

HTA Framework Used in the UAE -Raheel Siddiqui

1. Definition & Purpose of HTA

Health Technology Assessment (HTA) is a structured, multidisciplinary process used to evaluate the effects of health technologies before they are introduced into regular clinical practice, or while they are already in use. It considers a wide range of factors, including medical effectiveness, cost, organizational impact, social and ethical concerns, and legal issues. The World Health Organization describes HTA as an evidence-based tool that helps policy-makers decide whether a medicine, device, diagnostic method, public health program, or digital health solution provides enough value for the resources it requires, based on the needs and context of a specific healthcare system.

Purpose of HTA

Health Technology Assessment (HTA) is conducted to serve four main goals:

Improve population health:

By directing limited resources toward technologies that clearly extend life or improve quality of life, HTA supports national objectives. For example, the UAE Vision 2031 includes a target for increasing healthy life expectancy, which HTA helps advance.

Safeguard fiscal sustainability:

With global healthcare costs on the rise, HTA enables payers to focus on cost-effective interventions and avoid those with limited benefits compared to their price.

Strengthen transparency and legitimacy:

A structured and open evaluation process builds trust among clinicians, patients, suppliers, and the public. It shows that coverage and pricing decisions are based on solid evidence rather than unclear or closed-door negotiations.

Promote both innovation and equity:

HTA encourages the development of high-value technologies while also aiming to ensure fair access, including for vulnerable groups or people in remote areas.

Typical Assessment Dimensions:

While different countries may place different weight on specific types of evidence, most HTA frameworks include eight key dimensions:

- Clinical effectiveness: Impact on survival, disease progression, and quality-of-life outcomes when compared to existing alternatives.
- Safety: Rate and seriousness of side effects in clinical trials and real-world use.
- Cost-effectiveness: Comparison of added costs to added health benefits, often measured as the cost per quality-adjusted life year (QALY) gained.
- Budget impact: Estimated effect on healthcare budgets, based on population size, expected use, and pricing.

- Organizational feasibility: Needs related to staff, infrastructure, and training, along with potential changes to existing clinical workflows.
- Legal and ethical considerations: Compliance with laws on data protection, informed consent, and liability.
- Social and cultural acceptability: Public and patient views about the technology, including its purpose, method of use, and side effects.
- Equity implications: How the benefits and costs are distributed across different income levels, regions, or population groups, and whether the technology helps reduce or worsens health inequalities.

Each of these aspects is considered in comparison with current local practices. Together, they form a complete picture that helps decision-makers judge how well a new technology fits with both health priorities and budget limits.

Standard HTA Process

Most HTA processes follow a series of seven main steps:

- Topic identification and prioritisation:
Selecting technologies for assessment based on factors like disease burden, cost impact, or input from stakeholders.
- Scoping:
Defining the patient group, comparison treatments, desired outcomes, time frames, and type of analysis.
- Evidence submission:
Clinical, economic, and public health data are submitted, usually by manufacturers or independent research groups, in the form of a detailed technical dossier.
- Critical appraisal and modelling:
HTA teams review the submitted data, carry out economic modelling, and test how sensitive results are to changes in key assumptions.
- Deliberation by an expert committee:
A panel of experts reviews the findings, listens to stakeholder input, and drafts preliminary recommendations.
- Recommendation and publication:
The HTA body issues a final decision, which may include pricing conditions, risk-sharing arrangements, or requirements for further data collection after market entry.
- Post-implementation monitoring and reassessment:
Real-world outcomes are tracked to confirm effectiveness and safety, and to guide future updates to coverage or pricing decisions.

UAE's stance on HTA and any available guidelines

2. UAE's HTA Framework

Regulatory and Institutional Architecture

In the United Arab Emirates, decisions about health technologies are shared among three main regulatory bodies. The Ministry of Health and Prevention (MoHAP) oversees national strategy

and has recently built HTA capacity into its Innovation and Artificial Intelligence teams to support the country's Digital Health Strategy.

At the emirate level, both the Department of Health – Abu Dhabi (DoH) and the Dubai Health Authority (DHA) function as regulators, payers, and HTA users. These two authorities decide which medicines, devices, and digital tools are covered by their mandatory health insurance schemes.

In recent years, the UAE has taken steps toward creating a unified, federal HTA system. In 2024, the Dubai Research and Development Authority launched a multi-stakeholder project aimed at mapping current assessment efforts and designing a centralised, technology-driven HTA platform. This platform is intended to start in Dubai and expand nationwide. The project specifically aims to harmonise submission templates and evaluation methods across the emirates.

Official Mandates and Policies

Abu Dhabi currently leads HTA implementation. In April 2025, the DoH published its first mandatory Healthcare Payers HTA Guidelines, which require all licensed providers and third-party administrators to submit a detailed HTA dossier for any new, high-cost technology seeking inclusion in government-funded benefit packages, such as Thiqat.

The dossier must cover clinical effectiveness, safety, cost-effectiveness, budget impact, and expected local use.

Dubai, through DHA, still uses an internal Pharmacy and Therapeutics Committee but is participating in the development of the national HTA platform. Meanwhile, MoHAP is drafting federal HTA regulations that will apply to all technologies purchased through the national procurement programme, as well as AI-enabled tools certified under its upcoming Digital Health Sandbox.

Guidelines and Procedural Details

Scope and triggers:

The DoH guidelines apply to pharmaceuticals, medical devices, digital health tools (including AI), and new medical procedures that either change the standard of care or address an unmet medical need. Routine price updates or coding changes are not covered.

Submission pathway:

Providers must submit applications through the Daman electronic portal. Submissions must include a clinical evidence review, a new or adapted economic model, a five-year budget impact analysis, and an implementation plan detailing staffing and infrastructure needs. Incomplete applications are returned within ten business days.

Timelines and decision points:

Once a dossier passes the initial review, the HTA Section within the Healthcare Payers Sector performs a full assessment and submits a report to the Empanelment Committee. The committee issues a recommendation—approve, approve with conditions, or reject—within 120 calendar days. Appeals or resubmissions are processed within 60 days. Final decisions

are posted publicly on the DoH website. DHA decisions are typically faster, averaging 90 days, but are not yet published.

Post-launch monitoring:

Abu Dhabi requires companies to submit annual real-world data for at least three years. If the technology fails to meet its expected clinical outcomes or exceeds the budget cap, the DoH may renegotiate pricing or remove the product from coverage.

3. Regional Case Examples

Two Illustrative HTA Decisions in the UAE

Gene therapy for spinal muscular atrophy (SMA):

In March 2024, DoH approved funding for a single-dose gene therapy for a 44-day-old infant. The treatment cost approximately AED 8 million. The decision followed an accelerated HTA process, which took into account clinical urgency and imposed a budget cap. Approval was granted under an outcome-based payment agreement, requiring partial refunds if key milestones were not reached within two years.

First locally manufactured CAR-T therapy:

In November 2023, the Abu Dhabi Stem Cells Center, supervised by DoH, produced the UAE's first locally made CAR-T cells to treat an 11-year-old patient with leukaemia. The HTA balanced high initial costs with long-term health gains and potential cost savings from fewer relapses. Because the therapy was developed domestically, the DoH negotiated a price about 35 percent below international levels. Approval was conditional on tracking survival outcomes through a national registry.

Comparative Example from the GCC – Saudi Arabia

Saudi Arabia has moved slightly ahead of the UAE in establishing a formal HTA system. In 2021, it created the National Center for Health Technology Assessment under the Saudi Health Council. Starting July 2025, all applications for reimbursement of high-cost medicines must include full pharmacoeconomic dossiers.

Saudi Arabia is also close to setting a national cost-effectiveness threshold between SAR 50,000 and 75,000 per QALY, based on studies of health system opportunity costs.

One early test case involved tafamidis for treating amyloid cardiomyopathy. The HTA review found that the drug's launch price was far above the proposed threshold and recommended limited coverage until significant price discounts were secured. By contrast, the UAE has not yet adopted a fixed WTP threshold, choosing instead to negotiate on a case-by-case basis, especially for rare conditions.

Key Similarities and Differences

Both the UAE and Saudi Arabia now require detailed evidence on clinical outcomes, economic value, and budget impact before making coverage decisions. However, their HTA systems differ in structure and policy:

- Saudi Arabia uses a centralised, national agency with an explicit cost-effectiveness threshold, offering consistency but potentially longer timelines.
- The UAE uses a decentralised model led by individual emirates. This allows quicker adoption of high-priority innovations but may result in variation across regions.

Each approach has strengths. Saudi Arabia provides more predictability for manufacturers, while the UAE offers more flexibility and openness to innovation.

4. Pharmedic Product Alignment with UAE HTA Dimensions

Clinical effectiveness

Pharmedic describes itself as an AI-based medication guidance platform designed to reduce clinical errors by approximately 35 percent. This indicates meaningful potential to support patient safety and clinical accuracy. However, current HTA expectations in the UAE, particularly under the Department of Health – Abu Dhabi (DoH), require stronger evidence in the form of systematic reviews or real-world studies that demonstrate improvements in patient health outcomes—not just reductions in process errors.

While Pharmedic is directionally aligned with clinical effectiveness goals, further validation through controlled studies in local settings and publication in peer-reviewed outlets will help bring it in line with HTA evidence standards.

Safety

In the UAE, clinical decision-support systems are considered software medical devices and must meet corresponding safety and regulatory requirements. Pharmedic's real-time interaction checker aims to improve prescribing safety, but HTA reviewers will evaluate more than just intent. The DoH will look closely at the algorithm's accuracy, including false-positive and false-negative rates, its ability to explain decisions, and the quality of monitoring systems.

To meet HTA safety expectations, Pharmedic must validate its algorithm against an established gold-standard database and commit to routine performance audits after implementation.

Cost-effectiveness

Reducing medication errors can prevent hospital admissions and lower legal risks, but HTA committees require this potential value to be expressed in economic terms. Pharmedic will need to provide an incremental cost-effectiveness ratio (ICER), measured in dirhams per quality-adjusted life year (QALY) gained.

UAE payers generally evaluate cost-effectiveness over a three- to five-year period, using a discount rate of three percent. Pharmedic will need to develop a custom economic model that reflects local usage patterns, healthcare costs, and the average cost of adverse drug events in Abu Dhabi's hospital system.

Budget impact

Pharmedic may be offered through a subscription, licensing arrangement, or outcome-based contract. Each option has different cost implications for public insurers like Thiqa and Dubai's ISAHD program.

To support HTA review, Pharmedic should prepare several budget scenarios that account for costs related to licensing, integration, training, and system maintenance, as well as potential savings from avoided clinical errors.

Equity

Pharmedic states that it will operate across all seven Emirates. However, digital health solutions can unintentionally exclude patients with limited internet access, low digital literacy, or language barriers. HTA reviewers will assess whether the platform offers multi-language support, including Arabic, English, and Urdu, whether it is accessible to older adults, and how it performs in both public and private healthcare settings.

Addressing these equity issues early will help the platform align with national health inclusion goals.

Acceptability

Pharmedic has shown early engagement with clinicians, regulators, and patient advocacy groups, as seen in its public outreach and LinkedIn activity. These initial efforts suggest a positive reception. However, the DoH may request formal user satisfaction surveys and impact assessments to determine how well the platform fits into real-world clinical workflows.

Demonstrating strong clinician acceptance will be an important factor in the HTA process.

Infrastructure needs

Scaling Pharmedic across the UAE will require seamless integration with hospital systems that use HL7-FHIR standards. It will also need to comply fully with the UAE Personal Data Protection Law. Pharmedic must outline its data-hosting strategy within the country, cybersecurity protections, and results from interoperability testing.

A strong infrastructure plan will be essential to show readiness for secure and efficient nationwide adoption.

Summary:

Health Technology Assessment (HTA) is a structured, evidence-based process used to evaluate the value of medical technologies, including drugs, devices, and digital tools, based on clinical effectiveness, safety, cost, equity, and social impact. In the UAE, HTA is becoming increasingly important, with the Department of Health, Abu Dhabi (DoH) leading its implementation through formal guidelines and mandatory submissions, while the Ministry of Health and Prevention (MoHAP) and Dubai Health Authority (DHA) collaborate on a unified federal framework. The aim is to ensure that technologies adopted into the healthcare system are both clinically beneficial and economically viable, in line with national health goals and equitable access.

Pharmedic, an AI-driven medication guidance platform, aligns with HTA priorities such as improving clinical safety and reducing prescribing errors. However, to fully meet UAE HTA standards, it must enhance its clinical evidence base, develop locally relevant cost-effectiveness models, and address equity, usability, and data infrastructure needs. Early engagement with stakeholders is encouraging, but formal validation, outcome tracking, and robust economic analysis will be essential for successful integration into UAE healthcare systems.