation/addition/deletion) of existing health technologies.

Annexure: 1

Ministry of Health

Application Form
For
Introduction of Health Technology

The Health Technology Assessment Panel (HTAP) provides advice to the Ministry of Health regarding the uptake, diffusion, and distribution of health technologies, as well as removal of obsolete health technologies, based on evidence of effectiveness, economic and human resource considerations, societal impact, regulatory and ethical consideration, and utilization guidelines. The EMTD provides HTAP with health technology scientific literature and policy reviews to permit HTAP to evaluate the safety and effectiveness of health technologies and make recommendations accordingly based on the currently available evidence.

This Application is for Review of New or Updated Health Technologies for use in Bhutan.

Please complete the entire application, attach any relevant materials and submit to:
Essential Medicines & Technology Division (EMTD)
Department of Medical Services
Ministry of Health
Thimphu
Tel: +975 2 322602 (ext. 205)
Fax: + 975 2 322918
Email: emtd@health.gov.bt

Proposal for:			
For EMTD use only			
Approval for HTAP Review / Assessment?	☐ Yes	☐ No	Date:
More information required?	☐ Yes	☐ No	Date:
Main applicant contacted?	☐ Yes	☐ No	Date:

I. GENERAL INFORMATION

Application Date:	Proposal number #:
Principal Applicant	*(Do not complete – for administrative purposes only)*
Name and title:	
Complete address:	Telephone #:
	Fax #:
	Email address:
Affiliated healthcare facility (if applicable):	

Health Technology Request
Type of Health Technology (tick appropriate one)

☐ Medical Device ☐ Medical Equipment ☐ Treatment Strategy ☐ Pharmaceutical (use Form 1)

Name of the Proposed Health Technology:

Disease / Condition in which the Device / Equipment / Treatment Strategy will be of most benefit:

Level of Health Facility till which the Technology is to be made available

☐ Till BHU ☐ till DH ☐ till RRH ☐ only NRH

Target Patient Population (Gender, Age, etc.):	Incidence and Prevalence in Bhutan, if known:

Justification for Introducing New Technology:

II. DESCRIPTION OF DEVICE / EQUIPMENT / TREATMENT STRATEGY

Describe in detail the device / equipment / treatment strategy.

If applicable, please indicate if there are alternative/similar technologies currently available in Bhutan serving this purpose.

☐ YES ☐ NO

If YES, please indicate which one: _____

Please specify whether this new technology will substitute or add to the currently existing technologies.

Does the introduction of this new technology require up-gradation of skills and attainment of new knowledge of Health Workers?

☐ YES ☐ NO

[If YES, please give details on (a) the number and type of people; (b) type of trainings required and (c) budgetary provisions]

To the best of your knowledge, is this device / equipment / treatment strategy currently being used in any other countries? If so, where and under what conditions?

III. EVIDENCE

Please provide relevant evidence. If this is a diagnostic technology, please submit evidence of sensitivity and specificity.

IV. NOTE TO APPLICANT

1. The technology prepared for review in this application must improve the net health outcome and/or safety for patients and/or providers or improve health systems efficiency to be considered by EMTD.
2. The technology described in this application must be at least as beneficial as any established alternative. If the technology is not better, it must be shown to be more cost-effective.
3. All materials accompanying this application must comply with privacy and intellectual property principles and regulations.
4. No information identifying individual patients is to form any part of this application.
5. The applicant must have obtained consent from a manufacturer that information provided to an applicant can be submitted to EMTD.

V. EMTD AND HTAC RESPONSIBILITIES

1. All reviews / assessments / evaluations will be evidence-based and objective.
2. Applicant names and affiliations will remain confidential.
3. Materials that accompany the application may be shared with clinical / technological experts.
4. Applicants understand that by submitting this application, they are giving permission to reviewers at MoH to discuss the review with other governments and advisory bodies.
5. Consultation from various clinicians / technologists may be sought if the application is accepted for review.

Applicant Signature **Date:**

Thank you. You will be notified of the application outcome within 2 weeks after the HTA Panel meeting is conducted.

Annexure: II

Criteria used for Priority Setting

No.	Topics for Introduction of New Health Technology	Criteria					Score
		Effects on infrastructure and other services (include training, accreditation, education issues)	**Prevalence** (include disease burden, number of people affected)	**Availability of competing technologies** (other technology currently available for the same purpose)	**Possibility of changing health status** (include significance of technology-efficacy/effectiveness, safety and implication of introduction such as reduction in morbidity, mortality, early detection etc.)	**Cost** (include direct cost or cost effectiveness or other cost implication)	
	(Weightage)	(20)	(20)	(20)	(20)	(20)	%
1							
2							
3							
4							

Annexure III

Health Technology Utilization Report Format

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

Annexure: IV

HTA Report Feedback Form

Title of the Health Technology Assessment/Technology

Review: ……

1. Contact information
   Name:
   Designation:
   Organization:
   Phone no:
   Email Address:

2. How would you rate the Report? Please tick ONE of the following:

   Excellent ☐ Good ☐ Fair ☐ Poor ☐

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

   - Influence or develop policy/decisions ☐
   - Influence operational procedures/practices ☐
   - Influence guideline formulation ☐
   - Change awareness or increase understanding of the issue ☐
   - Influence or make operational/capital funding decision ☐
   - Other (please specify) ☐

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

   - Not in use and not being considered ☐
   - In use – full implementation ☐
   - Not in use but under review ☐
   - Other (please specify) ☐

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

   Really well ☐ Well ☐ Not so well ☐ Not at all ☐

   Comments (you can use separate paper for your comments)

Adopted from MaHTAs