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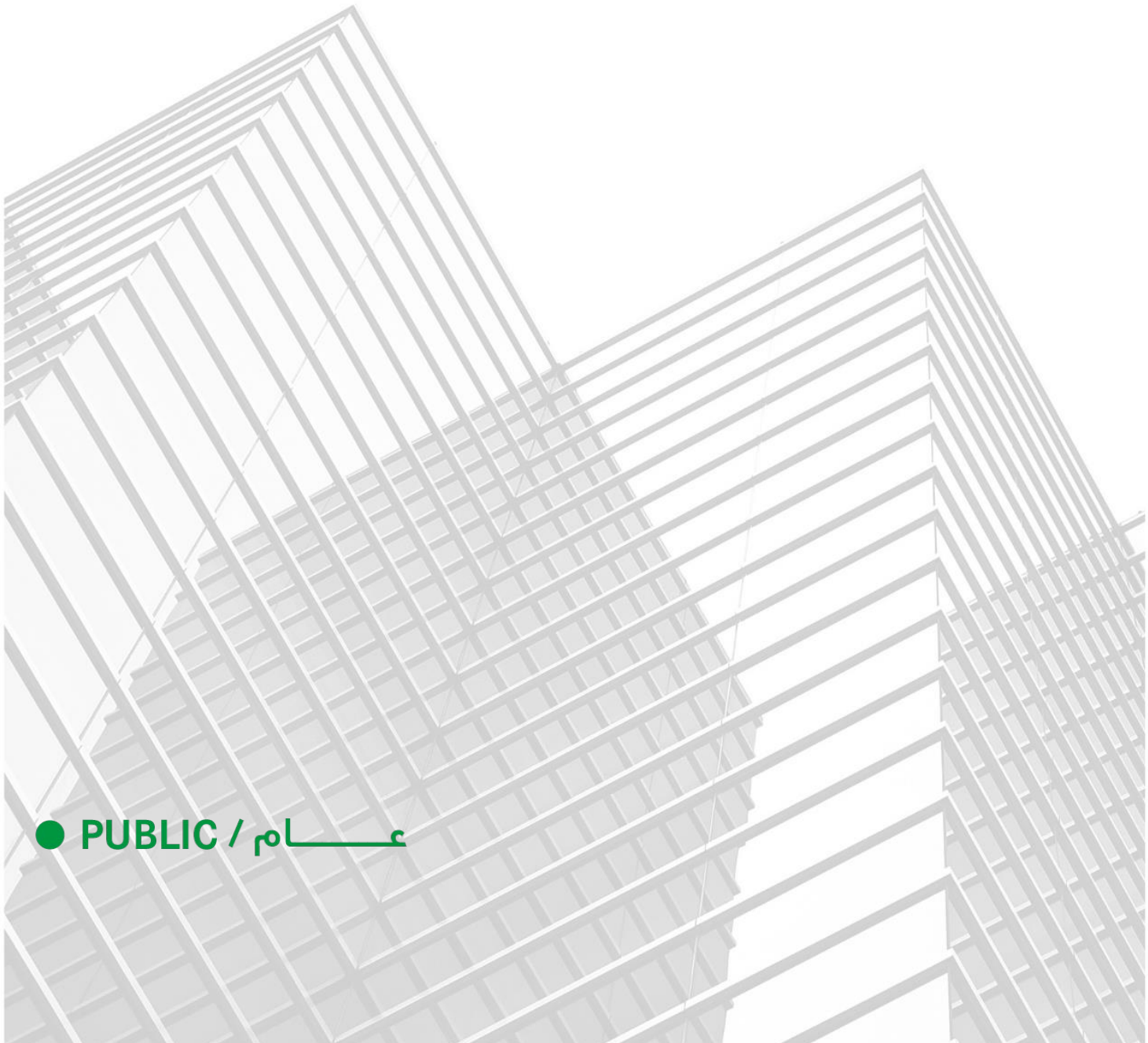
DEPARTMENT OF HEALTH

Health Technology Assessment Guidelines



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Introduction

Health Technology Assessment (HTA) critically examines the properties, effects, and impacts of health technologies, providing evidence-based information to shape policy decisions[1]. By considering a broad range of factors—including clinical, economic, social, ethical and information security dimensions—it ensures healthcare innovations are safe, effective, compliant and aligned with societal needs and values. HTA is a multidisciplinary process that uses explicit methods to determine the value of health technology at different points in its lifecycle[2]. The purpose is to inform decision-making to promote an equitable, efficient, and high-quality health system[3].

Establishing HTA guidelines is an essential part of the institutionalisation process for a functioning HTA system[1,4,5,6]. The primary aim of HTA guidelines is to produce good quality HTA studies that inform policy decisions, improve clinical practice, and enhance the credibility and sustainability of HTA-informed decision-making[7].

Beyond the evident advantage of enhancing the quality of Health Technology Assessments (HTAs), an often-overlooked benefit of HTA guidelines lies in the standardization of economic evaluations. This standardization ensures the comparability of results across different assessments, thereby solidifying the decision-making process. When methodologies diverge, variations in outcomes can arise from the differences in analytical approaches rather than from the intrinsic differences between the health technologies being evaluated. Thus, by establishing a uniform framework for economic evaluations, HTA guidelines play a crucial role in ensuring that distinctions in findings are genuinely reflective of the health technologies themselves, rather than artefacts of disparate evaluation techniques.

Several HTA guidelines have been developed globally, as highlighted by the World Health Organization (WHO) report on Health Technology Assessment by National Authorities[8]. Moreover, EUnetHTA has produced a comprehensive methodology guideline for HTA assessors, designed to address the specific methodological challenges encountered when conducting relative effectiveness assessments of both pharmaceutical and non-pharmaceutical health technologies[9].(EuNetHTA, 2015) Additionally, the International Network of Agencies for Health Technology Assessment (INAHTA) provides a set of checklists and instructions to guide the development and execution of HTA reports[10]. These guidelines are crucial as they offer vital insights into key components that need to be considered when formulating local HTA frameworks.

These HTA guidelines, crafted for Abu Dhabi, establish a framework to guide the adoption, utilization, and governance of emerging health technologies. They empower decision-makers to align new medical procedures and interventions with the Emirate's priorities, ensuring cost-effectiveness within our local healthcare context.

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1 Guideline Purpose and Brief

These guidelines aim to provide a structured and standardized framework for evaluating new health technologies and allowing the Department of Health (DoH) to make informed decisions about the adoption, utilization, and management of new health technologies. The guide can be used by anyone in the Abu Dhabi healthcare ecosystem who prepares technical documentation for health technology assessments. It is intended for manufacturers and other industry parties such as authorized distributors, DoH licensed healthcare providers, pharmaceutical companies, and healthcare technology companies who are interested in applying for the reimbursement of their product.

This guideline is also designed to assist decision-makers in ensuring that the introduction and use of health technologies, treatments, procedures, and interventions are safe, effective, in a way that will bring value to the healthcare system in comparison to current technology and in alignment with the Emirate priorities. Furthermore, it ensures that health technologies are cost-effective within the context of the local healthcare system.

These guidelines apply to a wide range of health technologies, medical products, including pharmaceutical products, medical equipment, diagnostic tests, surgical procedures, and health system interventions.

The key concepts are:

1.1 Clinical domains:

1.1.1 Evidence-Based Practice

1.1.2 Clinical Effectiveness

1.2 Economic domains:

1.2.1 Cost-Effectiveness

1.2.2 Affordability (budget impact)

1.2.3 Uncertainty Management: recognizing and managing uncertainties inherent in the assessment process, such as gaps in evidence or variability in outcomes. Horizon scanning identifies emerging health technologies needing future assessment.

1.2.4 Burden of Disease (relates to specific intervention/technology)

1.3 Others:

1.3.1 Ethical Considerations

1.3.2 Stakeholder Involvement

1.3.3 Transparency and Accountability

1.3.4 Health Equity & Accessibility

1.3.5 Lifecycle Approach: Considering the entire lifecycle of a health technology, from development and introduction to monitoring and re-assessment.

1.3.6 Health Technology Impact (clinical and financial)

1.3.7 Information and Cyber Security Compliance

1.3.8 Data Governance Compliance.

2 Definitions and Abbreviations

No.	Term	Definition
2.1.1	Advanced Medical Treatment Products	Pharmaceutical Products based on modern and innovative technologies such as gene and cell therapy, stem cell therapy, genetic engineering, and engineered tissues, which are designed to treat, prevent, or diagnose complex and genetic diseases and injuries by modifying genes or replacing abnormal cells and tissues.
2.1.2	Clinical effectiveness review	Assessment of the clinical domains occurs through a clinical effectiveness review comparing the intervention with the currently available options. The report would include recommendations for utilization (place in therapy, eligibility criteria, expected outcomes relative to other options) that would result in optimal outcomes as per available evidence.
2.1.3	Cost-effectiveness analysis (CEA)	An economic evaluation comparing various options, in which costs are measured in monetary units, then aggregated, and outcomes are expressed in natural (non-monetary) units[11].
2.1.4	Cost-Utility Analysis (CUA)	An economic evaluation consisting of comparing various options, in which costs are measured in monetary units and outcomes are measured in utility units, usually in terms of utility to the patient (using quality-adjusted life years, for example)[11].
2.1.5	Deterministic Sensitivity Analysis (DSA)	A means for evaluating the robustness of a mathematical model by testing a plausible range of estimates to account for parameter uncertainty[11]. It is usually done by varying parameters by a fixed value, usually ±10%, to assess their impact on the model's outcomes.
2.1.6	The Emirates Drug Establishment (EDE)	The Emirates Drug Establishment (EDE).
2.1.7	Government funded programs	Insurance programs financed by Government: 'Thiqa', the Government-funded, single-payer health insurance scheme for Nationals, was mandated by Resolution No. (83) of 2007 of the Abu Dhabi Executive Council concerning the application of the Law to Nationals and those of similar status in the Emirate. The Government also funds defined mandates for healthcare services and programmes that serve public good and that are not covered by the Health Insurance Scheme (Funded Mandates).

2.1.8	HTA early advice	Advice to the industry on their early pharmaceutical product development plans from an HTA point of view. Such advice helps the industry optimize the time to market for new therapies. The early advice is the first step in the HTA process where the technology is subjected to pre-evaluation before the submission of the HTA application for coverage and reimbursement.
2.1.9	Health Technology Assessment (HTA)	HTA is a multidisciplinary process that uses explicit methods to determine the value of health technology at different points in its lifecycle. The purpose is to inform decision-making to promote an equitable, efficient, and high-quality health system[2].
2.1.10	Healthcare Resources	Reporting on the utilization of healthcare resources associated with the implementation of new health technology, including changes in resource use directly attributable to the adoption of the technology (Detailed methodological).
2.1.11	Horizon Scans	The systematic identification of health technologies that are new, emerging or becoming obsolete and that have the potential to affect health, health services and/or society[11].
2.1.12	Incremental cost-effectiveness ratio	The additional cost of the more expensive intervention compared with the less expensive intervention, divided by the difference between the effects of the interventions on the patients (e.g. the additional cost per QALY, for example)[11].
2.1.13	Life Years Gained (LYG)	The number of years of life that are added due to a healthcare intervention.
2.1.14	Managed Entry Agreements (MEAs)/ Risk Sharing	Are contracts that can be used for mitigating the uncertainty regarding a medicine's relative
2.1.15	Marketing Approval (MA)	The approval granted by the EDE to a legal entity licensed in the State to market a specific Medical Product. This legal entity shall be responsible for all aspects of marketing, promotion, and follow-up of the product in the State.
2.1.16	Medical Equipment	A Medical Product that contains a substance, device, instrument, engine, implant, detector, or system, including accessories, and operating software thereof. It shall include wearable devices and products based on AI technology, which shall achieve the intended purpose of its use in or on the human or animal body without a pharmaceutical, immune, or metabolic effect. In addition, it is manufactured, sold, or offered for use in the following cases: 1. Diagnosis, treatment, cure, relief, or prevention of a disease, an injury, or a disability; 2. Detection, modification, or replacement of anatomical position. 3. Birth Control.

2.1.17	Medical Product	The Pharmaceutical Product, Medical Equipment or Healthcare Product as the product described in Article (2) herein Federal Decree-Law No. (38) of 2024 Governing Medical Products, Pharmacists and Pharmaceutical Establishments. Specifically for diagnostic and/or therapeutic purposes and necessary for its proper application.
2.1.18	Pharmaceutical Product	Any product that contains an active substance or group of active substances that achieves the intended purpose of use thereof in or on the human or animal body through a biological effect, and which is manufactured, sold, or offered for use in the following cases: 1. Diagnosis, treatment, cure, relief, or prevention of a disease. 2. Restoring, renewing, modifying, or correcting the physiological functions. The following shall also be included in Pharmaceutical Products: 1. BioPharmaceutical Products; 2. Food Supplements; 3. Cosmetics As defined in Federal Decree-Law No. (38) of 2024 Governing Medical Products, Pharmacists and Pharmaceutical Establishments.
2.1.19	Innovative Pharmaceutical Product	A medical product that has an altogether new active ingredient, and no medical product that contains the same ingredient has ever obtained a Marketing Approval within the State, and the marketing of products that contain its active ingredient has not been actually carried out for a period that exceeds two years. As defined in Federal Law No. (8) of 2019 on Medical Products, Pharmacy Profession and Pharmaceutical Establishments.
2.1.20	Probabilistic Sensitivity Analysis (PSA)	A means for evaluating the robustness of a mathematical model by testing a plausible range of estimates to account for parameter uncertainty[11]. It uses distributions for parameters to reflect their variability and conducts multiple iterations to assess the impact on the model's outcomes.
2.1.21	Quality-Adjusted Life Year (QALY)	A unit of outcome of an intervention where gains (or losses) of years of life subsequent to this intervention are adjusted on the basis of the quality of life during those years[11].
2.1.22	Reimbursement coverage review	The reimbursement coverage review is the full HTA assessment of health technology to decide on its coverage and reimbursement.
2.1.23	Relative Health Gain	Evaluated through incremental relative QALY gain, interventions demonstrating significant QALY gain receive multipliers on the baseline cost-effectiveness threshold.

2.1 Abbreviations		
No.	**Abbreviation**	**Full Form**
2.2.1	ADPHC	Abu Dhabi Public Health Center
2.2.2	AED	United Arab Emirates Dirhams
2.2.3	AI	Artificial Intelligence
2.2.4	AMTP	Advanced Medical Treatment Products
2.2.5	CEA	Cost-Effectiveness Analysis
2.2.6	CIHI	Canadian Institute for Health Information
2.2.7	CME	Continuing Medical Education
2.2.8	CRD	Centre for Reviews and Dissemination
2.2.9	DoH	Department of Health
2.2.10	DSA	Deterministic Sensitivity Analysis
2.2.11	EMA	European Medicines Agency
2.2.12	FDA	Food and Drug Administration in USA
2.2.13	GBD	Global Burden of Disease
2.2.14	HCUP	Healthcare Cost and Utilization Project
2.2.15	HERC	Health Economics Research Centre
2.2.16	HTA	Health Technology Assessment
2.2.17	ICER	Incremental Cost-Effectiveness Ratio
2.2.18	LYG	Life Year Gained
2.2.19	MA	Marketing Approval
2.2.20	MAH	Marketing Approval Holder
2.2.21	PSA	Probabilistic Sensitivity Analysis
2.2.22	QALY	Quality-Adjusted Life Year
2.2.23	RSA	Risk Share Agreement
2.2.24	SCAD	Statistics Centre Abu Dhabi
2.2.25	WHO	World Health Organization

3 Guideline Content

This guideline provides a comprehensive framework for Health Technology Assessment (HTA) in Abu Dhabi highlighting its importance in evaluating the properties, effects, and impacts of health technologies to inform policy decisions.

This document covers various aspects of the HTA process, including the submission process, evaluation criteria, transparency, and timelines. It details who can initiate evaluation requests and the specific requirements for clinical assessments, cost-effectiveness analysis, budget impact analysis, and considerations for disease burden and equity issues. Additionally, the document provides guidance on clinical and economic evaluation submissions, describing the necessary data, assumptions, and methodologies to be used. It emphasizes the importance of standardized reporting formats and includes specific requirements for economic models, sensitivity analyses, and post-approval studies.

The process for notification of outcomes, resubmission following negative recommendations, and the implementation of funding decisions are stated. Overall, the guideline aims to ensure that health technologies adopted in Abu Dhabi are clinically effective, cost-effective, and aligned with the local healthcare system's priorities and needs.
The HTA process will not be used as a substitute for any price reduction initiatives or negotiations led by the government entities. Any government-driven pricing actions, including reductions or adjustments, will remain independent of the HTA assessment process.

3.1 Scope

The scope of the guidelines involves the assessment of the following categories of health technologies:

3.1.1 New Medical Products

3.1.1.2 Innovative pharmaceutical products (innovative branded pharmaceutical products)

3.1.1.3 Medical Equipment

3.1.1.3.1 Hardware devices, equipment, diagnostic tests, and supplies: Special, unique, and new technologies.

3.1.1.3.2 Digital products, software, and artificial intelligence (AI)

3.1.1.3.2.1 Software with device (IOT)

3.1.1.3.2.2 AI without hardware device

3.1.1.3.3 Medical procedures and surgeries: minimally or noninvasive medical interventions used to diagnose, treat, monitor, or examine various conditions and diseases. Invasive medical intervention using incisions allows a healthcare provider to structurally change the body to treat or diagnose an illness or condition. Special, unique, and new procedures and surgeries only.

3.1.1.4 Wearable devices supported with Vital signs sensors.

3.1.1.5 Remote Patients Application.

3.1.1.6 Public health programs (education and awareness programs)

The current guidelines are not intended for reassessing or re-evaluating previously reimbursed technologies. However, future revisions of the guidelines will include previously reimbursed technologies. Specific criteria for evaluating digital health solutions will be considered in future updates of the guidelines.

Table 1 outlines the scope of health technologies that manufacturers are obligated to submit for appraisal by the DOH.

Table 1 Scope of Health Technologies to be assessed by these guidelines

	Examples
Health Technologies assessed by the guidelines	Innovative health technologies* (Medical devices, equipment, diagnostic tests, digital products, artificial intelligence (AI), VR, robotics and supplies) pharmaceutical products (Advanced Medical Treatment Products); i.e Gene therapies, specialized biologics and oncology products) • previously approved pharmaceutical products that have been approved in new settings, such as for a different disease, a new patient population (e.g., children), or a new dosage form or formulation • New disruptive dosage form of a health technology that comes with innovation) • For pharmaceutical products, estimated product costs > AED10 million a year or exceeds AED 100,000 per patient per year
Health Technologies Out of Scope of the guidelines	• Generic pharmaceutical products** • Low pharmaceutical product costs / budget impact; expected annual utilization < AED 10 million a year or per patient cost less than AED 100,000 per year** • New dosage form of a pharmaceutical product with minimal modification of original dosage form** • Products or procedures without established clinical efficacy data • Cosmetics and food supplements. • Pharmaceutical product evaluation for the sake of marketing approval or entry to market

*The scope includes both pharmaceutical products and medical equipment.

** Pharmaceutical products out of scope will not require a full HTA review and will be automatically covered for reimbursement without assessment. (e.g. generics, biosimilars, etc.)

With these guidelines, the DoH will mandate HTA for coverage and reimbursement decisions for all new innovative branded pharmaceutical products. The priority will be for biologics and pharmaceutical Advanced Medical Treatment Products, i.e. gene therapies, specialized biologics, and CAR-T cells. Eventually, the HTA process will be applied to all new innovative branded pharmaceutical products.

Additionally, the DoH will mandate HTA for coverage and reimbursement decisions for pharmaceutical products with an expected high product cost of > AED10 million a year, Or/And a product cost that exceeds AED 100,000 per patient per year.

3.1.2 Health technology assessment is initiated by the DoH through one of the following triggers:

3.1.2.1 Horizon Scans: Overviews of new or emerging health technologies that have the potential to impact the delivery of care to forecast any future expected technologies but have not been officially approved.

3.1.2.2 Health Technology Reviews for new technologies to decide their appropriateness and recommend on the optimal use and place in the therapy/care pathways. Independent assessments of pharmaceutical products, and other health technologies, which may also include recommendations on the appropriate use of the assessed technologies.

3.1.2.3 Class review: Evaluation for class or group of medications that are from the same group to decide and recommended the place in therapy (ex: the first line/ second line & eligibility criteria). This is usually for multiple pharmaceutical products at the same review

3.1.2.4 Reimbursement coverage reviews. For new technologies, to decide coverage and funding recommendations related to public funded pharmaceutical products programs where a comprehensive assessment of the clinical effectiveness and cost-effectiveness, as well as patient and clinician perspectives, of a health technology will be assessed.

Note: More than one trigger could be addressed in one assessment.

3.2 HTA Processes

3.2.1 DoH has two health technology assessment processes:

3.2.1.1 Innovative pharmaceutical products (innovative branded pharmaceutical products or Biologics)

3.2.1.2 Medical equipment

Although there are some differences between the two processes, the principles relating to decision-making, the methods of assessment and the decision are consistent.

3.2.2 Generally, the health technology assessment involves two steps:

3.2.2.1 **Step 1: Clinical Assessment (Market Entry Approval)**

The **clinical** domains of assessment for market entry (access) purposes include:

3.2.2.1.1 the identification of a health problem and current health technology,

3.2.2.1.2 the examination of the technical characteristics of the health technology under assessment,

3.2.2.1.3 its relative safety,

3.2.2.1.4 its relative clinical effectiveness.

Assessment of the clinical domains occurs through a **clinical effectiveness review** comparing the intervention with the currently available options. The report would include recommendations for utilization (place in therapy, eligibility criteria, expected outcomes relative to other options) that would result in optimal outcomes as per available evidence. This process is conducted by the Health Life Science Sector of DoH.

The process will also involve early engagement of Healthcare Facilities Pharmacy and Therapeutics Committees to seek their opinions on clinical efficacy and to align with DoH on the final recommendations that will be applied across Abu Dhabi.

3.2.2.2 **Step 2: Economic Assessment (coverage and reimbursement)**

Coverage and reimbursement depend primarily on the **economic** assessment of the intervention including but not limited to the cost-effectiveness of the health technology, its economic/budget impact and the burden of the disease.

The economic assessment process is conducted by the Healthcare Payer Sector of the DoH.

3.2.2.3 **Other Assessments**

The HTA process includes other assessments when needed including ethical, organizational, social, environmental, technological, legal, data governance and information security aspects.

3.3 HTA Submission Requirements

3.3.1 Clinical Assessment

Requirement: Mandatory. A thorough evaluation of the health technology's clinical efficacy and safety in comparison to current standards of care. Real-world evidence is not mandated by the DoH to be submitted by the company but in certain cases, such as during class reviews, it may be requested by the DoH.

3.3.2 Cost-effectiveness Analysis

Requirement: Mandatory. An analysis to determine the health technology's value for money, comparing its costs and outcomes to those of existing treatments.

3.3.3 Budget Impact Analysis

Requirement: Mandatory. An assessment of the financial implications of adopting health technology within the healthcare system's budget over a specified timeframe varying between 3-5 years.

3.3.4 Burden of Disease

Requirement: On request by the DoH. The burden of disease study is mandated when the impact of the disease is not clear. An in-depth examination of the disease's impact on the population, considering humanistic, economic, and clinical burden.

3.3.5 Equity Issues

Requirement: To be submitted if equity concerns exist. The DoH is responsible for determining the presence of equity issues. Assessments should include a narrative description of any potential equity implications related to the access and impact of health technology.

The concept of **equity** in healthcare emphasizes fairness in the allocation of resources, technologies, and outcomes among individuals or groups. Several factors can contribute to vulnerability in accessing healthcare including:

- **3.3.5.1 Rare diseases**, which often have limited effective treatments and high associated costs, making care access more difficult.
- **3.3.5.2 Geographical location**, where remote or underserved areas may face inadequate healthcare infrastructure and resources, leading to access disparities.
- **3.3.5.3 Socioeconomic status, race/ethnicity, and gender**, which can also influence access.

The necessity to reimburse health technologies may be advised if a certain condition/disease affects a certain population group disproportionately even though other criteria may not be entirely fulfilled.

3.3.6 Data Governance & Privacy:

Requirement: All data-based technologies need to submit Data Security model of the device in alignment with DoH Digital health & Information security requirements and standards. Also, Data Governance requirements (Data Catalogue, Data Quality, Data Architecture, etc..) shall be considered to ensure integrity, security and interoperability of data.

Table 2 HTA requirements

HTA Requirement	Mandatory
Clinical Assessment	Yes
Cost-effectiveness Analysis	Yes
Budget Impact Analysis	Yes
Burden of Disease	No (On-request)
Equity Issues	If equity issues exist

3.4 Guidance on Clinical Evaluation

3.4.1 Investigated health technology

An overview of the investigated health technology and its therapeutic indications and contra-indications should be presented. The emphasis should be on target health conditions and populations, the intended purpose of the health technology, its current utilization, and variations already in use and intended patient eligibility.

3.4.2 Overview of the investigated health technology

The overview of the investigated health technology shall contain specific elements that elaborate on the technical aspects and characteristics of the health technology being assessed. These elements include:

3.4.2.1 Clear identification of the health technology, including its commercial name, generic name, classification (e.g., pharmaceutical product, medical device), and any relevant codes or identifiers (e.g., product code, identification number).

3.4.2.2 A detailed description of the technology, its components, and technical specifications (if applicable) and any special properties that differentiate it from similar technologies.

3.4.2.3 The health procedure that can be performed with the health technology.

3.4.2.4 Detailed description of all approved indications of the investigated health technology with highlighting the indication which will be investigated in the economic evaluation.

3.4.2.5 Clear specification of the intended purpose or use of the technology, along with its intended clinical indications, patient population, and conditions or diseases it is designed to address.

3.4.2.6 Information on the technical performance characteristics, such as accuracy, precision, sensitivity, specificity, reliability, durability, usability, interoperability, and any other relevant performance metrics (if applicable).

3.4.2.7 Details on how the technology is administered, delivered, operated, or applied. This may include dosing regimens (for pharmaceutical products), application procedures (for medical products), route of administration, or any specific instructions for use.

3.4.2.8 Description of how the investigated technology changes existing patient treatment pathways.

3.4.2.9 Information about the current application of the investigated technology in the UAE, as well as reimbursement status in other indications in the UAE (if applicable).

3.4.2.10 Compliance with the applicable Laws and regulations for Information Security

3.4.3 Target indication

3.4.3.1 Therapeutic areas targeted by the investigated health technol

3.4.3.2 The approved target indication and the target population should be clearly presented. It should be clear that the target indication for coverage cannot be broader but can be narrower than what is described in the summary of product characteristics determined by the approved indication.

3.5 Clinical Assessment

3.5.1 Disease area

The disease or health condition in the scope of the assessment should be presented in a verifiable manner with the following focus areas:

3.5.1.1 Known risk factors for the disease or health condition.

3.5.1.2 Symptoms and the burden of disease or health condition for the patient.

3.5.1.3 Its natural course (basic data on the onset (age), average time of course, prognosis by subgroup, gender differences, frequency of relapses, spontaneous cures, mortality, average survival time, comorbidities etc.)

3.5.1.4 Consequences of the disease or health condition for the society.

3.5.1.5 The aspects of the consequences/burden of disease that are targeted by the technology.

3.5.2 Health gain

The health gain that is expected through the use of the health technology needs to be presented. The assessment of health benefits should primarily consider policy-relevant outcomes such as mortality, morbidity, and quality of life. The following elements should be considered:

3.5.2.1 Mortality: the expected beneficial effect of the health technology on mortality.

3.5.2.2 Morbidity: the impact of the health technology on disease or health condition symptoms, magnitude, and frequency of morbidity and progression (or recurrence).

3.5.2.3 Health-related quality of life: the effect of the health technology on generic and/or disease-specific quality of life.

3.5.2.4 Function: the impact of the health technology on body functions, work ability, return to previous living conditions and activities of daily living.

3.5.2.5 Patient satisfaction: satisfaction of patients with the health technology.

3.5.2.6 Benefit-harm balance: the overall benefits and harms of the health technology in health outcomes.

3.5.3 Epidemiology (incidence, prevalence)

It is mandatory to define the epidemiological and demographic characteristics of the target indication as well as the health-status-related context in which the health technology will be used. These include the socio-economic situation, incidence and prevalence of the disease, gender distribution, the number of patients to be treated, the number of patients currently being treated/cared for, the number of mild, moderate and severe patients, etc.

Trends in disease and patient population over the last 5-10 years should be highlighted. If data from the UAE is not available, international references shall be applied to estimate/model the prevalence of the disease, preferably based on data from the Arab countries or the Middle East (if data from Arab countries is not available). International data references are not always directly applicable without adaptation, as there may be differences in the population covered by the technology, in the health access environment, legal and cultural characteristics compared to the local setting. In the absence of high-quality local data, the global burden of disease studies could be useful[13]. It is recommended to follow good epidemiological practices when addressing prevalence and incidence values[14].

3.5.4 Current management of the condition

Current routine diagnosis, treatment and care practices used for the target indication should be presented where possible supported by published local and international guidelines or other verifiable papers. It is also necessary to describe the level of care currently provided for the disease or health condition (e.g. primary care, outpatient and in-patient specialist care, home care, etc.) and the relevant service provision in addition to the current therapy data (e.g. outpatient turnover, number of hospital admissions, etc.) and trends in a verifiable manner. Please follow the latest DoH clinical guidelines for disease management[15].

3.5.5 Unmet health needs

It is necessary to clearly define the public health need that is currently not or only partially fulfilled with standard technologies (e.g. early detection, low cure rate, resistance to therapy, adherence, severe side effects, etc.), which can be addressed by investigated health technology.

3.5.6 Current therapeutic alternatives coverage status

A brief overview of the reimbursed technologies in the target indication should be described and alternatives available in the UAE or abroad should be stated.

3.5.7 Evidence on clinical effectiveness

3.5.7.1 **Elements of clinical evidence**

The clinical benefits of the investigated health technology can be measured in clinical trials and in real-world studies. A good understanding of the clinical benefits supporting the technology should be included with the following elements included:

3.5.7.1.1 An overview of the clinical trials or real-world studies conducted to evaluate the health technology including objectives, endpoints, inclusion and exclusion criteria, duration, and methodology used.

3.5.7.1.2 Details about the characteristics of the patient population involved in the clinical trials and real-world studies and a clear description of the intervention or use of the health technology in the clinical studies, including dosing regimen (if applicable), treatment protocols, and any variations across studies.

3.5.7.1.3 Information about the control groups, comparator technologies, alternative treatments, or standard-of-care treatments used for comparison highlighting how the new technology was evaluated against existing options.

3.5.7.1.4 Primary and secondary outcomes assessed in the clinical trials and real-world studies, including clinical and safety endpoints and patient-reported outcomes.

3.5.7.1.5 Strengths and limitations of the clinical evidence, highlighting factors such as study design, sample size, duration, patient population, biases, uncertainties, and potential sources of or confounding.

3.5.7.1.6 Information on publication status and regulatory submissions.

3.5.7.1.7 Efficacy measured in clinical trials and effectiveness measured in real-world studies related to the investigated health technology.

3.5.7.1.8 The strength of the evidence will follow the hierarchy of evidence with systematic reviews and meta-analyses at the top, providing the most reliable evidence by synthesizing results from multiple high-quality studies. Randomized controlled trials (RCTs) follow, as they reduce bias through randomization and are considered the gold standard for individual studies. Next are cohort studies, case-control studies, cross-sectional studies, case series and case reports[16].

3.5.7.2 **Clinical trials**

Clinical trials, particularly randomized controlled trials (RCTs), are considered the gold standard for evaluating interventions. Several criteria should be followed to allow for their acceptance:

3.5.7.2.1 Study Design and Methodology:

3.5.7.2.1.1 **Randomization:** Ensures the equal distribution of known and unknown confounders between treatment groups.

3.5.7.2.1.2 **Blinding:** Helps to prevent bias in outcome assessment, particularly in placebo-controlled trials.

3.5.7.2.1.3 **Control Group**: A comparator group (e.g., placebo or standard of care) must be used to measure the intervention's effect.

3.5.7.2.1.4 **Sample Size and Power**: Adequate sample size to detect statistically significant differences between groups.

3.5.7.2.1.5 **Statistical Analysis:** Use of appropriate statistical methods and pre-specified endpoints.

3.5.7.2.1.6 **Primary and Secondary Endpoints:** Clearly defined, clinically meaningful outcomes, often pre-registered in trial registries.

3.5.7.2.1.7 **Inclusion/Exclusion Criteria:** Well-defined patient population relevant to the treatment, generalizable to real-world settings.

3.5.7.2.1.8 **Ethical Approval and Informed Consent:** Ethical guidelines must be followed, and informed consent must be obtained from participants.

3.5.7.2.2 **Data Quality and Integrity:**

3.5.7.2.2.1 Good Clinical Practice (GCP) Compliance: The trial must follow GCP to ensure data quality and patient safety.

3.5.7.2.2.2 Adherence to Protocol: Any deviations from the protocol must be justified and reported transparently.

3.5.7.2.2.3 Adverse Events Monitoring: A robust system to monitor and report adverse events and safety concerns.

3.5.7.2.3 **Regulatory and Ethical Standards:**

3.5.7.2.3.1 Approval by Regulatory Authorities: Trials must often be registered with or approved by national and international regulatory bodies like the FDA or EMA.

3.5.7.2.3.2 Publication in Peer-Reviewed Journals: Preferably published in reputable, peer-reviewed medical journals.

The clinical evidence in the Technical Review Report focuses on utilizing high-quality, existing evidence syntheses, such as systematic reviews of randomized controlled trials (RCTs), when available. Primary studies are selected only if recent, high-quality systematic reviews are lacking. If RCTs are not available or additional context is needed, other types of studies may be included to provide supplementary or contextual information, ensuring a comprehensive assessment of the medical product's efficacy compared to its comparator.

3.5.7.3 **Real-world evidence**

Regarding real-world evidence, it is often accepted when it is used to supplement existing RCT data, especially to demonstrate the effectiveness of treatments in broader, real-world populations that may not have been represented in controlled trials.

The criteria for acceptance of real-world studies (RWE) by international bodies such as regulatory agencies and health technology assessment (HTA) organizations like the FDA, EMA, NICE, and CADTH generally include several key elements:

3.5.7.3.1 Study Design and Research Question: An appropriate study design that matches the question being asked.

3.5.7.3.2 Data Quality and Relevance: Reliable and relevant data sources

3.5.7.3.3 Transparency and Bias Mitigation: Transparency in how the data is collected, cleaned, and analyzed and addressing biases and confounding factors.

3.5.7.3.4 Statistical Methods: Rigorous acceptable methods for analyzing real-world data.

3.5.7.3.5 Generalizability: Clear interpretation of how the results apply to the wider population.

3.5.8 Evidence on safety

Safety information, balanced with data on efficacy and effectiveness, forms the basis for any further assessments of a health technology, therefore proven data on these is fundamental. Hazards (direct or indirect harm) of the health technology on patients, staff and environment should be presented in an evidence-based manner along with measures to reduce the risk of those hazards occurring. Crucial elements that should describe the safety profile based on available evidence:

3.5.8.1 Summary of safety-related data available for the health technology, derived from clinical trials, observational studies, post-market surveillance, adverse event reporting systems, or other sources.

3.5.8.2 Description of adverse events, side effects, adverse reactions, and any untoward incidents associated with the use of the technology.

3.5.8.3 Known safety issues, risks, warnings, contraindications, precautions, and any specific populations where safety concerns may arise (e.g., pediatric, elderly, pregnant women).

3.5.8.4 Dose-dependent effects, toxicity profiles, overdose risks, or any known safety concerns related to dosage, administration, or exposure to the technology.

3.5.8.5 Information on risk minimization strategies, risk management plans, or measures implemented.

3.5.8.6 For medical equipment, stricter risk assessment protocols are required incorporating ISO 14971 for risk management[17].

3.5.8.7 Safety aspects in specific populations, such as patients with comorbidities, vulnerable populations. The EQUATOR Network offers a comprehensive array of reporting guidelines for different types of studies

3.5.8.8 The strength of the evidence will follow the hierarchy of evidence with systematic reviews and meta-analyses at the top, providing the most reliable evidence by synthesizing results from multiple high-quality studies. Randomized controlled trials (RCTs) follow, as they reduce bias through randomization and are considered the gold standard for individual studies. Next are cohort studies, case-control studies, cross-sectional studies, case series and case reports[16].

Incorporating real-world data could help mitigate uncertainty about a health technology's long-term safety and performance in broader populations. Therefore, post-marketing studies to ensure safety after approval are required, especially for high-risk medical equipment and pharmaceuticals[18,30].

3.6 Guidance on Economic Evaluation

3.6.1 General

The aim of the costs and economic evaluation domain within HTA is to inform value-for-money judgements about health technologies with information about costs, health-related outcomes and economic efficiency[19].

Since economic evaluation is one of the mainstays of HTA, this section of the guideline aims to guide applicants on methods, and tools to use while submitting health technologies for economic evaluations as part of HTA process.

3.6.1.1 Value drivers

Value drivers are essential in economic evaluations, fundamentally influencing the outcomes of cost-effectiveness and budget impact analyses. These key factors, such as mortality reduction, disease progression delay, exacerbation reduction, morbidity reduction, and healthcare cost savings, define the value proposition of a health technology. The manufacturer should clearly identify and articulate these drivers when structuring the economic evaluation to effectively capture and compare the benefits of a new health technology against existing practices. This approach facilitates informed decision-making by highlighting the specific advantages and cost efficiencies introduced by the technology.

3.6.1.2 Assumptions

In economic evaluations and economic analysis, such as cost-effectiveness analysis or budget impact analysis, assumptions are a necessary component. It is essential that these assumptions are transparently articulated, detailing their expected influence on the analysis. This includes specifying whether each assumption is likely to be conservative or potentially advantageous to the health technology under scrutiny. This clarity ensures the integrity and interpretability of the evaluation, allowing for a nuanced understanding of how assumptions may bias the outcomes in favor or against the technology being evaluated. Assumptions should be evaluated through sensitivity analysis to assess their impact on the final outcomes.

3.6.1.3 Clinical data and relative health gain

Adoption of clinical or relative health gain data from international sources is permissible, provided that the data choice aligns with global recommendations for evidence-based medicine and systematic literature reviews. Data sources must be explicitly documented, ideally in a tabular layout. If the analysis uses international scientific evidence from routine practice, its transferability should be investigated and presented as part of the analysis. In cases where randomized clinical trials lack sufficient data on hard endpoints, surrogate endpoints may be considered for use in the health technology assessment with clear justification for the use of surrogate endpoints. Furthermore, the quality of studies included should be appraised using tools recommended in the HTA Core Model V3.0 by EUnetHTA, specifically found within the “Clinical Effectiveness (EFF)” domain, under the “Tools for critical appraisals” subsection. HTACoreModel3.0-1.pdf (eunethta.eu)

3.6.1.4 Cost Data

Regarding data sources for cost data, these are typically derived from healthcare resource utilization and associated unit costs. Both components, particularly unit costs, often lack international transferability due to significant geographical and institutional variations. Consequently, it is imperative to gather both sets of data from local sources that accurately reflect the perspective of the entity for which the evaluation is being conducted. The healthcare resources elements can be collected from published literature internationally for guidance in collecting the data locally. However, the unit cost and the frequency of use of the healthcare resources must be collected from local resources. Efforts should be made to ensure that unit costs and healthcare resource utilization data closely reflect the actual expenses borne by the payer.

Various costing methods are available for estimating cost data, including bottom-up, top-down, activity-based costing, etc[20].

3.6.1.5 Managed Entry Agreements

If managed entry agreements (MEAs) are proposed, they must be integrated into the economic model. The model should present both the base case results without the MEA and a separate scenario incorporating the MEA. Details regarding the managed entry agreements policy in Abu Dhabi are discussed elsewhere[12].

3.6.1.6 Software

The preferred format for economic models is Excel, without external links. The Excel model should be compatible with versions from 2016 onward, or Office 365. Other software may be used provided that access is granted for review purposes.

3.6.1.7 Self-validation report

Submissions for HTA should include a preliminary chapter featuring a critical appraisal checklist completed by the submitting organization, ensuring all necessary evaluation components are thoroughly addressed.

3.6.2 Cost effectiveness-analysis

3.6.2.1 Perspective

Primary Perspective: Payer evaluations should primarily consider the financial implications from the publicly funded healthcare payer's viewpoint.

3.6.2.2 Comparator

At least two or more health technologies are compared to each other in a health technology assessment. A comparator is a health technology to which the investigated health technology is compared. It is a crucial part of the assessment to identify the adequate comparator.

In coverage submissions, the comparator is always an authorized and covered health technology. The comparator health technology could also be a different type of technology (e.g., a pharmaceutical product could be compared to a surgical intervention or a medical device). The investigated and comparator health technologies must have the same indication and patient population on which the health technology assessment is conducted. If currently no effective therapy is available or reimbursed in the target indication, best supportive care should be chosen as the comparator. If the investigated health technology is an add-on therapy, the comparator should be the base treatment without the investigated add-on technology.

If several health technologies could potentially be comparators, for the relative effectiveness and cost-effectiveness analyses the routinely used or standard of care covered technology should be chosen which may be replaced by the investigated health technology. Any difference from this should be highlighted and substantiated. For the budget impact calculations, a basket of health technologies could be chosen.

The choice of the comparator is based on national and international clinical practice guidelines and considers the financial circumstances in case of coverage. Usually, the comparator is a health technology which is:

3.6.2.2.1 Authorized in the investigated indication and treatment line.

3.6.2.2.2 Covered in the investigated indication and treatment line.

3.6.2.2.3 Justified by good quality scientific evidence of efficacy, effectiveness and safety published in the international medical scientific literature.

3.6.2.2.4 Validated in the current clinical practice guidelines.

3.6.2.2.5 Routinely used in the daily clinical practice.

It is important to present the characteristics of the comparator health technology and the detailed justification of choice in the health technology assessment.

3.6.2.3 Preferred outcome measures

Quality-Adjusted Life Years (QALYs) are essential, with the inclusion of clinically significant endpoints as applicable.

3.6.2.4 Preferred analytical method

Cost-utility analysis should be the primary analytical method, and cost-effectiveness analysis should be conducted for clinically significant endpoints whenever applicable.

3.6.2.5 Utility Index Value in Cost-Utility Analysis

It is recommended to assess the quality-of-life of patients using standard, validated quality-of-life questionnaires. The choice of disease-specific and non-disease-specific tools relies on the nature of the intervention and the disease. In case the EQ-5D questionnaire is available, use the published national EQ-5D score sets to determine utility scores if applicable. In the absence of a national published set, the validated mapping function to derive utility values for the EQ-5D-5L from the existing EQ-5D (-3L) may be used (available from http://www.euroqol.org).

3.6.2.6 Effectiveness preference

In general, both efficacy and effectiveness are acceptable, real-world evidence should be used as another scenario and only used for the base case scenario if the quality of the data was assessed. (consider also the relevance of the effectiveness data if it is coming from a relevant setting – geographical, health care system (GCC could be considered the most relevant)).

3.6.2.7 Time horizon

When conducting economic evaluations in healthcare, it is crucial to select a time horizon that is sufficiently long to capture all relevant costs and benefits associated with the health technology being assessed. A lifetime horizon is generally recommended, as it allows for a comprehensive evaluation of long-term impacts, particularly for chronic conditions or interventions with lasting effects.

However, in cases where the model relies heavily on extrapolated data—such as with partitioned survival models using Kaplan-Meier (KM) curves—the time horizon must be chosen with caution. While extrapolation is an accepted practice, it should only extend to the point where there is high confidence in the accuracy of the predictions. Beyond this, the uncertainty introduced by continued extrapolation may compromise the validity of the model's outcomes, making it preferable to conclude the model at that stage, even if it results in a shorter time horizon.

The specific point at which to stop extrapolating cannot be rigidly defined in these guidelines, as it depends on factors such as the data quality, the shape of the survival curve, the goodness of fit, and the characteristics of the disease. The modeler must make an informed decision on where to end the model, providing a clear rationale supported by evidence. Transparency in this decision-making

process is essential, and the rationale should be well-documented, citing the data and analyses that support the choice.

Additionally, sensitivity analyses should be conducted to assess the impact of different time horizons on the model's results. This approach ensures that decision-makers are aware of the potential tradeoffs between capturing long-term benefits and maintaining the reliability of the evaluation, allowing for a balanced and informed assessment of the health technology.

3.6.2.8 Modelling method

Choosing a modelling framework for health technology assessment (HTA) requires evaluating different methodologies based on the disease and intervention characteristics detail a taxonomy of decision models, considering dimensions like time, interaction, and heterogeneity[21]. Models range from static, ignoring interaction and time, to dynamic, including time and interactions. The selection hinges on the model's fit to simulate patient outcomes and the intervention's impact accurately. It's about choosing the most suitable model, not the right or wrong one, ensuring it aligns with the intervention's and disease's specifics. The crucial step is justifying the selected model based on these specifics.

3.6.2.9 Cycle length

Defining the cycle length in a model is crucial for capturing the dynamics of disease progression and intervention effects accurately. The cycle length should reflect the natural progression of the condition being modeled and the timing of critical events or decisions. It must be short enough to capture all relevant changes in health states and long enough to ensure the model remains manageable and interpretable. Common practice involves selecting a cycle length that aligns with the frequency of clinical decision-making or the timing of significant health state transitions. The choice of cycle length can significantly impact the model's outcomes and cost-effectiveness results, requiring a balance between precision and practicality in model construction.

3.6.2.10 Discounting

A standard discount rate of 3% applies in the model to both costs and QALYs to account for time preferences as recommended by the WHO[22]. An alternative discount rate of 0% (no discounting) should be applied to examine the impact of discounting on the results[23].

3.6.2.11 Copayments

Evaluations must include the full price of the health technology, incorporating copayments. Alternative scenarios should present the cost excluding copayments for comparative analysis.

3.6.2.12 Cost-effectiveness threshold

CEA results are reported in terms of an incremental cost-effectiveness ratio (ICER), which is defined as the ratio of the change in costs of a therapeutic intervention (compared to the alternative, such as doing nothing or using the best available alternative treatment) to the change in effects of the intervention.

Incremental cost-effectiveness ratio (ICER) = (C1 – C0) / (E1 – E0)

Where C1 is the cost of the health technology; C0 is the cost of the comparator technology; E1 and E0 are the consequences of the health technology and the comparator, respectively.

The change in effects is usually measured in terms of the number of life-years gained or quality-adjusted life years gained by the intervention[24].

Reports on CEA results must provide sufficient information in the public domain to enable independent analysts and policymakers to critically evaluate the validity of the estimates of the costs and effectiveness of the interventions studied. Results on cost-effectiveness ratios should be provided in both numerical and graphical documentation[25].

In a recent initiative by the Emirates Health Economics Society, in collaboration with several key stakeholders, a solid framework for a multiple threshold linked to the country's GDP was proposed.

To align with societal healthcare priorities, the Cost-Effectiveness Threshold (CET) is adjusted using a multiplier system based on three key factors: 1) Disease Severity, 2) the Relative Health Gain from the intervention, and 3) Disease Rarity. This approach modifies the baseline threshold, initially set at 0.75 times the Gross Domestic Product (GDP) per capita, to ensure it resonates with the overarching goals and values of health policy.

3.6.2.12.1 Disease Severity

The impact of disease severity is quantified using the **proportional/relative shortfall** method, with the potential to augment the baseline by a **maximum multiplier of 2X** for the most severe conditions. A continuous approach is used to assign the multiplier (Figure 1).

Proportional Shortfall	Multiplier (2X)
0	1.0
0.25	1.25
0.50	1.5
0.75	1.75
1.00	2

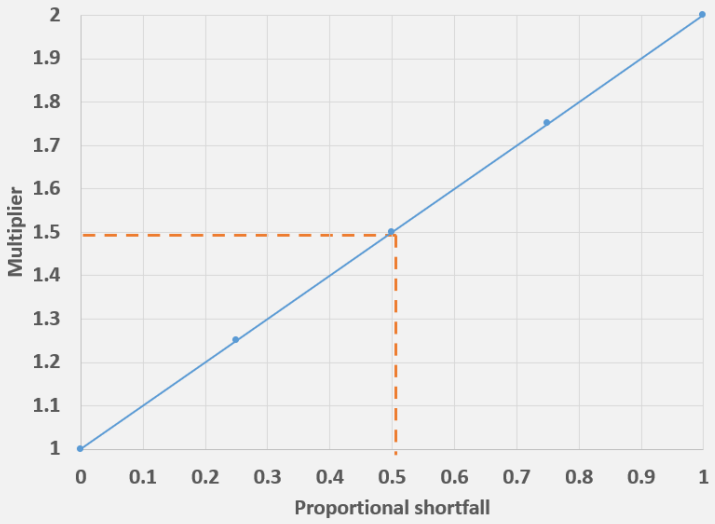

Figure 1 Continuous Multiplier for Relative Shortfall

Proportional shortfall is a measure to quantify disease severity by comparing the remaining health (in terms of quality-adjusted life years, QALYs, or life years) a patient is expected to lose because of a specific disease relative to the total remaining health they would have if they were in perfect health. The formula for proportional shortfall can be expressed as:

$$Proportional\ shortfall = \frac{Disease - related\ QALY\ loss}{Remaining\ QALY\ expectation\ in\ the\ absence\ of\ the\ disease}$$

3.6.2.12.2 Intervention's Relative Health Gain

Evaluated through **incremental relative Quality-Adjusted Life Year (QALY) gain**, interventions that demonstrate a significant QALY gain of 1 receive up to a **2X multiplier** on top of the baseline. (Table 3) A continuous approach is used to assign the multiplier as shown in Figure 2.

Table 3 Continuous Multiplier for Relative Health Gain (IRQG)

Band	Relative Health Gain Multiplier (IRQG)	
Minimal health gain	0.00	1.00 x baseline threshold
Low relative health gain	0.25	1.25 x baseline threshold
Moderate relative health gain	0.50	1.50 x baseline threshold
High relative health gain	0.75	1.75 x baseline threshold
Very high relative health gain	1.00	2.00 x baseline threshold
IRQG= incremental relative QALY gains		

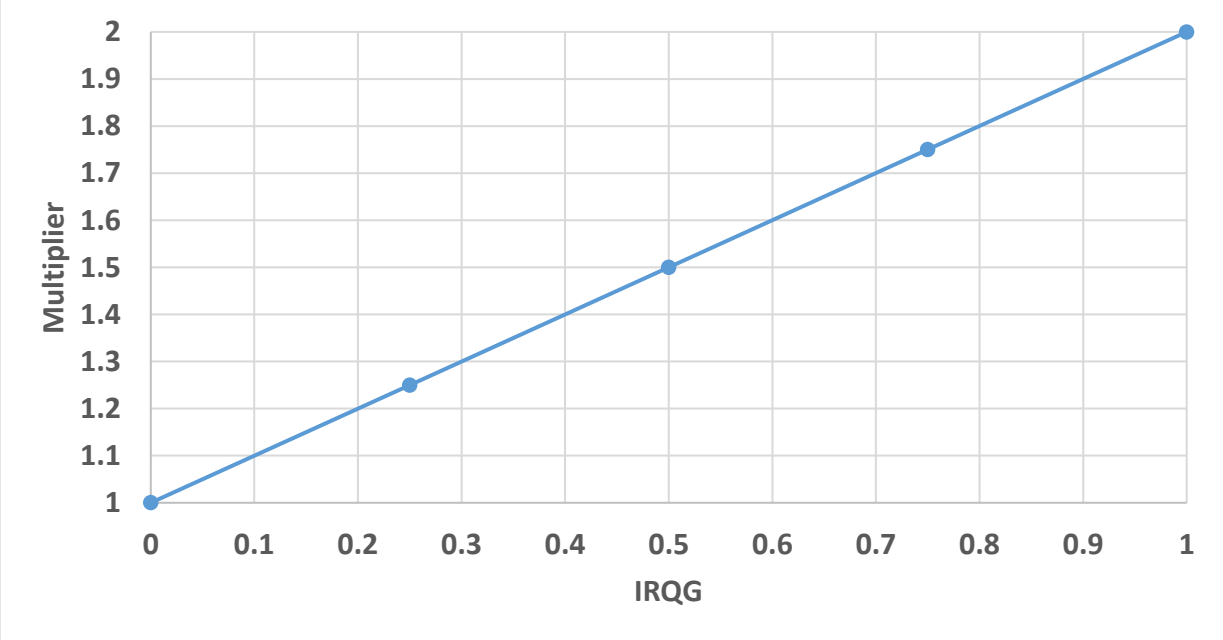

Figure 2 Continuous Multiplier for Relative Health Gain (IRQG)

3.6.2.12.3 Disease Rarity

Diseases classified as rare based on the European Medicines Agency (EMA) or Food and Drug Administration (FDA) definitions are eligible for **a multiplier of 3X** on top of the baseline, reflecting the societal value placed on addressing less common conditions.

For ultra-rare diseases, they will be assessed on a case basis. Finally, the established cost-effectiveness threshold applies uniformly across both public and private healthcare sectors.

The CET is thus calculated using the following formula:

$$CET\ (localcurrency) = 0.75 \times GDP/Capita \times Multiplier$$

Where the multiplier itself is determined by:

$$Multiplier\ =\ (Relative\ Shortfall\ +\ 1)\ \times\ (IRQG\ +\ 1)\ \times\ (is\_rare \times 2 + 1)$$

IRQG: incremental relative QALY gain

3.6.2.13 Reporting Format

For presenting cost-effectiveness analysis findings, adhere to the Consolidated Health Economic Evaluation Reporting Standards (CHEERS) 2022 guidelines. This framework, established by Husereau

et al. provides updated guidance for reporting health economic evaluations, ensuring comprehensive and standardized disclosure of study methodologies and results[26].

All financial outcomes and analyses should be reported in the local currency to ensure clarity and relevance to the intended audience.

3.6.3 Budget Impact Analysis

3.6.3.1 General

Budget Impact Analysis (BIA) provides information about the estimated financial consequences of introducing one or more health technologies to the health system. It reflects an estimated cost for the eligible population over a specified time period, for both the existing context (current mix of treatments or the standard of care) and the new health technology (implementation scenario), as well as the incremental cost between the existing scenario and each implementation scenario. The budget impact analysis will indicate the affordability of the new technology across the health system, where the results of the analysis can be used to aid budgeting and planning following the decision.

The key elements of a BIA include estimating the size of the eligible population, the current mix of treatments and the expected mix after the introduction of the new intervention, the cost of the treatment mixes, and any changes expected in condition-related costs. Where possible, the BIA calculations should be performed by using a simple cost calculator approach because of its ease of use for budget holders[27].

3.6.3.2 Analytic Framework for Impact Analysis

BIA is required along with a CEA, as part of a listing or reimbursement submission. A BIA addresses the expected changes in the expenditure of a health care system after the adoption of a new intervention[27]. (Sullivan et al., 2014) The BIA should be designed, conducted and reported in accordance with the internationally accepted principles of ISPOR[28,27].

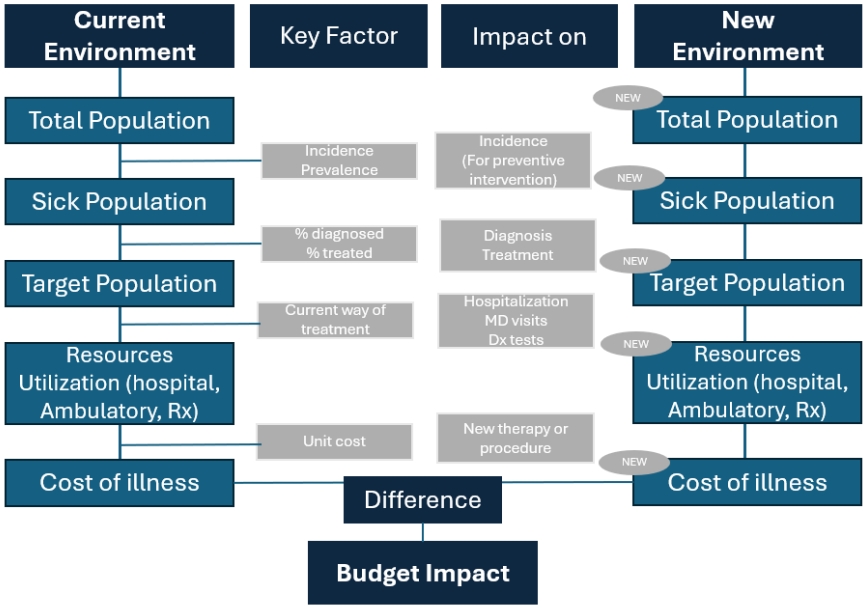

Figure 3 Budget Impact Analysis Framework (adapted from Brosa et al.)

3.6.3.3 Costs Included

Incorporate direct medical costs and, where applicable, direct non-medical costs covered by the budget holder. Cost data may be obtained from publicly available government reports, published local

literature, and existing databases. Cost data may be obtained from publicly available government reports and registries, published local literature, and existing databases. Consult DOH HTA team on the data to be included for further assistance send your queries on the following email HealthSystemFinancing@DoH.gov.ae. **(Appendix 1: INPUT DATA SOURCES)**

3.6.3.4 Comparator

The analysis should compare the expected mix after the introduction of the new health technology against the current mix of treatments or the standard of care if no existing treatment is available.

3.6.3.5 Patient Population

3.6.3.5.1 Inclusion Criteria: Account for all individuals likely to receive the new technology, considering eligibility criteria.

3.6.3.5.2 Diagnosis and Treatment Rates: Analyze the potential impact of the new treatment on diagnosis rates and the proportion of diagnosed patients receiving treatment.

3.6.3.5.3 Treatment Arm Integration: Exclusively include the new intervention in a single treatment arm to clearly assess its impact.

3.6.3.5.4 Market Share Dynamics: In constructing budget impact models, it is imperative to integrate a well-founded projection of the new technology's market penetration. This projection should be grounded in empirical data, ideally mirroring the adoption trajectory of a precedent intervention within the same therapeutic area. In the absence of direct precedents, the adoption pattern of interventions in analogous indications may serve as a reference. Such estimations must be predicated on realistic assumptions about the rate and extent of market uptake, facilitating a more accurate and credible assessment of the technology's financial implications over time. Consider the capacity constraints if applicable.

3.6.3.5.5 It is anticipated that the market adoption of the novel intervention will progressively displace the share held by the most viable existing alternatives. This transition in market share is predicated on the intervention's comparative advantage in efficacy, safety, cost-effectiveness, or other relevant attributes, thereby reshaping the current therapeutic mix towards the new option.

3.6.3.5.6 In the analytical framework, when an alternative intervention is projected to increase its market share concurrently within the study period, it is imperative to incorporate this intervention equitably across both the new scenario and current scenario, not solely in the scenario introducing the new intervention. Neglecting to do so may introduce bias, skewing results to reflect the impact of the competing intervention rather than the one under investigation. This approach ensures a balanced assessment, isolating the effect of the new intervention from market dynamics involving other treatments.

3.6.3.5.7 Persistence and Adherence: Include considerations of treatment persistence and adherence where relevant.

PATIENT COHORT DYNAMICS

Budget impact models are dependent on two main inputs: ***cost per cycle***, usually derived from detailed cost-effectiveness analyses that elucidate patient prognosis, and ***patient numbers***, characterized by a dynamic open cohort that evolves over time. Initially, the model incorporates the eligible population at the starting time point, ascertained from prevalence data and adjusted for eligibility criteria. This population fluctuates dynamically increasing with new patients (due to incidence or existing patients who were not eligible that turned out to be eligible) and decreasing as patients exit the treatment pool due to mortality (which is usually accounted for in the cost data coming from the cost-effectiveness), cure, or due to patients who turned not to be eligible anymore. The meticulous

management of these dynamics is vital for the model's precision and the reliability of its budgetary impact outcomes.

3.6.3.6 Time horizon

A 3-year period is recommended to adequately capture the budget impact.

3.6.3.7 Consistency with Cost-effectiveness Analysis

Ensure the budget impact analysis adheres to the same assumptions and inputs as the cost-effectiveness analysis.

3.6.3.8 Discounting

Discounting should **NOT** be applied for budget impact analyses.

3.6.3.9 Copayments

Do not include co-payments in the health technology cost calculations in the budget impact model.

3.6.3.10 Off label use

Evaluate the potential impact of off-label use on the budget and patient outcomes.

3.6.3.11 Reporting format

3.6.3.11.1 Guidelines: Follow the ISPOR 2012 Budget Impact Analysis Good Practice II Task Force recommendations for a structured and comprehensive report[27].

3.6.3.11.2 Currency: Present all financial results in the local currency to ensure relevance and clarity.

3.6.3.11.3 Impact Presentation: Report both the absolute budget impact and the relative budget impact as a percentage of the current budget, providing a clear picture of the new technology's financial implications.

3.6.3.11.4 Cost Breakdown: A detailed breakdown of the budget impact analysis is mandatory, highlighting specific cost components to understand the allocation and drivers of costs within the budget.

3.6.3.11.5 Healthcare Resources: Reporting on the utilization of healthcare resources associated with the implementation of the new health technology is recommended whenever possible. This includes quantifying changes in resource use directly attributable to the adoption of the technology.

3.6.4 Sensitivity Analysis

The sensitivity analysis, encompassing both Deterministic Sensitivity Analysis (DSA) and Probabilistic Sensitivity Analysis (PSA), along with Scenario Analysis, and subgroup analysis applies equally to Cost-Effectiveness Analysis (CEA) and Budget Impact Analysis (BIA). These analyses are integral components of a comprehensive health economic evaluation, designed to assess and illustrate the robustness and reliability of the outcomes under various conditions of uncertainty. By implementing these analyses, stakeholders can better understand the potential variability in the results, ensuring that decisions made based on CEA and BIA are informed and resilient to changes in key parameters and assumptions. Sensitivity analysis evaluates the influence of key model inputs, value drivers, and assumptions.

3.6.4.1 **Deterministic Sensitivity Analysis (DSA)**

3.6.4.1.1 **Requirement**: Mandatory for all health economic evaluations to account for parameter uncertainty.

3.6.4.1.2 **Parameters to Include**: All model parameters subject to uncertainty should be considered. This includes any parameter where the real value could differ from the

model's mean value. Parameters not subject to uncertainty, such as discount rates, are excluded.

3.6.4.1.3 **Variation Range**: Parameters should be varied by a fixed value of ±10% to assess their impact on the model's outcomes.

3.6.4.1.4 **Preferred Representation**: The results of DSA are best represented through both Tornado Diagrams and Tabular formats. Tornado Diagrams should clearly define upper and lower bounds with color coding, showcasing the top 15 input parameters by their impact magnitude. Tabular representations can supplement this in the main report or appendices for detailed scrutiny.

3.6.4.2 **Probabilistic Sensitivity Analysis (PSA)**

3.6.4.2.1 Distributions used in PSA should be justified and/or evidence-based. Here are proposed distributions based on the input type for guidance: weighted beta or Dirichlet for transition probabilities, Beta for utilities, Log-normal for relative risks, and Gamma for cost parameters. This ensures each parameter is modeled in a manner reflecting its inherent variability.

3.6.4.2.2 **Iterations**: A minimum of 100 iterations is advised for computationally intensive models, though 1000 iterations are preferable for robustness.

3.6.4.2.3 **Standard Errors**: In the absence of specific standard errors, assume standard errors to be 10% of the mean value for each parameter.

3.6.4.2.4 **Preferred Representation**:

3.6.4.2.4.1 **For Cost-effectiveness Analysis**: Utilize Scatter Plots (Cloud Diagrams) and Cost-Effectiveness Acceptability Curves to visualize PSA outcomes, offering insights into the probability of cost-effectiveness at various willingness-to-pay thresholds.

3.6.4.2.4.2 **For Budget Impact Analysis**: Box and Whisker Diagrams are recommended to represent the cumulative incremental budget impact, both in monetary terms and as a percentage of the budget change, providing a clear visual of variability and uncertainty.

3.6.4.3 **Scenario Analysis**

Scenario analysis is essential for examining the impact of major assumptions or combinations of uncertain inputs on the model's outcomes. Scenario analysis allows for the exploration of the effects of alternative plausible scenarios on the evaluation's conclusions, thus providing a broader understanding of potential variability in outcomes.

3.6.4.4 **Sub-group Analysis**

Sub-group analysis is used to evaluate the intervention's effects on specific population segments (e.g., by age, gender, disease severity, etc.). This analysis is crucial for identifying whether the intervention's cost-effectiveness or budget impact varies significantly among different patient groups. Incorporating sub-group analyses as part of sensitivity analysis enables a deeper understanding of how outcomes may change in various population subsets and ensures that health policy decisions consider these variations.

3.7 Submission Process

3.7.1 General

3.7.1.1 Apply through the email for an initial evaluation.

3.7.1.2 The application will be assigned to the responsible team.

3.7.1.3 The responsible team will assess the completeness and correctness of the HTA dossier and communicate with the applicant to finalize this step.

3.7.1.4 After completing the dossier, the new proposed healthcare technology will be performed with the published timeline according to the technology category [Medical Device or Pharmaceutical Products].

3.7.1.5 The opinion will be shared for final revision and decision purposes.

3.7.1.6 Publish the recommendation/advice.

3.7.2 Pharmaceutical Products

For the purpose of this guidance, the detailed process for coverage and reimbursement review will be described hereafter. The pharmaceutical products coverage and reimbursement decisions in Abu Dhabi for publicly funded programs are made by DoH.

This process will be started by a pre-evaluation step "HTA Early Advice". HTA Early advice is advice to the industry on their early pharmaceutical product market access plans from an HTA point of view. The advice helps the industry optimize the time to market for new therapies and is the first step for pre-evaluation before the submission of the Health Technology Reviews and Reimbursement coverage reviews.

Marketing approval holders (MAH), pharmaceutical products agents, healthcare facilities and Government funded initiatives, can submit a pre-evaluation form (Appendix 2) to DoH HTA Taskforce through the e-mail address adhtac@DoH.gov.ae for HTA early advice. This submission, which can precede marketing approval requests to EDE, is reviewed by the multidisciplinary HTA team. Providing the technical report or the economic model in this phase is optional rather than mandatory.

A preliminary decision regarding the necessity of a full HTA (reimbursement coverage review) will be based on this initial review. DoH will notify the manufacturer within 20 working days from submission and completion of all required documents and clarifications, about the need for reimbursement coverage review submission.

Market access provides market entry approval of the new technologies to the Abu Dhabi healthcare ecosystem but does not equate to coverage and full reimbursement of services (to the provider delivering the services). Coverage for government-funded programs is determined by DoH.

During HTA Early Advice, DoH will evaluate the HTA applications using a pre-evaluation form. This can be done **early, before or during** the product marketing approval evaluation by **EDE**. HTA Early Advice will allow DoH to advise the industry on their early pharmaceutical products development plans from an HTA point of view. Upon completion of the HTA Early Advice, the HTA application will be reviewed and decided if the product in question is qualified/ needs a **full HTA** review (Reimbursement coverage review). The early advice will help the industry optimize the time to market for new therapies.

Pharmaceutical products that do not require **full HTA review** (Reimbursement Coverage Review) will be granted access to the Abu Dhabi healthcare ecosystem per the regular DoH pharmaceutical product coding process, where pharmaceutical products are coded and listed on the DoH pharmaceutical products list (Circular 63 05/07/2020 Drug Suppliers of MOHAP registered products New System for Drug Coding). Pharmaceutical Products that qualify for **full HTA review** can be listed and coded on the DoH pharmaceutical products list, however, they will not be authorized for coverage in publicly funded programs until the HTA process is finalized by the DOH (Table 1).

A full HTA Report (Technical Review Report) will be compiled for all pharmaceutical products assessments that undergo full HTA review. The technical review report will contain the medicine/s details, a description of the scope of the assessment, an evaluation of the comparative clinical evidence, a calculation of the acquisition costs of the medicine/s and comparator/s, identification of relevant healthcare costs, a summary of decisions made by other HTA agencies (if available), as well as a description of equity considerations.

3.7.3 Medical Equipment

Manufacturers with UAE distributors, authorized UAE distributors and healthcare providers are required to submit an application for new technology by filling out the submission form and providing all the listed application requirements for the new health technology & therapeutic practices (Appendix 3: submission form & Appendix 3: list of requirements). Through the e-mail: ADHTAC@DoH.gov.ae.

The Health Technology assessment process for new medical equipment involves two steps:

3.7.3.1 Efficacy, safety and information security evaluation: As a pre-requisite all submissions need to be reviewed and evaluated by DoH in cooperation with strategic partners and technical experts in the health sector to ensure patients' safety and efficacy. Technology approval needs to be issued after successful evaluation (Circular No 31 / 2021 Mandatory DoH Approval for New Health Technologies and New Therapeutic Practice).

3.7.3.2 Coverage and reimbursement: For the medical equipment approved for market entry (access), the economic evaluation of health technology assessment is made for reimbursement decisions. The recommendations for reimbursement are based on cost-effectiveness and budget impact analysis as well as on therapeutic added value compared to existing alternatives. Subject Matter Expert (SME) and multidisciplinary team feedback is requested from other sectors on therapeutic added value.

Submission for new / innovative medical equipment that either modify the existing standard of care or meet an unmet need and are intended for inclusion in a government-funded program for coverage and reimbursement of healthcare services is done by the provider through the Daman portal online and evaluated through the Empanelment process.

3.7.4 Who can initiate the evaluation request?

The **evaluation request is initiated** by healthcare facilities, manufacturers, pharmaceutical product agents or even by the DoH, for example in cases of re-evaluation of therapeutic classes of certain health technologies.

The submission of the application and the preparation of the HTA dossier are the responsibilities of the manufacturer who owns the pharmaceutical product, MAH, or provider. For medical equipment the submissions for clinical domains of assessment for market entry (access) purposes are the responsibility of the manufacturers with UAE distributors, authorized UAE distributors or healthcare providers. The applicant has the right to hire a third-party company to work and submit the HTA dossier or the effectiveness/budget impact models, still, the applicant will be liable for the correctness of the information provided.

The HTA process is initiated by the DoH and/or payers where evidence in the HTA dossier should be provided by the applicant. In case the MAH is not available, the applicant should be responsible for providing the evidence.

For funding the generation of data, research, and analytics, the MAH will be responsible in case of a product (pharmaceutical product or medical device) while others (the provider raising the request) in case of intervention or class review.

The opinion of DoH is issued by pharmaceutical products and not by molecule, especially for the high-budget impact pharmaceutical products. The evaluation is made indication by indication. Some information may be eligible for reimbursement and others may not be based upon the submitted data.

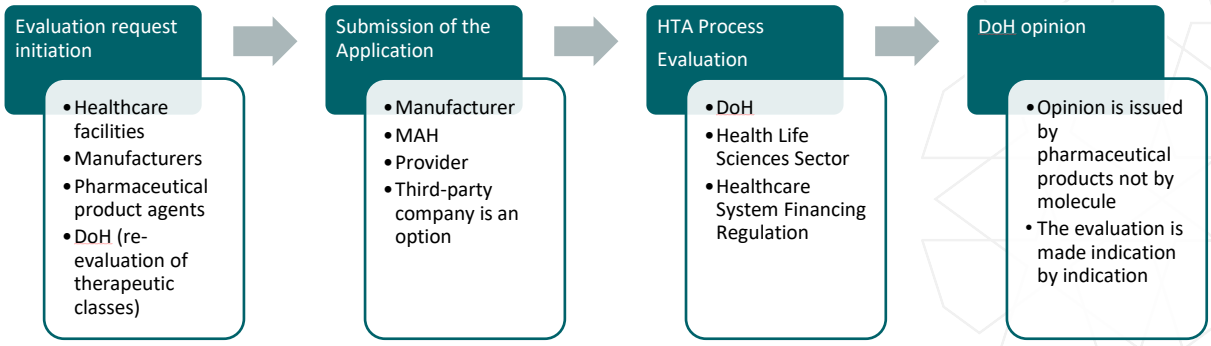

Figure 4 Submission process

3.7.5 Expedited Access Evaluation

"Expedited access" is a newly launched pathway that allows patients at a therapeutic impasse to benefit, on an **exceptional** and **temporary** basis, from certain pharmaceutical products that are specially authorized in a specific therapeutic indication. These pharmaceutical products usually have a high level of uncertainty regarding their provided data but have shown promising results through clinical trials. In such cases, they are approved on a **temporary basis** while collecting real-world data to reassess the provided technology again once deemed necessary.

DoH could evaluate the pharmaceutical products in the context of **"expedited access"**. It is an exceptional derogation procedure that allows the availability and early coverage of one or more indications for certain medicines when very specific conditions are met. The manufacturer can apply for expedited access evaluation if the following conditions are met:

3.7.5.1.1 The pharmaceutical product should be intended to treat serious, rare, or disabling diseases.

3.7.5.1.2 There is no appropriate alternate treatment available.

3.7.5.1.3 The implementation of the processing cannot be postponed (urgency or emergency of the technology).

3.7.5.1.4 The pharmaceutical product is presumed to be innovative, in particular regarding a possible clinically relevant comparator.

3.7.5.2 Expedited access evaluation applies to:

3.7.5.2.1 Pharmaceutical products that have a Marketing Authorization (MA) from a reference regulatory authority but not yet fully approved in UAE in the indication in question but which have not yet been reimbursed by the Health Insurance.

3.7.5.2.2 Pharmaceutical products that have a special MA in the indication in question for special patients to meet their needs which could not be met by other available treatments. In this case, the DoH gives its assent on its efficacy and safety in view of the results of therapeutic trials.

Criteria for accepted trials include updated data from the Phase III trial. Other study designs, such as real-world evidence to address additional evidence gaps, may be considered on a case-by-case basis; however, this evidence must complement**, not replace,** the Phase III trial data.

Note: Health Technologies still under pivotal trial clinical studies are out of the scope of early access.

The submission for **expedited access evaluation** must provide a cover letter with the subject [Expedited Access Evaluation Request]* Appendix-1 to HTA email ADHTAC@DoH.gov.ae as a separate attachment beside attaching the pharmaceutical product dossier.

3.7.5.3 **For expedite access pre-appointments, please follow the following key points:**

3.7.5.3.1 For applications for pre-marketing approval for expedited access, DoH offers appointments for manufacturers who wish to do so before the application is submitted which is done through an appointment request template via the same email.

3.7.5.3.2 These appointments are free, confidential, and not mandatory. They are strongly encouraged to discuss the eligibility of the application regarding the criteria for expedited access, the content of the application to be submitted, the filing schedule and the type of data to be collected in the therapeutic use.

3.7.5.3.3 The pre-submission appointment should be made within one month before the planned date of submission of the expedited access request.

3.8 Appraisal Process

3.8.1 Methods of Appraisal

In HTA, model validation is a crucial process to ensure that the models used in decision-making accurately reflect real-world scenarios. The methods of validation can be classified into three main categories: input validation, computational validation, and external validation. Each of these plays a distinct role in the validation process and requires specific steps to ensure the reliability and accuracy of the model outcomes.

3.8.1.1 **Input Validation:** The validation of inputs ensures that the data driving the model is accurate and comes from reliable sources, forming a solid foundation for further model analysis. This process involves several steps:

3.8.1.1.1 **Source Verification**: The accuracy of the data is checked by verifying that values were copied correctly from their source, and if calculations were used to derive input values, those calculations must also be validated.

3.8.1.1.2 **Reliability of Data Sources:** It is essential to ensure that the data sources are consistent with the majority of literature and considered reliable.

A standardized table recording input details such as input name, value, and source is essential

3.8.1.2 **Computational Validation**

Computational validation aims to verify the correctness of the model's calculations and whether they align with the model design and assumptions. Key methods include:

3.8.1.2.1 **Extreme Value Testing:** This involves testing the model's behavior under extreme conditions to ensure that calculations remain stable and accurate.

3.8.1.2.2 **Equation Tracing:** Tracing calculations backwards from the output to the input parameters can reveal both computational mistakes and logical errors in assumptions.

3.8.1.2.3 **Mathematical Integrity and Transition Probabilities:** Validating that formulas correctly reflect the intended model logic and ensuring that transition probabilities are properly adjusted to fit the cycle length of the model.

3.8.1.3 External Validation

External validation compares the model's outputs to real-world data from clinical trials or observational studies to determine how closely the model mimics real-world scenarios. This process involves:

3.8.1.3.1 Adjusting the Model to Match Real-World Settings: The model must be slightly modified to reflect the patient characteristics and settings of the real-world study. The results generated by the model are compared with the actual data. While the model is not expected to produce an exact replica of real-world results, significant discrepancies should be investigated.

3.8.1.3.2 Tracing Discrepancies: If discrepancies arise, a backward tracing of values is conducted to identify potential sources of error, which are then adjusted and tested again**.**

3.8.1.3.3 Revalidation: If necessary, the model can be revalidated using another dataset to ensure consistency and reliability.

External validation confirms that the model can accurately simulate real-world scenarios and helps identify any major issues in model design, input assumptions, or calculations.

3.8.2 Appraisal Recommendations

DoH issues an opinion on the proposed healthcare technology regarding its medical care providing categories [high, moderate, low or insufficient]. A “high” recommendation indicates that the drug should be reimbursed. “Moderate” recommendation implies reimbursement with conditions such as limited-time reimbursement followed by a future re-assessment, or reimbursement subjected to risk-sharing agreements (RSA). A “low/insufficient” recommendation suggests that the pharmaceutical product should not be reimbursed. This assessment is based on medical data: severity of the pathology treated, disease burden, effectiveness of the pharmaceutical product, its adverse effects and its place in the patient pathway.

In case the decision regarding a health technology involves high uncertainty the DoH may request that additional studies be carried out, known as **post-approval studies**. These are most often "real-life" studies/data, i.e. studies/data carried out/collected as part of the patient's usual management to describe the use of the pharmaceutical product in routine practice and to evaluate its clinical benefit and adverse effects after marketing. The data collected from these studies can influence future decisions and affect reimbursement criteria.

3.9 Notification of outcome

DoH will send a Notification of Outcome (Technical Review Report) to the company to advise them of the HTA’s recommendation. Companies that receive a negative recommendation can schedule a post-decision meeting with the DoH (via teleconference or in-person) to discuss the DoH’s reasons for the decision and any revised pricing proposals or evidence that the company would like to consider addressing the key uncertainties in the evidence base. All decisions will be published on the DOH website along with a short recommendation report. Companies that receive conditional approval (moderate recommendation) will enter negotiations with the Department of Health, with the possibility of implementing a risk-sharing or managed entry agreement. Various types of managed entry agreements are accepted, whether financial or outcome based.(Department of Health, 2023b)

3.10 Resubmission following a negative recommendation

During the post-decision meeting, DoH will advise the company about the type of additional information required to address the DoH concerns that led to the negative recommendation. For technologies not recommended based on uncertain or unacceptable cost-effectiveness or budget impact, the company may register their intent to resubmit a revised price proposal for Abu Dhabi Health Technology Assessment Committee (ADHTAC) consideration.

Uncertain or unacceptable cost-effectiveness or budget impact refers to:

3.10.1 incremental cost-effectiveness ratio exceeding the threshold value

3.10.2 budget impact exceeding 0.5% - 1% of the total healthcare budget

If a negative recommendation is issued, the company has 15 working days from the issuance date to submit an appeal. If accepted, the appeal process typically takes around 8-10 weeks from the submission date to reach a final decision.

3.11 Coverage (Reimbursement) effective date

Funding implementation (i.e. listing on Shafafiya) technology list is updated bimonthly, for DoH-approved technologies the funding implementation starts once the technology coverage condition is updated in Shafafiya.

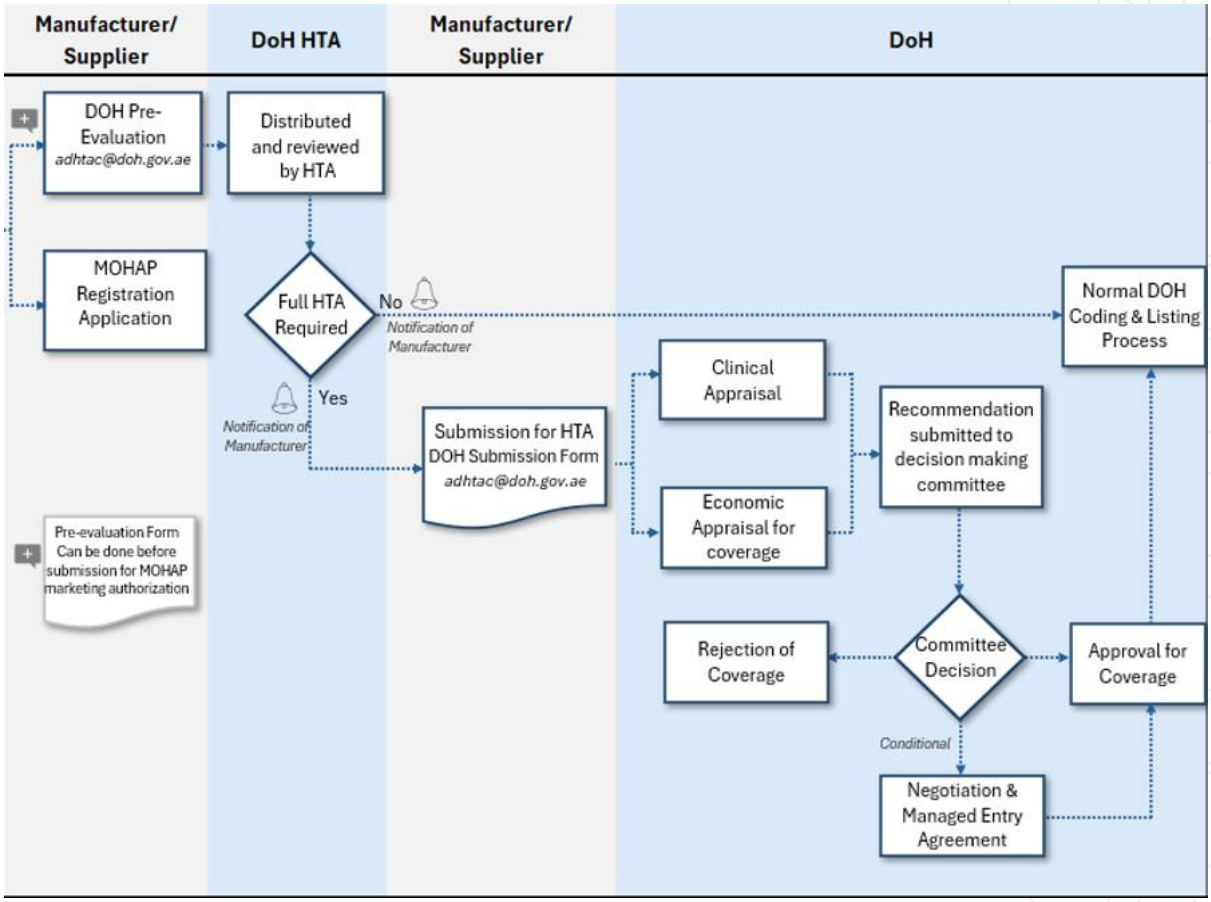

Figure 5 DoH Health Technology Assessment Process – Pharmaceutical Products

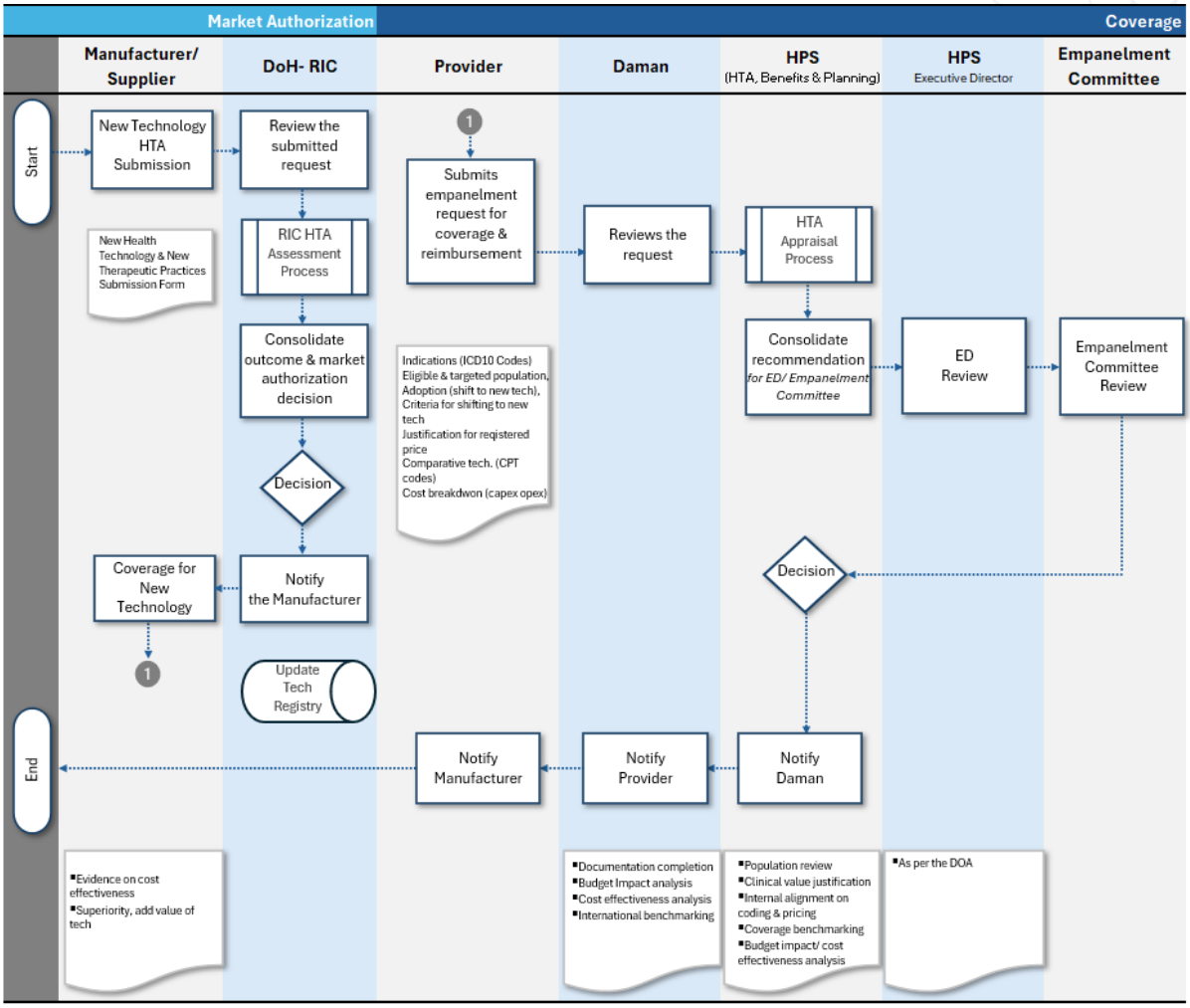

Figure 6 DoH Health Technology Assessment Process – Medical Equipment

3.12 Transparency

3.12.1 HTA dossier

Ensuring transparency regarding the scientific evidence related to investigational health technology is essential to educate the public, particularly clinicians, patients, and researchers who are not directly engaged in the HTA process but will be impacted by the introduction of new technologies.

To achieve this, the following details contained in the HTA dossier should be made public:

3.12.1.1 The HTA submission should be prepared in two documents for dissemination.

3.12.1.2 The "Full Version" should be accessible exclusively to experts and decision-makers involved in critical appraisal, pricing, and reimbursement processes.

3.12.1.3 The "Published Version" of the HTA dossier should be made available to the wider public, with potentially confidential information concealed by the submitting organization (e.g., pharmaceutical or consulting company).

The below details of the HTA dossier should be published (Table 4).

Table 4 Details of the HTA dossier to be published

HTA dossier chapters	Publication of details
1. Clinical assessment	
a. Epidemiology of the target indication (incidence, prevalence)	Mandatory
b. Current patient pathways with highlights on unmet medical need	Mandatory
c. Efficacy and safety of the new technology	Mandatory
d. Efficacy and safety of the comparator technology	Mandatory
2. Cost-effectiveness analysis	
a. Methodology of calculating the health gain by the new technology	Mandatory
b. Estimated health gain	Mandatory
c. Methodology of cost calculations	Mandatory
d. Estimated current resource use and treatment costs of patients	Mandatory
e. The proposed price of the new technology	Mandatory
f. Estimated resource use and treatment costs of patients with the new technology	Mandatory
g. Economic modelling methodology (model type, time horizon, discount rate, etc.)	Mandatory
h. Cost-effectiveness results (incr. health gain, costs and cost-effectiveness ratio)	Mandatory
i. Sensitivity analysis results for the cost-effectiveness analysis	Mandatory
3. Budget Impact Analysis	Mandatory
a. Methodology of budget impact calculations	Mandatory
b. Current treatment mix of patients	Mandatory
c. Estimated patient numbers and market share of new technology in the next 3-5 years	Mandatory
d. Budget impact of the new technology	Mandatory
4. Burden of disease	
a. Publishing results for the clinical burden of the disease	Recommended
b. Publishing results for the economic burden of the disease	Recommended
c. Publishing results for the humanistic burden of the disease	Recommended
5. International reference	
a. Summary of international disease treatment guidelines	Mandatory
b. Summary of reimbursement decisions of international agency	Mandatory
6. CMC, cGMP and supply chain certificates for early access evaluation of AMTPs	Mandatory

The applicant must provide justification for not submitting any mandatory data.

3.12.2 HTA Appraisal Report

The Department of Health (DoH) will publish the technical appraisal HTA report alongside its official recommendation to promote transparency throughout the HTA process. However, for managed entry agreements, any confidential information will be omitted from the published HTA report.

3.13 Detailed timelines for the HTA Process

Timelines are designed to enhance transparency and ensure timely patient access to new health technologies. The following table represents the detailed timelines for the HTA process performed by the DoH (Table 5).

Table 5 HTA Process Timelines

<table>
<tr><th>HTA pathway</th><th colspan="4">Timeline</th></tr>
<tr><td></td><td colspan="2">Pharmaceutical Products</td><td colspan="2">Medical Equipment</td></tr>
<tr><td></td><td>Expedited Access Evaluation</td><td>Full HTA</td><td>Equipment Diagnostic tests Procedures</td><td>Digital and AI Products</td></tr>
<tr><td>Pre-evaluation submission</td><td colspan="4" rowspan="3">5 working days</td></tr>
<tr><td>Review of the pre-evaluation submission (HTA early advice)</td></tr>
<tr><td>Notification of submitter on HTA requirement</td></tr>
<tr><td>HTA Submission</td><td colspan="4" rowspan="3">Depends on completeness of submission</td></tr>
<tr><td>Technical Engagement meeting</td></tr>
<tr><td>Acceptance of submission</td></tr>
<tr><td>Clinical and economic appraisal</td><td rowspan="3">30 working days</td><td rowspan="3">60 working days</td><td rowspan="3">60 working days</td><td rowspan="3">60 working days</td></tr>
<tr><td>Initial Recommendation</td></tr>
<tr><td>Final Appraisal Report</td></tr>
</table>

Depending on the volume or complexity of the material to be reviewed, an extension of the review time frame deadlines may be required. The applicant will be notified of any extensions, as well as the reasons for the extensions. The assessment timeline starts after receiving full information, and only covers the total review time of DoH, the timer will be paused for additional information requests that the applicant could be requested to provide.

3.14 HTA guidelines development process and stakeholder consultation

Broad HTA stakeholder consultation has been instrumental towards the establishment of a comprehensive HTA framework in Abu Dhabi, and the development of a roadmap.

A series of activities were undertaken that informed the subsequent development of the roadmap. They comprised a situation analysis using a combination of desk research and semi-structured (group) interviews with stakeholders. The findings were discussed in two workshops, face-to-face with non-industry stakeholders from Abu Dhabi, and online with industry representatives.

The adoption and Development of an evidence-informed deliberative processes (EDPs) framework that would guide reimbursement and possible disinvestment decisions, using HTA was explored. Guided by the EDP framework, the roadmap provides instructions on how to organize stakeholder involvement, how to identify and operationalize decision criteria, and how to ensure that the decision-making process is transparent, a five-year plan was proposed. Specific guidance is given on establishing an HTA structure with an appropriate policy framework, the formulation of an HTA program, a communication strategy, as well as building and leveraging HTA expertise.

The five-year road map put emphasis on the development of general principles that support standards of transparency, good governance and credible, evidence-informed decision-making.

The roadmap further foresees formulation of an HTA program, especially the development of methodological HTA guidelines for the conduct of HTA.

For the development of methodological guidelines, a workshop was held with the involvement of relevant stakeholders. As an outcome of the workshop the guidelines started to be drafted. As part of the process, international guidelines were reviewed through desktop research, the guidelines were finalized with DOH internal and external stakeholder feedback.

4. Relevant Reference Documents			
No	**Date**	**Reference Name**	**Publication Links**
1	2021	Bertram, M., Dhaene, G., Tan-Torres Edejer, T. & Organization, W. H. 2021a. Institutionalizing health technology assessment mechanisms: a how to guide.	https://iris.who.int/handle/10665/340722
2	2020	O'rourke, B., Oortwijn, W. & Schuller, T. 2020. The new definition of health technology assessment: A milestone in international collaboration. *International journal of technology assessment in health care,* 36**,** 187-190.	https://pubmed.ncbi.nlm.nih.gov/32398176/
3		The International Network of Agencies for Health Technology Assessment (Inahta). "*HTA: Multidisciplinary Policy Research for Achieving Best Value in Healthcare*". (Accessed July 2024].	https://www.inahta.org/#:~:text=HTA%20is%20a%20multidisciplinary%20process,different%20points%20in%20its%20lifecycle.
4	2022	Fontrier, A.-M., Visintin, E. & Kanavos, P. 2022. Similarities and differences in health technology assessment systems and implications for coverage decisions: evidence from 32 countries. *PharmacoEconomics-Open***,** 1-14.	https://pubmed.ncbi.nlm.nih.gov/34845671/
5	2013	Haderi, T. W. a. E. F. a. A. (2013) "*A comparative analysis of therole and impact of HealthTechnology Assessment: 2013. Charles River Associates*": Charles River Associates. (Accessed 2023 25 September].	https://www.efpia.eu/media/25706/a-comparative-analysis-of-the-role-and-impact-of-health-technology-assessment-2013.pdf
6	2015	Organization, W. H. 2015. Factors conducive to the development of health technology assessment in Asia: impacts and policy options.	https://iris.who.int/handle/10665/208261
7	2023	Mbau, R., Vassall, A., Gilson, L. & Barasa, E. 2023. Factors influencing institutionalization of health technology assessment in Kenya. *BMC health services research,* 23**,** 681.	https://bmchealthservres.biomedcentral.com/articles/10.1186/s12913-023-09673-4
8	2015	World Health Organization. (2015) "*2015 Global Survey on Health Technology Assessment by National Authorities*".	https://iris.who.int/bitstream/handle/10665/375063/9789241509749-eng.pdf?sequence=1
9	2015	Eunethta. (2015) "*Methodology Guidelines*". (Accessed 21 October 2023].	https://www.eunethta.eu/methodology-guidelines/

10	2007	Inahta. (2007) "*A checklist for health technology assessment reports*".	https://www.inahta.org/hta-tools-resources/briefs/
11		Hta Glossary. (Accessed 25 October 2024].	https://htaglossary.net/List-all-terms
12	2023	Department of Health. (2023b) "*POLICY of Establishing Managed Entry Agreements / Risk Sharing Agreements in the Emirate of Abu Dhabi*".	https://www.DoH.gov.ae/-/media/25A9111BDD3A49E3929D37CB4302A00C.ashx
13		Global Burden of Disease. "*GHDx*". (Accessed 24 October 2024].	https://vizhub.healthdata.org/gbd-results/
14	2020	Alba, S., Verdonck, K., Lenglet, A., Rumisha, S. F., Wienia, M., Teunissen, I., Straetemans, M., Mendoza, W., Jeannetot, D. & Weibel, D. 2020. Bridging research integrity and global health epidemiology (BRIDGE) statement: guidelines for good epidemiological practice. *BMJ Global Health,* 5**,** e003236.	https://pubmed.ncbi.nlm.nih.gov/33115859/
15	2023	Department of Health. (2023a) "*Guidelines for Standard Treatment Guidelines*". (Accessed 23 October 2024].	https://www.DoH.gov.ae/en/resources/guidelines
16	2018	Murad, M. H., Sultan, S., Haffar, S. & Bazerbachi, F. 2018. Methodological quality and synthesis of case series and case reports. *BMJ evidence-based medicine*.	https://pubmed.ncbi.nlm.nih.gov/29420178/
17	2019	Iso. (2019) "*Medical devices — Application of risk management to medical devices".*(Accessed 23 October 2024]	https://www.iso.org/standard/72704.html
18	2024	European Medicines Agency. "*Post-authorisation safety studies (PASS)*". (Accessed 23 October 2024].	https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/pharmacovigilance-post-authorisation/post-authorisation-safety-studies-pass
19	2016	Eunethta. (2016) "*EUnetHTA JA2 WP8 DELIVERABLE*". (Accessed 10 June 2024].	https://www.eunethta.eu/wp-content/uploads/2018/01/HTACoreModel3.0.pdf
20	2020	Špacírová, Z., Epstein, D., García-Mochón, L., Rovira, J., Olry De Labry Lima, A. & Espín, J. 2020. A general framework for classifying costing methods for economic evaluation of health care. *The European Journal of Health Economics,* 21**,** 529-542.	https://pubmed.ncbi.nlm.nih.gov/31960181/
21	2006	Brennan, A., Chick, S. E. & Davies, R. 2006. A taxonomy of model structures for economic evaluation of health technologies. *Health economics,* 15**,** 1295-1310.	https://pubmed.ncbi.nlm.nih.gov/16941543/

22	2021	Bertram, M. Y., Lauer, J. A., Stenberg, K. & Edejer, T. T. T. 2021b. Methods for the economic evaluation of health care interventions for priority setting in the health system: an update from WHO CHOICE. *International Journal of Health Policy and Management,* 10**,** 673.	https://pubmed.ncbi.nlm.nih.gov/33619929/
23	2018	Attema, A. E., Brouwer, W. B. & Claxton, K. 2018. Discounting in economic evaluations. *Pharmacoeconomics,* 36**,** 745-758.	https://pubmed.ncbi.nlm.nih.gov/29779120/
24	2010	Generics and Biosimilars Initiative. (2010) "*What is the incremental cost-effectiveness ratio (ICER)?*". (Accessed 05 March 2024].	https://www.gabionline.net/generics/general/What-is-the-incremental-cost-effectiveness-ratio-ICER
25	2003	World Health Organization. (2003) "*WHO GUIDE TO COST-EFFECTIVENESS ANALYSIS*". (Accessed 10 June 2024].	https://iris.who.int/bitstream/10665/42699/1/9241546018.pdf
26	2022	Husereau, D., Drummond, M., Augustovski, F., De Bekker-Grob, E., Briggs, A. H., Carswell, C., Caulley, L., Chaiyakunapruk, N., Greenberg, D. & Loder, E. 2022. Correction to: consolidated health economic evaluation reporting standards 2022 (CHEERS 2022) statement: updated reporting guidance for health economic evaluations. *Applied Health Economics and Health Policy,* 20**,** 781.	https://pubmed.ncbi.nlm.nih.gov/35031096/
27	2012	Sullivan, S. D., Mauskopf, J. A., Augustovski, F., Caro, J. J., Lee, K. M., Minchin, M., Orlewska, E., Penna, P., Barrios, J.-M. R. & Shau, W.-Y. 2014. Budget impact analysis—principles of good practice: report of the ISPOR 2012 Budget Impact Analysis Good Practice II Task Force. *Value in health,* 17**,** 5-14.	https://www.ispor.org/heor-resources/good-practices/article/principles-of-good-practice-for-budget-impact-analysis-ii#:~:text=Sullivan%20SD%2C%20Mauskopf%20JA%2C%20Augustovski%20F%2C%20et%20al.,%E2%80%93%20Budget%20Impact%20Analysis.%20Value%20Health.%202014%3B17%20%281%29%3A5-14.
28	2007	Mauskopf, J. A., Sullivan, S. D., Annemans, L., Caro, J., Mullins, C. D., Nuijten, M., Orlewska, E., Watkins, J. & Trueman, P. 2007. Principles of good practice for budget impact analysis: report of the ISPOR Task Force on good research practices—budget impact analysis. *Value in health,* 10**,** 336-347.	https://pubmed.ncbi.nlm.nih.gov/17888098/
29	2005	Brosa, M., Gisbert, R., Rodríguez, J. & Soto, J. 2005. Principios, métodos y aplicaciones del análisis del impacto presupuestario en el sector sanitario. *Pharmacoeconomics-Spanish research articles,* 2**,** 65-78.	https://www.researchgate.net/publication/257288382_Principios_metodos_y_aplicaciones_del_analisis_del_impacto_presupuestario_en_el_sector_sanitario
30	2024	Food and Drug Administration 2024. Best Practices for FDA Staff in the Postmarketing Safety Surveillance of Human Drug and Biological Products	https://www.fda.gov/media/130216/download?attachment

4.1 Appendices

4.1.1 Appendix 1: Input Data Sources

Table 6 INPUT DATA SOURCES

Input Data Sources				
No.	**Input Data**	**Value**	**Source**	**Relation Explanation / Coding / Publication Links**
1	Cost of pharmaceutical products	multiple	Use the DoH pharmaceutical products list	https://www.DoH.gov.ae/en/resources/drug-search-page
2	Cost of hospitalization		Collect from external sources	
3	Cost of diagnostic procedures	multiple	Collect from external sources	
4	Costs associated with adverse events	multiple	Collect from external sources	
5	Resource utilization	multiple		
6	Currency exchange rates	multiple	Central Bank AE	https://www.centralbank.ae/en/forex-eibor/exchange-rates/
7	Discount rate	multiple	Central Bank AE	https://www.centralbank.ae/en/forex-
8	GDP data		Ministry of finance	Home Page - Department of Finance (abudhabi.ae)
9	Mortality data	full table	SCAD	https://scad.gov.ae https://www.who.int/data/gho/data/themes/mortality-and-global-health-estimates
10	Incidence and prevalence	multiple	ADPHC, SCAD	https://www.adphc.gov.ae https://www.scad.gov.ae https://data.who.int/countries/784
11	Utility data	multiple	Cost-Effectiveness Analysis (CEA) Registry	https://cevr.tuftsmedicalcenter.org/databases/cea-registry
12	Risk data (baseline risk, ARR, RRR, etc.)	multiple	Clinical Studies	

International Data Warehouses

- **Center for the Evaluation of Value and Risk in Health - Cost-Effectiveness Analysis (CEA) Registry** https://cevr.tuftsmedicalcenter.org/databases/cea-registry
- Singapore Management University (SMU) https://researchguides.smu.edu.sg/c.php?g=422056&p=2881212
- University of York Centre for Reviews and Dissemination (CRD) https://www.crd.york.ac.uk/CRDWeb/ (no updates after March 31, 2018)
- World Health Organization (WHO) Europe https://dw.euro.who.int/
- Pediatric Economic Database Evaluation (PEDE) http://pede.ccb.sickkids.ca/pede/index.jsp
- Oxford University Health Economics Research Centre (HERC) (UK) https://www.herc.ox.ac.uk/downloads/health_datasets

International Databases

- **WHO Global Estimates** https://www.who.int/data/gho/data/themes/mortality-and-global-health-estimates
- World Bank HealthStats https://datatopics.worldbank.org/health/health
- healthdata.org Global Burden of Disease Study (GBD) https://vizhub.healthdata.org/gbd-compare/
- Healthcare Cost and Utilization Project (HCUP) (USA) https://hcupnet.ahrq.gov/#setup
- Canadian Institute for Health Information (CIHI) (Canada) https://www.cihi.ca/en/canadian-patient-cost-database-metadata

GBD results tool Presents Global Burden of Disease Study 2019 (GBD 2019) data http://ghdx.healthdata.org/gbd-results-tool

Local Data Sources

- **UAE Central Bank** CBUAE | Exchange Rates (centralbank.ae)
- **SCAD** https://www.scad.gov.ae
- **ADPHC** https://www.adphc.gov.ae
- **DoH** https://DoH.gov.ae

4.1.2 Appendix 2: Pre-evaluation form

- **Fill in general information about the innovative medical technology/ pharmaceutical product/ medical equipment:**

Manufacturer	
Trade name	
Generic name	
Distributor (Local UAE representative)	
Dosage form	
Doses Available	
Dose frequency	
Administration route	
Length of a course of treatment	
Inpatient or outpatient setting	
FDA indication/s	
EDA Registration date	
Disease burden for indication/s	
Unmet medical need	
Comparative efficacy compared to the current standard of care	
Proposed treatment cost per unit	
Annual Cost of a course of treatment/patient	
Estimated number of target population in public sector (mention your source)	
Target market share	
Current standard of care / suggested comparators	
Suggested position in treatment protocol (e.g. first line, second line, etc.)	

- **Mark the available documents attached to the Pre-Submission template:**

☐ Signed Information Reliability Consent
☐ EDE / MPHAP Market Approval Documents / Proof that the pharmaceutical product is in the Market Approval process
☐ Economic Evaluation Model (Optional)
☐ Technical Report (Optional)
☐ Clinical Evidence Documents ex:(Clinical trials, Systematic literature review, Meta Analysis)
☐ Target population and market share calculation and supporting references

4.1.3 Appendix 3: Submission form

Health technology assessment (HTA) refers to the systematic evaluation of properties, effects, and/or impacts of health technology. It is a multidisciplinary process to evaluate the social, economic, organisational, ethical and compliance issues of a health intervention or health technology. The main purpose of conducting an assessment is to inform a policy decision making (WHO, 2017).

New health Technology and New therapeutic practices "include all but not limited to new emerging products, medical equipment, surgical procedures and therapeutic practices". The main goal of HTA is to provide decision makers with evidence-based information on all policy alternatives. Taking into consideration all the clinical (safety, efficacy, effectiveness), economical and societal outcome of healthcare policy.

Kindly, fill in all the requested information given below. This is a mandatory step in order to proceed further. Failure to provide information will result in a delay in the processing of the applicant request. Please give us adequate time for the review process. In case further information is required, the provider will be contacted.

A maximum of two product applications are accepted per month per applicant.

All documents should be submitted together electronically via e-mail to (ADHTAC@DoH.gov.ae)

Please submit your application according to the DoH Guidelines.

The submission consists of the following sections:

1. Clinical Evaluation
    a. General Information
    b. Brief Description of the Technology
    c. Clinical Indications and Targeted Population
    d. Clinical Effectiveness
    e. Safety – Risk and adverse events
2. Economic Evaluation
    a. Cost of Technology / therapy
    b. Economic Evaluation
    c. Additional Information
    d. Information Security Compliance and Data Privacy

A. General Information:	
Requester Name	**English:**
	Arabic:
Requester Position	**English:**
	Arabic:
Company Name	**English:**
	Arabic:
Company Address:	
Contact Number:	**Email:**
Pharmacovigilance Focal Point Name for Medical device reporting*:	
Contact Number:	**Email:**
Type of Request: ☐ Evaluation of a new health technology. ☐ Evaluation of a new therapeutic practices.	

* Medical Device Reporting

Manufacturers, importers, agents, distributors or any other person who is responsible for placing the device on the market are required to report to DOH Pharmacovigilance Program (PVE@DoH.gov.ae) when they learn that any of their equipment may have caused or contributed to death or serious injury. They must also report to the DOH pharmacovigilance program when they become aware that their device has malfunctioned and would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

B. Brief Description of the Technology/therapy

Non pharmaceuticals

1. **Name of proposed Technology/therapy:**
2. **Version or Model Number:**
3. **Manufacturer Name:**
4. **Country of origin:**
5. **Technology Type:**
   ☐ Device ☐ System/Software/App ☐ Technique/Procedure ☐ Diagnostic Test ☐ Product/Kit ☐ AI
   ☐ Others (specify): ……
6. **Technology class (in reference to USA FDA Medical Device Classification**
   Classify Your Medical Device | FDA
7. **Technology Category:**
   ☐ Diagnostic ☐ Therapeutic ☐ Others (specify): ……
8. **Technology speciality:**
9. **Description of the Technology:**
10. **Introduction:**
11. **Mechanism of action:**
12. **Clinical evidence/efficacy:**
13. **Population:**
14. **Intervention:**
15. **Comparator:**
16. **Outcomes:**
17. **Safety/risk issues:**
18. **Technology Website/link:**

Pharmaceuticals

19. **Name of proposed Technology/therapy:**
20. **Active ingredient (If applicable):**
21. **Dosage form:**
22. **Concentrations:**
23. **Proposed price:**
24. **Manufacturer Name:**
25. **Marketing approval holder:**
26. **Local agent:**
27. **Country of origin:**
28. **Technology Category:**
    ☐ Diagnostic ☐ Therapeutic ☐ Others (specify): ……
29. **Technology speciality:**
30. **Description of the Technology:**
31. **Introduction:**
32. **Mechanism of action:**
33. **Clinical evidence/efficacy:**
34. **Population:**
35. **Intervention:**
36. **Comparator:**
37. **Outcomes:**
38. **Safety/risk issues:**

39. Technology Website/link:

40. Category for requested proposed Technology/therapy:

- ☐ Proven new technology – Clinical safety and effectiveness have been demonstrated but not been used in Abu Dhabi (approved by Health Regulator in country of origin).
- ☐ Innovative/Experimental new technology/ therapy (Not yet approved by Health Regulator in country of origin).
- ☐ New Pharmaceutical Product Therapies / Medical Treatments

41. Previous marketing authorizations in other countries:

42. Is the technology/therapy Approved from International Bodies? If Yes, please state the name of the Organization.

- ☐ EDE / MoHaP (UAE)
- ☐ Others (specify): ……

C. Clinical Effectiveness and Targeted Population:

43. What are the clinical indications (health problem or disease that the technology / therapy intends to prevent or treat)? (Describe Included and Excluded indications, and ICD 10 codes for those indications)

44. Describe the expected health benefits/improvements in patient outcome compared to current practice (KPI's) (comparative efficacy)

Value drivers

- **Clinical (morbidity or mortality) benefit**
- **Improved quality of life (utilities)**
- **Cost efficiency (better utilization of resources)**
- **Other**

45. The Impact of this Technology/therapy on Current Practices will be:

☐ Minor Change in Current Practice. *Please explain:*

OR

☐ Significant change in current practice. *Please explain:*

46. What is the clinical need or the gap that the current practice does not address while the technology being assessed does? (Unmet need) Kindly elaborate.

47. Evidence on clinical effectiveness

Where there any clinical trial conducted? Where? How long? And what stage is it at? Has it been published and where? *(International and if any local data clinical trials or RWE is available, please provide a description and reference.)*

Table 1: Characteristics of the studies

Study reference/ID	Objective	Study design	Eligibility criteria	Intervention and Comparator (N enrolled)	Primary outcome measure and follow-up time point	Secondary outcome measures and follow-up time points	URL to access the study publication

Table 2: Description of study methodology

Study reference/ID	Method of recruitment	Method of randomization	Method of allocation concealment	Methods of blinding

48. **Targeted population:**

A. **What are the most important clinical characteristics of the patients that technology/therapy will serve?**

B. **What are the incidence and prevalence rate of the above clinical characteristics?**

C. **What is the estimated number of patients for every indication that might use this technology/therapy in Abu Dhabi?** *The estimated cost for the same number studied somewhere else*

E. Safety – Risks and Adverse Events

49. What are the Risks associated with this Technology/therapy?

☐ Risks are the same as the current practices.

☐ Risks are different than current practices. *Please Describe:*

☐ Risk is Unknown (Safety Has not been Determined).

50. Adverse events and side effects when it comes to pharmaceuticals. (break it down by severity)

Specify the source of data (reference)

Table 3: Frequency and severity of adverse events

Study [INSERT STUDY REFERENCE / ID]									
System organ/ class/adverse events	**All grades**				**Serious adverse events**				**Death**
	Intervention (n = x) n (%)	**Comparator (n = x) n (%)**	**Relative risk (95% CI)**	**Risk difference (95% CI)**	**Intervention (n = x) n (%)**	**Comparator (n = x) n (%)**	**Relative risk (95% CI)**	**Risk difference (95% CI)**	**Intervention (n = x) n (%)**
Class 1 (for example, nervous system disorders)									
Adverse event 1									
Adverse event 2									
Class 2 (for example, vascular disorders)									
Adverse event 3									
Adverse event 4									

CI, confidence interval
Adapted from European Public Assessment Reports published by the European Medicines Agency
From tables 3a and 5 of the EUnetHTA safety guideline

51. Are there known or potential contraindications, product warnings, or risks to:

Patients ☐ Yes ☐ No Health care practitioners ☐ Yes ☐ No

If yes to either of the mentioned above, kindly elaborate:

F. Cost of the Technology/therapy:

1. What is the estimated contractual price for the requested technology/therapy? *Is there any signed agreement with others for future application. Explain.*
2. How did you calculate the proposed price? Please provide the breakdown in detail.
3. Will additional training or certification be required to operate the technology/therapy? ☐ Yes ☐ No *Or Ongoing CME, or other Local and international certification after approval. How /where*
4. Treatment frequency and dose (chronic, acute) is the pharmaceutical product /intervention taken for a limited duration or until death or progression of disease (if the intervention use stops after a specific number of doses or applications, or is it until progression, or lifetime.
5. Estimated average annual cost per patient per year.
6. Will the technology/therapy drive any cost savings? (Include impact on health care resource utilization.)

G. Economic Evaluation:
7. The chosen type(s) of economic evaluation **(cost-effectiveness, cost-utility, cost-benefit, cost-minimization or cost-consequence -analysis)** *Attach the economic evaluation models*
8. What is the financial impact of introducing this technology/therapy? *Financial impact compared to standard of care ..outcomes ..mention details such as CEA, costs, QALYS,,etc*
9. Brief About the burden of disease (international data is sufficient) *Costs (direct and indirect medical costs), medical resource use (hospital admissions, length of stay, physician and specialist visit, medications) and non-medical resource use (lost productivity and homecare or caregiver's time)*

10. Health related outcomes - QoL data

Preferred measure(s) of health effects that are used in the analysis or analyses (e.g., QALY, LYG). Preferred source of data for measurement of health-related quality of life, if applicable. Source of preference data for valuation of health-related quality of life, if applicable

11. If using the intervention affects equity, please provide a description

12. If the intervention is reimbursed in other countries

13. Cost effectiveness studies

Provide available Cost Effectiveness studies

Table 4: Cost effectiveness studies

Study reference/ID	Objective	Study design	Eligibility criteria	Intervention and Comparator (N enrolled)	Primary outcome measure and follow-up time point	Secondary outcome measures and follow-up time points	Result *(p-value)*	URL to access the study publication

14. Sensitivity analysis included if not justification

H. Additional comments:

Kindly elaborate on any additional information that could be of an added benefit.

Details of reference, economic evaluation…etc

Thank you for your time. You will be approached shortly by provider relations department for further guidance.

I. Information Security Compliance and Data Privacy:

No	Action	Y	N	N/A	Remarks
1.	Technology/Therapy involves health data	☐	☐	☐	
2.	Health data transferred/made available and/or hosted or accessed from outside UAE	☐	☐	☐	
3.	Secure data exchange channels defined & agreed for health data exchange	☐	☐	☐	
4.	NDA signed with data recipients as needed/applicable	☐	☐	☐	
5.	Data retention period defined & agreed	☐	☐	☐	
6.	The technology/therapy involves parties from outside UAE	☐	☐	☐	
7.	Utilization of Cloud Infrastructure and Services from outside UAE	☐	☐	☐	
8.	Technological dependency on vendors/parties from outside UAE, for the purpose of operations/support	☐	☐	☐	
9.	Technology compliance with DoH Standard on the Internet of Medical Things [IoMT]	☐	☐	☐	
10.	Technology and initiative compliance with DoH Standard on Patient Healthcare Data Privacy Standard	☐	☐	☐	

A. Compliance Requirements

1. It is not permitted to store, develop, or transfer data and health information outside the UAE that is related to health services provided within the country (Reference: Federal Law No. (2) For the year 2019 On the Use of Information and Communications Technology (ICT) in healthcare)
2. Information Exchange
   a. All information exchanged shall be classified, tagged and controlled, as per the requirements of the classification. Please refer to ABU DHABI HEALTHCARE INFORMATION AND CYBER SECURITY STANDARD (ADHICS) for more details about Information Classification.
   b. All information exchanged shall be in a pre-defined structure agreed by both parties, which provides the minimum information required for the specific purpose.
   c. All information exchange shall only be approved through channels agreed by both parties, in compliance with the requirements of the classification.
3. Administration
   a. All receiving parties shall sign separate NDAs for ensuring maintenance of confidentiality of all information handled.
   b. There shall be binding agreements with parties to ensure maintenance of confidentiality of all information handled.
4. Further sharing of information
   a. Any, and all requirements to share the information further with any third parties at any circumstances shall be only after obtaining written consent from the Discloser party and DOH.
   b. Any information shared further shall be only after the assurance that the information be classified, tagged and controlled, as per the requirements of the classification.
   c. No third party shall share the information further under any circumstances.
5. Incident Management
   a. Any, and all compromises and breaches shall be informed to the DoH immediately along with the impact analysis and consequences

J. Supplementary documents

No	Action	Y	N	N/A	Justification in case of not attached
1.	**Cost-effectiveness model (excel or other software)**	☐	☐	☐	
2.	**Cost-effectiveness analysis report**	☐	☐	☐	
3.	**Budget impact model (excel or other software)**	☐	☐	☐	
4.	**Budget impact analysis report**	☐	☐	☐	
5.	**Price certificate**	☐	☐	☐	
6.	**Marketing approval from MOHAP / EDE**	☐	☐	☐	
7.	**CE certificate**	☐	☐	☐	
8.	Self-validation report	☐	☐	☐	

9.	**Sensitivity analysis**	☐	☐	☐	
10.	**FDA approval**	☐	☐	☐	
11.	**EMA approval.**	☐	☐	☐	
12.	**Any other international body**	☐	☐	☐	
13.	**Product artwork and product specifications or catalogue copy (PDF, JPEG or GIF).**	☐	☐	☐	
14.	**Quality and impact of the technology/Therapy: Major clinical studies proving efficacy and safety published in peer reviewed journals.**	☐	☐	☐	
15.	**Impact on clinical practice, expected health benefits, risks, warning and contraindications (place in therapy compared to other standard of care alternatives).**	☐	☐	☐	
16.	**Guidelines or other HTA bodies recommendations.**	☐	☐	☐	
17.	**Recommendation by international reputed clinical societies and international clinical practice guidelines if possible.**	☐	☐	☐	

If the product is not FDA, EMA or EDE / MOHAP approved/ cleared, all the following are mandatory:

1.	**Free sales certificate in the country of origin, or similar**	☐	☐	☐	
2.	**GMPs for manufacturing/ production site.**	☐	☐	☐	
3.	**Letters from facilities in Abu Dhabi that they will use the product in their facility (undertaken letter)**	☐	☐	☐	