THE PRICING INFLECTION POINT

Why 2026 Will Redefine Pharma Market Access

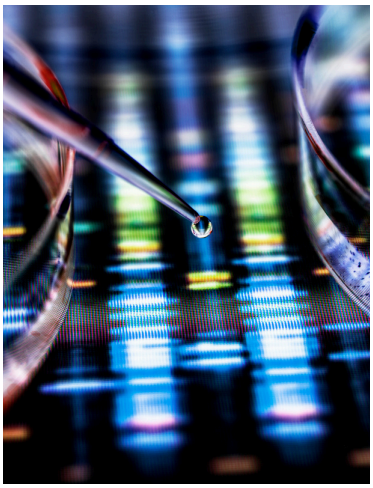
Essential predictions and strategies from GPI's pricing specialists.

Global Pricing Innovations | January 2026

Contents

INTRODUCTION

The 2025-2026 Inflection Point



We're at a Turning Point

2025 proved what many suspected but few wanted to acknowledge. The pharmaceutical pricing landscape doesn't evolve, it accelerates. And most companies aren't keeping pace.

The launch sequencing rules from five years ago are obsolete. Pricing corridors that once provided strategic guidance now shift unpredictably. Payer dynamics that appeared manageable have become complex, multi-variable equations requiring constant recalibration.

Yet the pattern is unmistakable. Companies integrating pricing strategy across the asset lifecycle, not treating it as a pre-launch negotiation, are securing market access 30-40% faster than competitors. They're launching with confidence, obtaining reimbursement at target prices, and maintaining commercial performance whilst others struggle to get products to patients.

At GPI, we spent 2025 working alongside pharmaceutical companies navigating precisely these challenges. We tracked regulatory shifts across 63+ markets. Monitored 15,000+ HTA decisions in real time. Helped clients model IRP scenarios that would have seemed paranoid 24 months earlier. Our data revealed something critical.

2026 isn't another year of gradual change. It's the year pricing assumptions break.

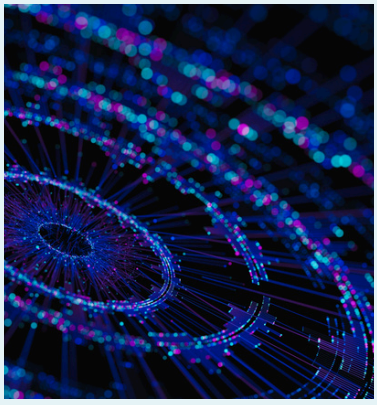
Why This eBook Matters Now

This is not retrospective analysis. Yes, we will examine what 2025 revealed: regulatory shifts, geopolitical pressures, payer behaviours that caught experienced teams unprepared. But the strategic value lies in what is happening right now, in Q1 2026.

The trends we observed throughout 2025 are not slowing. They are compounding.

EU-HTA implementation is not settling into a comfortable routine. It is forcing fundamental rethinks of evidence generation timelines and pricing architecture. International Reference Pricing is not becoming more predictable. More countries are monitoring more markets with shorter lag times between price publication and policy impact. Payer scrutiny is not moderating. Transparency expectations that seemed aggressive five years ago are now baseline requirements.

This is occurring against accelerating patent cliffs, biosimilar competition that is more sophisticated than previous waves, geopolitical instability that has moved from risk register to weekly pricing calls, and technology shifts that fundamentally challenge traditional pharmaceutical value propositions.



The question is not whether your pricing strategy requires evolution. It is whether you are prepared for the velocity of that evolution.

What You Will Find in This eBook

We have structured this eBook in two main parts:

Part One: What 2025 Taught Us
Evidence-based analysis of the pricing and market access developments that defined 2025. From Joint Clinical Assessments transitioning from concept to operational reality, to geopolitical risk becoming pricing variable, to biosimilar competition patterns emerging across major European markets. This is not comprehensive policy cataloguing. It is strategic analysis of the shifts that will define your 2026 decision-making.

Part Two: The 2026 Landscape
Forward-looking predictions from GPI consulting team, grounded in market intelligence from 63+ markets and direct client advisory work. Where will pressure points emerge? Which assumptions will fail? What should pricing and market access leaders be doing differently?

Throughout, you will find insights grounded in validated data, actual client challenges, and observable market dynamics. This is strategic intelligence designed to move you from reactive response to proactive positioning.

Who This Is For

If you are responsible for pharmaceutical pricing, market access, or commercial strategy, whether at global or regional level, this analysis is designed for you.

That includes:

- Pricing Directors managing international reference pricing risk and navigating price corridor strategies
- Market Access Directors building reimbursement strategies across increasingly complex payer landscapes
- HEOR Leaders developing economic models under heightened scrutiny and evolving value frameworks
- Business Development Teams valuing assets where pricing assumptions determine deal viability
- Early Pipeline Strategists making go/no-go decisions where commercial viability trumps clinical promise
- CRO Feasibility Teams assessing whether markets will actually reimburse what is in development
- Consultants helping clients navigate uncertainty with frameworks that work in practice

If pricing decisions determine whether your products reach patients, this eBook addresses the questions you are already asking.

How GPI Can Help

At GPI, we do not observe the market from a distance. We operate within it, shaping how our clients succeed through integrated pricing intelligence and strategic advisory.

Our work spans the complete product lifecycle:

• Early-stage valuation using our proprietary Horizon methodology, validated with direct payer feedback
• Launch planning informed by 250M+ validated data points across 63+ markets, updated continuously
• Real-time price monitoring through GPI Pulse, delivering intelligence on competitor moves and policy shifts
• Strategic advisory for complex pricing challenges where data alone is insufficient

Whether you require platform access, API integration, tailored reports, or consulting support, we are structured to match how you work. But fundamentally, we are specialists. Pharmaceutical pricing and market access is not one service among many. It is what we do. In a market where everyone claims pricing expertise, that exclusive focus creates tangible client advantage.

WHAT 2025 TAUGHT US

The Year That Redefined the Landscape

Introduction: A Year of Acceleration

2025 was the year pharmaceutical pricing moved from theoretical complexity to operational reality. The regulatory changes anticipated for years became live systems requiring execution. Geopolitical risk shifted from quarterly board updates to weekly pricing decisions. Payer expectations accelerated faster than most strategies could adapt.

At GPI, we tracked these developments throughout 2025. Our clients navigated Joint Clinical Assessments, recalibrated launch sequences against tariff uncertainty, and watched biosimilar competition rewrite pricing assumptions across Europe. Through our platform intelligence and continuous market monitoring, the patterns emerged clearly.

This chapter examines developments that matter most, those establishing the foundation for what is coming in 2026.

EU-HTA: From Concept to Reality

Joint Clinical Assessment officially came into force in January 2025, covering new oncology medicinal products and ATMPs, with plans to expand to new orphan medicinal products in 2028 and eventually all new medicinal products in 2030. JCA aims to streamline HTA processes, minimise duplication of HTA body efforts, enhance efficiencies, and ultimately support EU member states in their national HTA processes. Research questions are developed as PICOs, defining population, intervention, comparator and outcome, giving a consolidated unified scope for the assessment.

In April 2025, the European Commission confirmed that the first two JCAs had started. The first JCA is for a treatment of paediatric low-grade glioma, with Ireland's National Centre for Pharmacoeconomics as the assessor and Germany's Institute for Quality and Efficiency in Health Care as co-assessor. The second JCA is for an ATMP for melanoma treatment, with France's National Authority for Health as assessor and Poland's Agency for Health Technology Assessment and Tariff System as co-assessor. While JCA promises several efficiencies, it is not without challenges. Evidence requirements are extensive and complex, with high volumes of PICOs per assessment. Investment from different departments within pharmaceutical companies, including HEOR and market access, is necessary. There is uncertainty around the number and nature of PICOs and evidence acceptance thresholds during dossier review.

Timelines between PICO finalisation and dossier submission are tight, putting additional pressure on health technology developers. Resource requirements need to be foreseen, as the JCA process runs in parallel with the regulatory EMA process. Manufacturers need to seek country-level reimbursement soon after JCA completion to prevent JCA from becoming outdated. Alignment of JCA outputs with local, jurisdiction-level requirements is complex and demanding. Potential differences in methodology standards between JCA and local HTAs add layers of complexity. Commercial and market access strategy now requires consideration earlier in the asset's development cycle.

For years, EU-HTA represented something teams prepared for theoretically. In 2025, it became something they executed in practice. The Joint Clinical Assessment framework did not merely add a regulatory step. It fundamentally altered evidence requirements, submission timelines, and the strategic calculus underpinning pricing decisions. Companies treating JCA as compliance exercise struggled. Those integrating HTA thinking early, shaping evidence generation around payer priorities, secured faster reimbursement pathways.

The lesson: EU-HTA is not a hurdle to clear. It is a strategic framework separating companies that understand evidence-based pricing from those operating on outdated assumptions.

Geopolitical Risk Becomes Pricing Reality

The pharmaceutical industry faces disruption as global protectionism reshapes trade, manufacturing, and pricing. From tariff increases and reshoring policies to regulatory restrictions and supply bottlenecks, uncertainty is mounting. For an industry built on cross-border collaboration and global sourcing, the implications are profound. COVID-19 exposed supply chain fragility. Since then, rising geopolitical tensions, energy shocks and industrial policy shifts have compounded risks. In this landscape, pharmaceutical companies must think beyond regulatory approval and focus on operational and pricing resilience.

Tariffs are import taxes applied to raw materials, active pharmaceutical ingredients, intermediates, or finished drug products. While traditionally low for most pharma categories, they have re-emerged in political rhetoric, particularly around China, India, and other major API exporters. Non-tariff measures include regulatory hurdles, local certification requirements, quotas, price caps, and Buy Local mandates. These create barriers that delay access and increase compliance burdens. At-risk supply corridors include China and East Asia to EU for APIs and precursors, India to global markets for generic APIs and intermediates, and EU to UK facing post-Brexit regulatory divergence.

Pharma supply chain complexity means production is often spread across continents. Key vulnerabilities include API dependence, with approximately 70% of global API supply from China and India, low redundancy from lean manufacturing strategies, regulatory delays, and geopolitical exposure where trade wars or export bans can halt supply. Trade barriers do not just disrupt logistics. They undermine pricing and reimbursement planning. Unexpected cost increases can make previously negotiated prices unsustainable. IRP chain reactions occur when high-price reference countries adjust upward, amplifying pricing risk. Payers may push back on inflation-linked justifications unless accompanied by robust value data.

Companies strengthening their pricing backbone through structured Standard Operating Procedures across local affiliates and headquarters ensure consistency and rapid decision-making when markets shift unexpectedly. Success depends on embracing data-driven decision-making and integrating insights early in the planning process. In previous years, geopolitical risk occupied quarterly risk registers. 2025 transformed it into weekly pricing variable. Trade tensions, tariff threats and supply chain vulnerabilities moved from monitoring to action.

For pricing teams, implications extended beyond logistics. Launch sequences required mid-flight recalibration. IRP exposure demanded stress-testing against politically volatile scenarios. We observed clients delaying reference market launches to avoid pricing lockdown, restructuring supply agreements to mitigate tariff exposure, and running IRP scenarios that would have seemed alarmist 18 months earlier.

The insight: Pricing strategy and geopolitical strategy are now inseparable disciplines. Companies that recognised this in 2024 maintained strategic optionality when volatility materialised.

The European Pricing Landscape: What the Data Reveals

Reforms to national reimbursement and pricing processes are increasing pressure on pricing strategies across Europe. Budget impact assessments are becoming more critical in determining access and pricing decisions. Health systems focus on achieving cost containment while balancing access to innovative therapies. Updates to reimbursement and pricing processes in certain markets aim to accelerate access to innovative medicines. Initiatives in Germany and France focus on reducing delays between regulatory approval and reimbursement decisions. Early access programmes, innovation funds, and conditional reimbursement mechanisms are increasingly used to ensure faster patient access whilst addressing uncertainties around long-term outcomes.

The adoption of Real-World Evidence is growing, particularly in countries like the UK, where NICE has shifted towards health technology management. This approach emphasises continuous assessment of therapeutic performance based on real-world data rather than relying solely on initial clinical trial results. Collaborative initiatives such as Beneluxa, the Nordic Pharmaceutical Forum, and FiNoSe enable countries to share resources, coordinate negotiations, and achieve better pricing outcomes. These alliances aim to streamline the launch pipeline and control escalating costs through shared intelligence and collective bargaining.

There is increased openness among stakeholders to collaborate on data infrastructure, critical for accessing expensive, innovative medicines through outcomes-based agreements. Advanced technology solutions are simplifying execution and administration of complex agreements, improving tracking and evaluation. Many agreements, especially for lifecycle management brands, are manually intensive, requiring significant administrative effort. This complexity results in delays, suboptimal agreements, or gaps in patient access. The high degree of confidentiality surrounding agreements limits the sharing of insights and best practices. Oncology remains the most common therapy area for these agreements, driven by high unmet needs and robust data availability. In contrast, adoption for chronic diseases is less frequent due to greater complexity. Manufacturers and payers favour simpler models such as average weighted pricing or price caps for lifecycle management products, providing substantial benefits without extensive data requirements.

European pharmaceutical pricing has one constant: nothing stays constant. Throughout 2025, we tracked pricing policy shifts across major markets, HTA outcomes that surprised experienced access teams, and reimbursement timelines varying dramatically by therapeutic area and geography.

The data revealed critical insight: there is no longer a single European strategy that works. France, Germany, and the UK are diverging in their approaches. Countries once considered fast followers now assert independent pricing frameworks.

What this means: Success in Europe demands country-specific intelligence, not regional assumptions.

Biosimilars and the Originator Price Erosion Reality

In the coming years, the pharmaceutical market will see significant biosimilar influx, as nearly 110 biologics are projected to lose exclusivity in Europe by the end of 2032. This next wave will crowd the market, prompting manufacturers to adopt innovative pricing tactics as strategic differentiation.

Biosimilar pricing frameworks across European markets differ significantly, shaped by each country's regulatory structure, negotiation mechanisms, and tendering practices. EU4 markets typically employ regulated pricing, ensuring biosimilars launch at defined discounts from originators. France mandates 30-40% below, Italy 20-30% below. In contrast, the UK and Sweden follow free pricing, allowing greater flexibility but leading to more variable outcomes.

While EU4 relies on regional or hospital-level tenders, the Nordics utilise national and regional tenders, fostering stronger competition and transparency. This has significant implications for post-launch price erosion and market sustainability.
Humira, approved in Europe in 2003, lost patent exclusivity in 2018. The first biosimilar, Amgevita, was approved in 2017, setting the stage for one of the most competitive biosimilar launches in Europe. In EU4 and the UK, Amgevita's list price was 10-40% lower than Humira's. In the Nordics, Amgevita's list price was 16-56% lower, reflecting a more aggressive tender-driven environment.

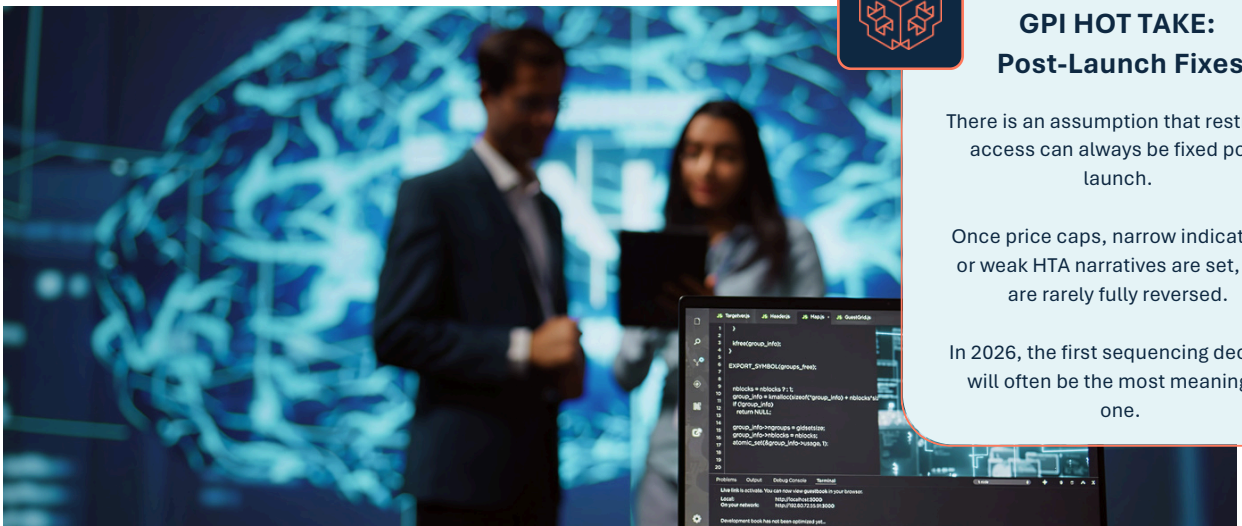
Significant list price erosion of Humira was observed only in Denmark at negative 37% and Norway at negative 49%, whilst other markets maintained relatively stable list prices. The absence of visible price erosion in EU4 and the UK may be attributed to confidential discounts and rebates, suggesting net price erosion occurred but remains unreported.

Intensifying price competition and aggressive tendering put pressure on biosimilar sustainability in mature European markets. With declining margins, some manufacturers shift supply to higher-priced regions like the US or scale back biosimilar R&D. These signals point to growing need for policy recalibration, one that tempers excessive price erosion whilst safeguarding long-term viability of the biosimilar ecosystem.

Humira biosimilar launches across Europe provided real-world testing of how originator pricing performs under competitive pressure. Our analysis tracked price erosion market by market, comparing published list prices against discounting reality negotiated privately.

The pattern was stark. Biosimilar competition is not merely market share erosion. It is pricing discipline under sustained pressure. Markets where originators maintained pricing were those where payers valued continuity. Everywhere else, price erosion was swift.

The lesson: Loss of exclusivity planning cannot begin 12 months before patent cliff. Pricing decisions made 2-3 years ahead determine how much value you retain when biosimilars arrive.



GPI HOT TAKE: Post-Launch Fixes

There is an assumption that restricted access can always be fixed post-launch.

Once price caps, narrow indications, or weak HTA narratives are set, they are rarely fully reversed.

In 2026, the first sequencing decision will often be the most meaningful one.

Transparency and the High-Cost Therapy Challenge

Rising drug costs and opaque pricing structures have led to mounting scrutiny of the pharmaceutical industry. As healthcare becomes more consumer-driven, the call for greater price transparency has grown, especially when facing rapidly escalating treatment costs. Healthcare price transparency involves clearly disclosing costs of medical services, treatments, and provider fees to consumers before care is delivered.

The financial burden of prescription drugs continues to swell. In 2023, US pharmaceutical spending reached 722.5 billion dollars. The cost of innovation is soaring. New drugs frequently launch at record-breaking prices. The median annual price for novel treatments hit 300,000 dollars in 2023, a 35% increase from the previous year. The growing push for price transparency is rooted in belief it can enable policymakers to negotiate more equitable pricing, curb potential price manipulation, and strengthen public trust. For patients, accessible pricing information supports better informed healthcare decisions and promotes fairer access to treatment.

The debate presents compelling arguments on both sides. Advocates argue transparency promotes fairness, accountability, and more efficient spending. But significant trade-offs exist, especially regarding international reference pricing. Public disclosure of net prices could disrupt the IRP system, which relies on confidential launch strategies and discounting to maintain profitability. Increased openness might reduce payer leverage, disincentivise market launches in lower-income countries, or homogenise pricing in competitive tenders.
Greater visibility can support fairer pricing across regions, enable better budget forecasting, and enhance accountability for manufacturers and payers. Yet these benefits may not translate into more equitable access, particularly in countries depending on steep discounts to afford breakthrough therapies.

High-profile cases illustrate how a lack of transparency amplifies challenges:

- Zolgensma launched at 2.125 million dollars per dose.
- Kymriah carries a list price of 475,000 dollars per infusion, with total treatment costs exceeding 1 million dollars.
- Yescarta pricing became a focal point in European debate, with Spanish authorities treating reimbursement figures as state secrets.
- Orkambi negotiations with NHS England stalled over its 105,000 pounds per patient per year price.

High-cost therapies faced mounting pressure throughout 2025. Payers demanded transparency beyond list prices. Health systems pushed for outcomes-based agreements. Patient advocacy groups called for affordability alongside innovation. For manufacturers, this created strategic tension. Products representing breakthrough science attracted the most intense scrutiny. Pricing models working for traditional small molecules felt inadequate for cell therapies with one-time administration.

What emerged: The transparency discussion is not moderating, it is accelerating. Companies embracing value-based pricing frameworks demonstrate advantage over those defending pricing opacity.

GPI HOT TAKE:
GLP-1 Access Innovation

GLP-1s are proving that access innovation now matters as much as clinical innovation.

With employers, PBMs, telehealth platforms, and cash-pay channels all playing a role, the winning GLP-1 strategies are those that help payers manage demand, not just justify price.

The ATMP Challenge: Transformative Value Meets Access Hurdles

Advanced Therapy Medicinal Products can deliver ground-breaking benefits by targeting underlying causes of diseases. These innovative treatments offer new opportunities for diseases with notable lack of effective treatments and potentially revolutionise therapeutic strategies.

Nevertheless, a primary challenge is affordability. Significant upfront costs must be paid for these one-off, potentially curative treatments, whereas patient benefits are realised only in the future. This directly impacts sustainability of healthcare system budgets, especially with ever-increasing numbers of ATMPs being developed and launched. This affordability concern, paired with uncertainty surrounding long-term clinical effect and risks, explains difficulties pharmaceutical companies face having ATMPs reimbursed. The case of Zolgensma in Germany highlights hurdles even highly promising ATMPs must navigate. Zolgensma is a one-off gene therapy for spinal muscular atrophy. Exceeding the turnover limit triggered full benefit assessment by G-BA, which determined additional benefit is not proven in any of four defined patient subgroups.

In patients with 5q SMA type 1, the pharmaceutical company presented comparisons of individual arms from different studies between Zolgensma and nusinersen, deemed unsuitable for benefit assessment due to large uncertainties and significant differences in considered patient populations. For other patient subgroups, the company did not present data for assessment of additional benefit compared to appropriate comparator therapy.

Still, it was recognised that Zolgensma may represent a relevant therapeutic option, given available evidence on medical benefit, disease severity, and scientific-medical society statements on current reality of care. However, requirement for routine practice data collection was put in place for better comparison with physician's choice of therapy, taking into account nusinersen and risdiplam. Unlocking successful market access for ATMPs requires engaging early with regulatory authorities, HTA bodies, and pricing committees to receive critical scientific and payer advice. Strategic planning must cover evidence generation requirements across the product lifecycle, working towards future HTA reassessments and novel payment models. Building comprehensive value stories capturing holistic value of the ATMP, including benefits and savings to patients, families, caregivers, healthcare systems, and society, remains essential.

Advanced Therapy Medicinal Products represented both promise and paradox throughout 2025. One dimension: genuinely curative treatments eliminating disease. The other dimension: price points challenging even well-resourced health systems. Access barriers were not merely willingness to pay. They were structural. Budget impact thresholds designed for chronic therapies cannot accommodate one-time curative treatments. Reimbursement systems built for pills struggle with manufacturing complexity.

For ATMP developers, 2025 crystallised uncomfortable reality: Scientific breakthrough does not guarantee commercial viability. Pricing strategy requires innovation matching the therapy itself.

New Drug Pricing Policies: MFN and the Global Pricing Domino Effect

On May 12, 2025, the US President signed Executive Order 14297, directing federal agencies to align domestic drug prices with the lowest prices paid in comparable developed nations, establishing Most Favoured Nation (MFN) pricing targets. By May 20, HHS defined MFN pricing as the lowest price in any OECD country with a GDP per capita ≥ 60% of the US average. The goal: reduce US drug prices, which often run 3–5 times higher than peer nations.

By July 31, the administration sent letters to 17 major pharmaceutical companies demanding they extend MFN pricing across Medicare, Medicaid and commercial payers, with a September 29 deadline. Non-compliance could trigger rulemaking, import expansion, antitrust actions, or tariffs. If fully implemented, MFN pricing could slash U.S. costs by 30–80%. But the risks are substantial. Confidential rebates abroad may distort true pricing comparisons. Lower US profits could push firms out of less lucrative global markets, harming access and innovation worldwide. Pricing could become dependent on foreign government decisions, potentially undervaluing breakthrough therapies. And MFN pressure could shrink margins for biosimilars, discouraging market entry and reducing competition over the next 3–5 years, undermining long-term savings.

The UK is facing similar tensions through its Voluntary Scheme for Branded Medicines (VPAG), which caps NHS spending on branded drugs. When sales exceed thresholds, companies must repay the excess. In August 2025, the government proposed raising the rebate rate to 22.9%, a level pharmaceutical companies rejected as unsustainable, warning of reduced investment and patient access delays.

Both policies reflect a global tightening of pricing frameworks. Whether through MFN benchmarking in the US or rebate caps in the UK, governments are asserting more control over pharmaceutical pricing, and the implications extend far beyond their borders. A price set in one market today becomes a reference point in another market tomorrow. And once that reference is locked in, pricing flexibility evaporates.

The policy shifts tracked in 2025, from proposed Most Favoured Nation clauses to IRA implementation to evolving HTA frameworks, weren't isolated regulatory changes. They represented a fundamental recalibration of how governments approach pharmaceutical value and pricing fairness. Most Favoured Nation provisions, in particular, are emerging as a critical planning consideration for 2026. MFN exposure doesn't appear overnight, it's created by the pricing and launch decisions companies make today. A product launches early in a lower-priced market to accelerate access. Twelve months later, that price enters multiple IRP baskets. Twenty-four months later, higher-value markets reference it as a benchmark, creating MFN-style pricing pressure. By the time the exposure is visible, pricing flexibility is gone.

The companies preparing for this now, before MFN becomes operational reality, are building MFN considerations into launch planning from day one, using global price tracking and IRP intelligence to model scenarios before committing to irreversible pricing decisions. The ones waiting to see how MFN plays out are already losing optionality.

GPI HOT TAKE: Turn risk into predictable outcomes

MFN exposure is created by the pricing and launch decisions you make today, not discovered later when flexibility is lost. GPI Pulse gives you control before it's locked in:

- Global price tracking - visibility into where lowest prices are forming and which prices drive MFN exposure
- IRP rules intelligence - understand how prices will be referenced and where MFN pressure surfaces next
- Launch sequence planning - model scenarios before committing to irreversible pricing decisions

GPI is assisting leading pharma companies in managing MFN as a strategic discipline, not a downstream problem.

Bridging 2025 and 2026: What the Patterns Reveal

Examining these 2025 developments, several patterns emerge with strategic significance:

First, regulatory complexity is increasing, not stabilising. More assessments, stricter evidence requirements, additional stakeholders with reimbursement veto power.

Second, pricing opacity is eroding systematically. Through formal transparency initiatives or informal intelligence sharing, payers have visibility into prices negotiated elsewhere.

Third, geographic assumptions are breaking down. The concept that a handful of reference markets determine global pricing is weakening.

Fourth, speed provides competitive advantage. Companies integrating pricing strategy early are launching faster and securing superior outcomes.

These are not isolated observations.
They are compounding trends.
In 2026, they will define who succeeds.

THE 2026 LANDSCAPE

Predictions from GPI Pricing Specialists

Introduction: Looking Forward

Understanding 2025 provides foundation. But pharmaceutical pricing teams need forward visibility, not speculation, but evidence-based prediction grounded in observable market dynamics, regulatory momentum, and strategic patterns emerging across our client base.

This chapter presents predictions from GPI's consulting team. These are strategic assessments derived from 63+ markets of continuous intelligence, advisory work with companies navigating these exact challenges, and pattern recognition across regulatory environments, payer behaviour, and competitive dynamics.

For each prediction, we examine the strategic implications, what this means for pricing teams making decisions right now, in Q1 2026.

Prediction One: Launch Sequencing Will Pivot from Speed to Strategic Control

By 2026, launch sequencing will pivot from speed to strategic control of price, evidence, and HTA risk across markets.

In 2025, pricing and market access teams faced several growing pressures: the need to prepare for EU joint clinical assessments, rising sensitivity to international reference pricing spillovers, and payer demands for more pragmatic, post-launch evidence. Together, these shifts exposed the limitations of traditional launch sequencing models that prioritised early revenue over long-term price integrity.

Policy Changes Observed in 2025

Europe:
From 12 January 2025, new oncology products and ATMPs with centrally filed MAAs were required to undergo EU Joint Clinical Assessment, with timelines linked to EMA submission and national HTA use of JCA outputs. This pushed companies to align EU evidence packages and potentially cluster or delay EU launches whilst JCA processes were being implemented, making high priority markets or non-EU launches more attractive first steps.

EFPIA 2025 work on unavailability and delay stressed that divergent national post-JCA processes and stricter budget controls can lead to later launches or non-launch in smaller or heavily constrained markets, increasingly becoming an explicit sequencing decision.

USA:
2025 analysis highlighted how a prospective US most favoured nation approach and tighter international reference pricing were expected to pull down US net prices using low EU list prices as benchmarks, directly exposing global launch sequences. As a result, manufacturers began reassessing which EU or low price markets to enter early, in some cases raising European list prices or delaying launches to protect US revenue and global price corridors.

What This Means for Pharma Teams

Teams should design launch sequences around price and evidence readiness, not approval timing. Build a global price corridor and map minimum evidence packages by wave. Explicitly define delay and non-launch markets early using pre-agreed criteria such as IRP role and JCA dependency. These should be strategic decisions to protect global price corridors, not outcomes of operational lag.

Align evidence generation with sequencing so that real-world and pragmatic data plans are timed to support first HTA assessments, not retrofitted post-launch. Elevate sequencing decisions to global governance level, as country-by-country execution models are no longer sufficient to manage cross-border pricing and HTA risk.

The traditional waterfall sequencing model, Germany first followed by UK and France, then tier-two Europe, reflected rational strategy when IRP linkages were looser and HTA processes less coordinated. That world is disappearing. In 2026, companies continuing to apply traditional waterfall sequencing without critical evaluation will create avoidable commercial damage.

GPI HOT TAKE:

Launch Sequencing Myth

"You should always launch where the price is highest first."

In a world of MFN, IRP and net price transparency, the right first market is the one that gives you the best long-term price corridor, not the highest headline list price.

Prediction Two: UK QALY Threshold Rise Will Reshape Value Conversations

The Government confirmed increase in NICE cost-effectiveness threshold from £20,000-£30,000 to £25,000-£35,000 per QALY from April 2026 will pivot UK market access strategy from threshold compliance to strategic value storytelling and prioritised sequencing for innovative therapies.

Why This Matters

In December 2025, the UK Government announced its first change to the core QALY threshold in over 25 years, increasing the range to £25,000-£35,000 per quality-adjusted life year to support innovation and better align NHS spending with the ambition for growth in life sciences. The adjustment is expected to allow NICE to recommend an additional three to five medicines or indications per year compared with the old range.

This change goes beyond a technical update to NICE economics. It reshapes how value will be tested, defended, and negotiated in the UK. Whilst higher thresholds create greater pricing headroom, they also sharpen payer expectations. Treatments will need to demonstrate clear, meaningful improvement over existing standards of care, not just incremental benefit, particularly as affordability pressures across the NHS remain intense.

What This Means for Pharma Teams

Re-frame value narratives. With a broader QALY range, success will no longer come from narrowly optimising to an ICER threshold. Teams should be prepared to clearly explain why their therapy matters, showing tangible improvements in real-world outcomes, reduced burden on patients and carers, and wider system benefits that resonate with NHS priorities.

Re-prioritise pipeline sequencing. Higher thresholds may open the door for more innovative and uncertain assets, but not all products should move first. Launch sequencing decisions will need to balance clinical impact, evidentiary risk, and the role each asset plays within the wider portfolio, rather than treating the UK as a default early-launch market.

Anticipate deeper payer dialogue. The question from payers will increasingly shift from "Does this meet the threshold?" to "Is this the best use of limited NHS resources right now?" This raises the importance of early evidence planning, clear commercial strategy, and proactive engagement that anticipates affordability and prioritisation concerns.

In 2026, UK strategy will be defined by value articulation and portfolio prioritisation, not threshold arbitrage.

Prediction Three: JCA Will Reshape Patient Access Patterns Across Europe

By 2026, the EU Joint Clinical Assessment process will be a defining influence on patient access across member states, not because it guarantees faster uptake, but because it reshapes where, how, and when patients gain access to innovation.

Why This Matters

With the EU HTA Regulation now in force, JCAs have moved from concept to reality, generating the first pan-European clinical assessments for new therapies, including oncology and advanced therapies, and setting a blueprint for broader rollout through 2030.[1,2] They consolidate relative clinical effectiveness and safety evidence into a single shared assessment, reducing duplication and aligning stakeholder understanding of core data across countries. [3]

However, the JCA is not a universal passport to reimbursement. It provides a common clinical foundation that all member states must give due consideration, but national pricing, budget impact, and health-system priorities remain sovereign decisions.[3] As a result, the JCA will shape access patterns in nuanced ways.

Smaller and resource-constrained markets may benefit, as shared clinical assessments reduce local evaluation workload and accelerate internal deliberations.[4] At the same time, any weaknesses or gaps in the evidence identified at the JCA level can echo across multiple markets, potentially delaying access in several countries simultaneously. JCA broader evidence requirements and compressed timelines will also raise the operational bar for manufacturers, meaning clinical development and access planning must be integrated earlier and more fully than ever before.[2]

What This Means for Pharma Teams

Build evidence for Europe, not country by country. JCA dossiers require broader PICOs and deeper justification for endpoints and comparators.[2] National access strategies must anticipate local interpretation of joint data. A strong JCA report provides the foundation, but it does not eliminate the need for tailored pricing and reimbursement engagement.[3]

Patient access timing will vary, not converge. Whilst JCA may reduce clinical uncertainty, countries will still negotiate price, budget impact, and prioritisation, meaning access acceleration will be uneven.

In 2026, JCA will not be a straight path to faster access. Instead, it will intensify the clinical evidence game, amplifying both opportunities and risks for patient access across Europe.

GPI HOT TAKE:

GLP-1 Competition Evolution

The GLP-1 battle is far from over. Competition will extend beyond obesity into cardiovascular, neurological, and musculoskeletal areas, but this will be less a pricing war and more an access war.

Companies will need innovative contracting strategies and patient support programmes, with an increasing shift toward the private market.

Sources

1. https://remapconsulting.com/services/launch/joint-clinical-assessment/
2. https://remapconsulting.com/hta/joint-clinical-assessment/jca-evidence-generation/
3. https://remapconsulting.com/hta/what-is-the-joint-clinical-assessment-and-what-does-it-entail/
4. https://mtechaccess.co.uk/eu-jca/

What These Predictions Mean Together

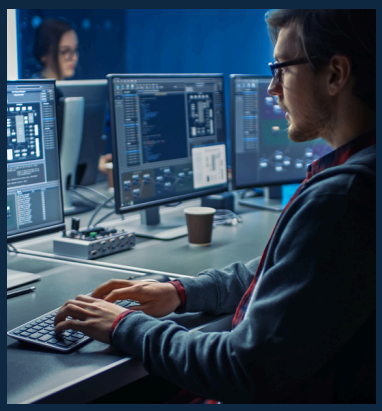
Examined individually, each prediction represents a significant strategic challenge.

Examined collectively, they reveal a fundamental shift in how pharmaceutical pricing must operate.

The companies that will thrive in 2026 treat pricing as strategic discipline integrated across asset lifecycle, not pre-launch negotiation. They model IRP exposure continuously, not quarterly. They integrate evidence generation with commercial strategy from protocol design. They make launch sequencing decisions based on sophisticated scenario analysis, not historical precedent. They invest in intelligence platforms and advisory support that enable proactive positioning rather than reactive response.

The companies that will struggle continue treating pricing as late-stage function, react to IRP implications rather than anticipating them, generate evidence independent of commercial strategy, follow traditional sequencing because that is how it is done, and rely on outdated intelligence and internal assumptions.

The gap between these two groups will widen throughout 2026. And it will be visible in time-to-market, pricing outcomes, and commercial performance.



From Pipeline to Payer: Integrating Pricing Strategy Across the Asset Lifecycle

Strategic Imperative for 2026

FROM PIPELINE TO PAYER:

Integrating Pricing Strategy Across the Asset Lifecycle

For many pharmaceutical organisations, pricing remains something that “happens later”, a downstream exercise triggered by pivotal data, regulatory milestones, or looming launch dates. Yet in an era of heightened payer scrutiny, accelerating competitive intensity, and global reference pricing, this approach is no longer fit for purpose. Pricing is not an event; it is a capability. And it must be embedded across the entire asset lifecycle, from early pipeline decisions to post-launch optimisation.

An integrated pricing strategy, one that evolves alongside clinical, regulatory, and commercial development, can be the difference between a successful launch and a value story that never fully lands with payers.

The Cost of Late-Stage Pricing

When pricing strategy is deferred until late development, organisations often find themselves constrained by earlier decisions. Trial designs may not support meaningful differentiation. Target product profiles may overpromise relative to payer expectations. Forecasts may assume prices that are misaligned with real-world willingness to pay.

The result is a familiar pattern: last-minute scenario planning, reactive discounting, and difficult trade-offs between access and revenue. These challenges are rarely the result of poor execution at launch; they are the consequence of pricing not being treated as a strategic input early enough.

Pricing as a Lifecycle Discipline

Leading organisations are reframing pricing as a lifecycle discipline that informs decision-making at every stage:

Early pipeline and asset selection:
Pricing strategy should begin as soon as an asset enters the pipeline. Early price potential assessments help teams understand whether a therapy's anticipated clinical profile can sustain meaningful reimbursement in the context of existing and future standards of care. This perspective can influence portfolio prioritisation, indication sequencing, and even investment decisions.

At this stage, structured price forecasting grounded in analogs, epidemiology, and payer behaviour provides a reality check. Access to comprehensive historical pricing and reimbursement data across markets enables teams to anchor early assumptions in precedent, rather than aspiration.

Clinical development and evidence generation:
As assets progress, pricing strategy should actively shape evidence plans. Payers are increasingly focused on outcomes that go beyond regulatory endpoints: comparative effectiveness, durability of benefit, and budget impact. Integrating pricing considerations into trial design ensures that evidence generation supports a credible and defensible value narrative.

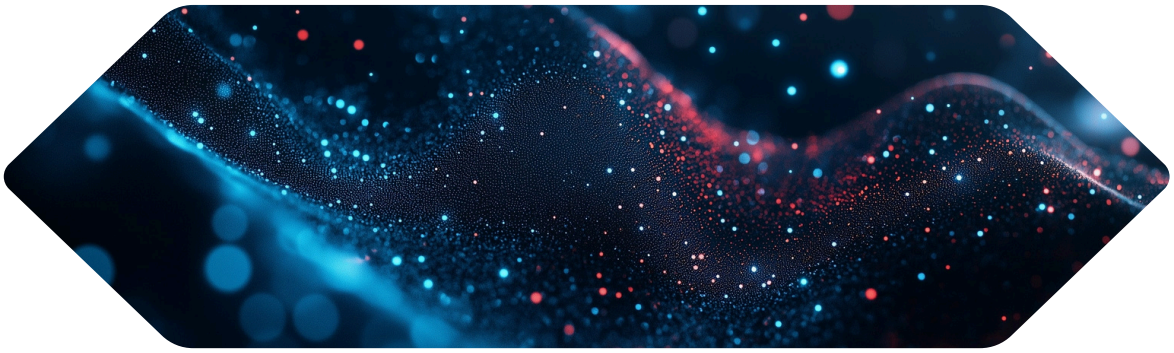
This is particularly critical in crowded or fast-moving therapeutic areas, where modest differences in clinical outcomes can translate into significant pricing consequences. Insights drawn from prior reimbursement decisions and comparator pricing trajectories can help teams anticipate where differentiation will matter most.

Pre-launch and launch readiness:

In the pre-launch phase, pricing strategy becomes more concrete, but it should not start from scratch. Robust price forecasting models allow teams to test scenarios across geographies, assess the implications of different launch sequences, and anticipate the effects of international reference pricing.

Equally important is consistency. A centralised, longitudinal view of pricing and reimbursement, capturing list and net prices, discounts, access conditions, and outcomes across markets, allows teams to ground decisions in evidence rather than assumptions. Comprehensive pricing and reimbursement databases such as **GPI Pulse™** can support this by providing a single source of truth, facilitating alignment across global, regional, and local teams at a time when misalignment can be costly.

Post-launch optimisation and lifecycle management:
Pricing does not end at launch. Real-world evidence, competitor entry, label expansions, and policy changes all necessitate ongoing refinement. Organisations that continuously monitor pricing performance and payer behaviour are better positioned to defend value, adapt contracting strategies, and extend the commercial life of their assets. Here, the integration of forward-looking forecasting with live, market-level pricing and reimbursement intelligence enables teams to move from reactive adjustments to proactive planning.



The Role of Tools and Mindset

Technology alone is not the answer, but it is a powerful enabler. Advanced price forecasting tools provide a structured way to explore uncertainty and make trade-offs explicit. Comprehensive pricing and reimbursement databases help create institutional memory, reducing reliance on anecdote and individual experience, and enabling faster, more confident decision-making.

However, the real transformation is cultural. Integrating pricing across the asset lifecycle requires cross-functional collaboration, early engagement, and a shared understanding that pricing is not simply a number; it is a strategic expression of value.

GPI HOT TAKE:
Looking Ahead

As payers demand greater justification for price and policymakers continue to challenge traditional pricing models, the organisations that succeed will be those that treat pricing as a continuous, integrated process.

By embedding pricing strategy from pipeline to payer, companies can make better decisions earlier, launch with confidence, and sustain value over time.

In a complex and evolving environment, integrated pricing is no longer a best practice; it is a prerequisite for success.

HOW LEADING COMPANIES ARE RESPONDING

Case Study 1: Navigating IRP Complexity in the Gulf

The Challenge

A neuroscience-focused biopharmaceutical company faced a critical decision: whether to launch Product X for congenital adrenal hyperplasia in GCC markets before Europe. GCC countries increasingly reference European pricing, creating potential IRP lockdown if sequencing went wrong. The client needed rapid, validated intelligence to guide their launch strategy. Timeline: five working days.

The GPI Approach

GPI deployed a three-stage rapid intelligence framework:

1. IRP Landscape Research

- Leveraged GPI Pulse internal IRP database to map pricing rules across all six GCC countries
- Conducted price evolution analysis for three analogue products to assess European pricing influence on GCC dynamics
- Identified formal versus informal IRP mechanisms and reference basket composition

2. Regulatory Intelligence

- Evaluated expedited approval pathways leveraging prior FDA authorisation
- Assessed GCC-DR (Gulf Central Committee for Drug Registration) joint approval routes
- Mapped 90-day fast-track mechanisms available across GCC markets

3. Strategic Analysis

- Modelled post-launch price decline scenarios based on analogue behaviour
- Quantified IRP exposure by market, identifying strongest downward pricing pressures
- Developed phased launch strategy prioritising markets by pricing sustainability

The Outcome

Three critical insights delivered within five days:

1. Managed Price Corridor Strategy:

Launch all GCC markets prior to Europe to establish controlled pricing baseline, protecting EU pricing strategy whilst capturing GCC revenue potential.

2. UAE as Strategic Entry Point:

Prioritise UAE first-launch to maximise price potential, create regional pricing anchor, and accelerate patient access in the region's largest market.

3. Phased Market Prioritisation:

Phase 1 focus on Kuwait, Qatar, Bahrain (looser IRP application, higher price sustainability); Phase 2 consideration for Saudi Arabia, Oman (stronger downward pricing pressure). Result: optimised long-term price integrity across the GCC region.

Case Study 2: Streamlining Feasibility Workflows at Scale

The Challenge

A global CRO conducting multiple clinical trial feasibility assessments simultaneously faced increasing pressure to deliver faster answers across multiple therapy areas and markets.
With turnaround expectations around two weeks, the feasibility team struggled with fragmented data, manual validation, and rework. Each assessment required analysis across multiple data types and sources, with variable quality and availability. Balancing speed with confidence in sponsor-facing recommendations was becoming increasingly difficult.

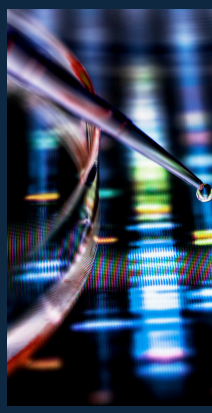
The GPI Approach

The team subscribed to GPI Pulse for three years, covering all therapy areas across 63 markets, with 45 users embedded across the feasibility function. The platform became part of day-to-day workflows: users search by indication or drug class, retrieve structured insights on commercial availability, regulatory approvals, reimbursement decisions, and pricing data, then export graphs and Excel files for analysis and sponsor presentations. Quarterly business reviews provided feedback loops and ongoing access to GPI support ensured clarity on data sources and methodology.

The Outcome

Approximately **100 unique searches per month supported completion of multiple feasibility assessments involving large data volumes**.
Confidence in recommendations increased, driven by transparent data sources and collection methods, improving quality assurance for clinical trial recommendations. Sponsor relationships strengthened, with GPI support responding to data queries within 24 hours, helping teams address uncertainties quickly. The CRO transformed feasibility from fragmented research into consistent, scalable workflow delivering faster assessments without compromising credibility.

Case Study 3: Forecasting Competitive Launch Timelines to Strengthen Market Entry Strategy



The Challenge

A pharmaceutical company advancing a novel therapy for rare oncology indications required evidence-based visibility into competitor launch timing across 45 global markets to guide its launch strategy.

Fragmented regulatory and HTA information made it difficult to identify when and where competitor products were expected to launch, creating uncertainty for internal planning.

The client sought validated competitor launch estimates to align pricing, access, and commercial readiness activities with anticipated market dynamics.

The GPI Approach

GPI employed a structured three-stage framework to forecast competitor launch timelines:

1. Data Curation & Analogue Identification

- Defined analogue selection criteria to identify relevant comparator products across target markets
- Consolidated regulatory, HTA, and indication data using GPI Pulse and validated secondary sources
- Established consistent parameters to ensure comparability across product types and markets

2. Modelling & Validation of Launch Estimates

- Analysed approval-to-launch intervals for identified analogues to derive predictive benchmarks
- Validated findings through regulatory and HTA databases to close data gaps
- Integrated findings into a robust model to estimate competitor launch timelines by market

3. Insight Integration & Client Alignment

- Developed comprehensive storyboard summarising methodology, key assumptions, and findings
- Delivered structured briefing sessions to align insights with client strategy and market access planning

The Outcome

Non-HTA markets demonstrated accelerated approval-to-launch timelines (often within 6 months), whilst HTA-driven markets extended launch readiness by approximately 12-19 months. This created distinct early- and late-launch waves across the 45-market scope.

Several smaller or non-traditional markets emerged as early launch countries due to streamlined access pathways, challenging traditional EU5-first assumptions. Launch planning needed to be grounded in actual regulatory and access efficiency rather than precedent alone.

Faster-access countries enabled early availability, initial revenue capture, and real-world evidence generation—providing a platform for refining positioning and value messaging before complex HTA submissions.

The data-driven understanding of competitor launch sequencing equipped the client to design a phased, evidence-backed global launch strategy, optimising readiness, access planning, and competitive positioning for its rare oncology product.

Your 2026 Action Plan

Turning Insight Into Strategy

Turning Insight Into Strategy

We have examined 2025 developments, analysed 2026 emerging landscape, and explored why lifecycle integration has become imperative. But insight without action generates noise.

This chapter translates everything into concrete next steps.

Priority One: Stress-Test Your IRP Assumptions

International reference pricing is no longer background risk requiring quarterly monitoring. It is live variable requiring continuous stress-testing and scenario planning. The tariff uncertainty explored in Chapter 2, combined with net price transparency pressures discussed in Chapter 3, means traditional IRP assumptions no longer hold.

Map your complete IRP exposure across all reference markets. Identify which countries reference which price points, understanding both formal linkages and informal intelligence sharing between payers. Model worst-case scenarios where reference markets adjust upward simultaneously. Stress-test launch sequences against IRP chain reactions.

Establish continuous IRP monitoring, not quarterly reviews. Track reference market price changes weekly. Build trigger points for strategic response when thresholds are breached. Integrate IRP considerations into every launch decision, not as compliance check but as strategic determinant of market entry timing and sequencing.

GPI HOT TAKE:
IRP Real Risk

The real risk of IRP isn't lower prices, it's slower access.

To protect global price integrity, companies may delay or limit launches in lower-price markets.

In 2026, IRP will increasingly be recognised as an access policy as much as a pricing one.

Priority Two: Integrate HTA Thinking Earlier

The Joint Clinical Assessment framework discussed in Chapter 2 and Chapter 3 fundamentally changed when HTA thinking must begin. Companies waiting until Phase III data lock to consider payer evidence requirements will struggle. Those integrating HTA perspectives from protocol design will secure faster pathways.

Audit your evidence generation timeline against HTA requirements. Identify gaps between what Phase III will deliver and what JCA or national HTAs will demand. Where endpoints, comparators, or subgroup analyses are missing, determine if protocol amendments are feasible or if post-hoc analyses can address gaps.

Pilot HTA integration in one therapeutic area. Bring market access and HEOR colleagues into Phase II discussions, not Phase III readouts. Test whether early payer advisory boards can shape evidence generation before commitments are locked. Measure whether this integration accelerates national reimbursement timelines following JCA completion.

The companies securing reimbursement in 12 months rather than 24 will be those treating evidence generation as commercial strategy, not regulatory compliance.

Priority Three: Rethink Launch Sequencing

Traditional launch sequencing, the Germany-first waterfall followed by UK and France, reflected rational strategy when IRP linkages were looser and HTA processes operated independently. That world is disappearing. Chapter 3 outlined why 2026 will force fundamental rethinking of which markets launch first, second, and which markets may not launch at all.

Challenge your default sequencing assumptions. If Germany remains first launch, document why based on current IRP dynamics, not historical precedent. If alternative sequencing protects global price corridors better, model the trade-offs explicitly. Consider whether non-EU markets or high-price outliers should move earlier to establish defensible reference points.

Model launch sequencing scenarios across your pipeline. For each asset, map best-case, base-case, and worst-case sequences. Quantify revenue implications, IRP exposure, and market access risk for each scenario. Elevate sequencing decisions to global governance level, requiring sign-off from commercial leadership, not delegation to country affiliates.

Launch sequencing in 2026 is strategic architecture, not operational logistics. Treat it accordingly.

Priority Four: Embrace Transparency On Your Terms

The transparency pressures detailed in Chapter 2, from Spanish court rulings on Yescarta pricing to NHS negotiations over Orkambi, are not moderating. They are accelerating. The question is not whether pharmaceutical pricing becomes more transparent, but whether companies shape transparency strategically or have it imposed reactively.

Develop proactive value communication frameworks. Articulate why your therapy merits its price through outcomes data, budget impact models showing net savings and real-world evidence demonstrating performance. Control the narrative before payers or media define it for you.

Explore outcomes-based agreements where appropriate. Performance-based pricing, indication-based pricing, or coverage with evidence development can address payer uncertainty whilst maintaining list price integrity. These agreements require data infrastructure and administrative capability, but they convert transparency pressure into commercial opportunity.

Transparency, handled strategically, strengthens negotiating position. Transparency imposed reactively weakens it. Choose which position you occupy.

Priority Five: Invest in Lifecycle Integration

Pricing decisions made at asset lifecycle inflection points, protocol lock, regulatory filing, first launch, loss of exclusivity, compound across commercial lifetime. Companies treating pricing as pre-launch negotiation rather than lifecycle discipline leave value on the table and create avoidable risk.

Map decision points across your asset lifecycle where pricing strategy intersects with development, regulatory, or commercial milestones. Identify where pricing considerations should influence upstream decisions but currently do not. Common gaps include Phase II endpoint selection made without payer input, regulatory strategy proceeding without IRP implications assessed, and launch sequences set without HTA readiness evaluated. Pilot integrated approach on one asset. Convene cross-functional governance covering clinical development, regulatory affairs, market access, and commercial strategy. Test whether early pricing integration changes upstream decisions and whether those changes improve downstream outcomes.

The integration challenge is not technical. It is organisational. Pricing cannot integrate across lifecycle if it reports into commercial function reviewing decisions after they are made. It requires seat at the table when decisions are being shaped.

Where GPI Fits

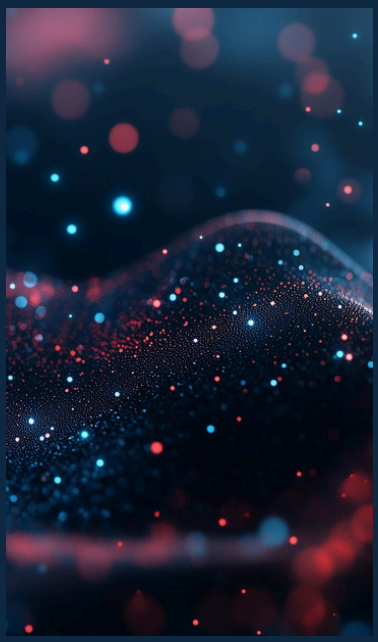
These five priorities require both intelligence and execution capability. GPI provides both through integrated platform and advisory support.

Our GPI Pulse platform delivers continuous intelligence across 63+ markets, tracking pricing decisions, HTA outcomes, and competitive dynamics in real-time. This is the foundation for stress-testing IRP exposure, modelling launch sequences, and anticipating payer requirements.

Our strategic advisory practice translates intelligence into action. We work alongside pricing and market access teams to design evidence generation strategies, navigate JCA requirements, optimise launch sequencing, and structure outcomes-based agreements. We bring pattern recognition from working with every major pharmaceutical company globally, combined with market-specific intelligence no internal team can replicate.

The combination of platform intelligence and hands-on advisory accelerates decision-making and improves outcomes. Companies treating pricing as strategic discipline, supported by validated intelligence and experienced guidance, will establish competitive advantages in 2026 that compound over time.

2026 will separate pricing teams executing with strategic clarity from those reacting to circumstances. That is where GPI expertise creates measurable client advantage.



Ready to transform your launch strategy?

The inflection point is here. Let us discuss how GPI can support your specific priorities.

BOOK A MEETING

+44 (0) 203 369 0039
info@globalpricing.com


GPI
Global Pricing
INNOVATIONS