

# EU HTA Advisory & Early Access Strategy

A two-phase engagement: rapid HEOR diagnostic across NICE, G-BA, and HAS, followed by early access strategy for a late-stage immunology pipeline asset

*Latif Strategic Advisory · 2026*

## **Latif Strategic Advisory Ltd**

Strategic Advisory · Market Access · Pricing · Policy

**3**

HTA Markets

**2 wks**

Diagnostic Sprint

**6-8 wks**

Total Engagement

**Won**

Follow-on Mandate

## THE SITUATION

A US-headquartered specialty biopharma was preparing simultaneous HTA submissions in three major EU markets for a novel oral treatment in a moderate-to-severe immunological condition — the first in its class to reach late-stage development.

The HEOR package was clinically strong but had not been stress-tested against the specific methodological demands of NICE, G-BA, and HAS running in parallel. Indirect comparison methodology, endpoint selection, and the benefit claim each carried market-specific risk that had not been mapped.

With dossier lock imminent and no internal capacity for a rigorous market-by-market review, the team needed rapid external advisory support and a clear view of where the value story would hold.

## THREE QUESTIONS THE TEAM NEEDED TO ANSWER

### 01

#### **Where is the HTA risk concentrated?**

Which markets present the greatest methodological challenge — and what specifically is the vulnerability?

### 02

#### **How robust is the payer narrative?**

Does the benefit claim survive scrutiny under each body's framework, and where must it be reframed?

### 03

#### **What is the follow-on access picture?**

How should early access strategy be structured for the pipeline asset in the same indication?

# 01

## HEOR Diagnostic Sprint (Wks 1-2)

- Reviewed evidence package vs NICE, G-BA, and HAS methodology
- Stress-tested indirect comparison and endpoint selection in each market
- Identified where benefit claim was vulnerable to reviewer challenge
- Produced market-specific HTA risk map
- Developed strengthened payer narrative for dossier incorporation

OUTPUT → HTA risk map + strengthened payer narrative

# 02

## Early Access Strategy (Wks 3-6)

- Scenario modelling under EU HTA and IRP for the pipeline asset
- Launch sequencing across five EU markets by risk and readiness
- Pricing corridor framework ahead of formal assessment window
- Early access programme design and feasibility assessment
- Alignment sessions with global market access leadership

OUTPUT → Launch sequencing + pricing corridor framework

# 03

## Integration & Handover (Wk 7-8)

- Final outputs presented to asset and commercial leadership
- Risk register with market-by-market mitigation strategies
- Frameworks designed for internal reuse without external dependency
- Follow-on mandate scoped and agreed

OUTPUT → Decision-ready outputs + reusable frameworks

## THE DELIVERABLES



### HTA Risk Map

Market-by-market assessment across NICE, G-BA, and HAS — identifying where the value story held and where the payer narrative required reframing before dossier lock.



### Strengthened Payer Narrative

Revised HEOR framing addressing endpoint selection and indirect comparison vulnerabilities in each market — incorporated into final dossier submissions.



### Pricing Corridor & Launch Sequencing

Scenario-modelled pricing corridor for the pipeline asset, with a five-market launch sequencing framework accounting for HTA timelines, IRP dynamics, and early access feasibility.

## WHAT MADE THIS WORK

Senior advisory lead with direct HTA experience across all three markets

Evidence reviewed as payers review it — not as the client hoped

Two-phase design created natural follow-on value from the initial diagnostic

## THE OUTCOME

Dossiers submitted with strengthened HEOR rationale across all three markets, on schedule. Pricing corridor established six months ahead of the first EU HTA assessment. The pipeline sequencing framework was adopted as the basis for the global launch plan.

### On-Schedule Submission

HEOR rationale strengthened and incorporated before dossier lock. All three HTA submissions filed on the planned timeline without delays attributable to the evidence package.

### Pricing Clarity

Pricing corridor for the pipeline asset established six months ahead of the first EU HTA assessment — giving leadership a defensible anchor for commercial planning.

### Follow-on Mandate

The early access strategy work led directly to a follow-on engagement. The pipeline sequencing framework was adopted by the global team as the launch plan baseline.

## WHAT THIS DEMONSTRATES

- Senior HEOR advisory across NICE, G-BA, and HAS running in parallel
- Ability to translate methodological risk into an actionable payer narrative under time pressure
- Commercial instinct to design engagements that generate natural follow-on value