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OBJECTIVE

The global payer environment is undergoing transformative changes, driven by new policy introductions and significant updates to the existing frameworks. The first half of 2025 has already underscored a decisive shift in global pricing and market access (P&MA) as evident from the payers doubling down on cost-containment levers, tightening HTA frameworks, and tying pricing to industrial and supply resilience goals.

Looking ahead, the second half of 2025 and beyond will test pharmaceutical manufacturers’ ability to be more agile, evidence-led, and globally coordinated as policies converge on value, sustainability, and equitable access.


We explored how these payer policies will impact pharmaceutical manufacturers and patient access to innovative therapies.

METHOD

Secondary research was conducted to identify and analyse highly impactful six key trends focusing on their individual opportunities and challenges, particularly from the lens of pharma manufacturers.



ACCESS & TRANSPARENCY

Focused on increased transparency with additional published data imparting guidance to future assets





HTA REFORMS & INNOVATION INCENTIVES

Focused on increasing importance of value demonstration, updated evaluation criteria, recognizing innovation impacting future assets’ P&MA potential




COST-CONTAINMENT MEASURES

Focused on stronger pricing headwinds thereby impacting future assets’ commercial potential




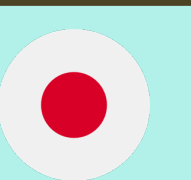







ADAPTATIONS TO REGULATORY/HTA FRAMEWORKS & TIMELINES

Focused on expediting market authorization/ HTA timelines thereby expediting patient access



RESULTS

MARKET >>						
 POLICY OVERVIEW	<ul style="list-style-type: none">The GLOBE Model to implement drug pricing reforms, particularly the Most-Favored-Nation (MFN) pricing policyBenchmarks US drug prices to lowest comparable global rates targeting high-cost drugsTariffs remain in play but uncertain	<ul style="list-style-type: none">The Medical Research Act abolishes the use of International Reference Pricing (IRP) thereby increasing opacity but requiring pharma to gear up for new AMNOG negotiation tactics	<ul style="list-style-type: none">NRDL prepping Category C: innovative, high-price drugs get hybrid reimbursement model (gain coverage via commercial insurance schemes)More frequent and dynamic NRDL updatesLower threshold of market access ensuring equal national treatment for foreign businesses and upholding fair market competition	<ul style="list-style-type: none">Major HTA and pricing control tightening with cost-effectiveness now at the core of premiumsBudget impact and QALY thresholds prioritizedAggressive repricing on the horizon	<ul style="list-style-type: none">Ministry of Health launches transparent funded drug reports which are now, detailed conditions, criteria, and pricing rationale published for every reimbursed medicine	<ul style="list-style-type: none">Health Canada and HTA agencies (CDA, INESSS) are moving toward “aligned review” which means parallel regulatory and HTA submissions to accelerate time-to-market, particularly for biosimilars and new indications
 P&MA IMPACT	<ul style="list-style-type: none">Launch sequencing disruptedRisk of market withdrawal in low-price countriesRebates likely to be destabilizedSpotlight on US manufacturing	<ul style="list-style-type: none">Weakens EU external reference corridorsParallel trade incentives are reduced, as confidential prices are unavailable to parallel importers/exporters	<ul style="list-style-type: none">Hybrid pricing and reimbursement models enables more flexible negotiation of prices, particularly for innovative therapiesAccelerated addition and removal of drugs in NRDL based on therapeutic innovation, clinical value, and real-world data	<ul style="list-style-type: none">Stricter QALY thresholds and budget impact caps puts premium pricing under direct threatRise in market access hurdles as health economic dossiers become central to reimbursement decisions	<ul style="list-style-type: none">Competitors, payers, patient groups, and clinicians will be able to compare across products and use Spain’s rationale as a precedent in pricing negotiations elsewhere in EuropePressure on “premium” narratives	<ul style="list-style-type: none">Faster access, but tougher scrutiny with less room available to adjust HTA strategy after regulatory approvalPotentially a price pressure on biologics with expedited biosimilar uptakeReduced regional variations
 POV ON PHARMA TO-DOS	<ul style="list-style-type: none">Scenario-planning across OECD anchorsPreparation of outcomes-based contracts as alternatives, as applicable	<ul style="list-style-type: none">Rebuild EU price corridor modelsPrepare deeper confidential discounting (alternative negotiation tactics)	<ul style="list-style-type: none">Anticipate a dual pathway reimbursement environment (NRDL plus Category C commercial insurance) that broadens options but requires nuanced navigationNeed to strengthen collaborations with Chinese payers, insurance bodies, and regulators	<ul style="list-style-type: none">Generate robust cost-per-QALY and real-world evidence for Japanese populationsBuild stronger budget impact models with mitigation strategies (e.g., risk sharing)Sequence launches strategically to avoid triggering early, aggressive repricing	<ul style="list-style-type: none">Build pricing cases that might withstand external scrutinyStrengthen clinical and economic differentiation, as applicableProactively engage clinicians and patient groups, who will now see exactly how the Ministry of Health values the product	<ul style="list-style-type: none">Early and integrated regulatory and HTA planningBiologics innovators should strengthen defense strategies amidst accelerated biosimilar launchesCoordinate pan-Canadian engagement with Health Canada, CDA, INESSS, and provincial payers

CONCLUSIONS

- These payer policies will potentially impact stakeholders across the healthcare value chain, from policymakers to patients
- 2025 has been the year payers have reset evidence standards and tie pricing and market access to commercial strategy. The winners? Teams that move early, evidence-first, locally aligned and who quickly adapt to these dynamically evolving global payer policies

SUPPORTED BY

In the loop

Policy updates from the world of pricing and market access

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