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Navigating the Global Pricing Policy Landscape and Leveraging AI for Strategic Insights

Tuesday, 11 November

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Speakers



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Learning objectives

1. Gain an understanding of the evolving global pricing landscape, and the influence of international market dynamics
2. Understand how current and proposed United States (US) policy changes may affect global pricing benchmarks and cross-border strategies
3. Learn about the role of proactive planning and early pricing scenario modeling in preparing for global product launches and policy changes
4. Discover how artificial intelligence can play a role in shaping pricing strategies and optimizing decision-making in the context of global markets
5. Explore the challenges and limitations of using artificial intelligence in pricing predictions, including data quality, transparency, and ethical considerations
6. Engage in collaborative exercises to apply insights on cross-border pricing challenges and policy navigation among peers

Agenda



Welcome and objectives



Global pricing policy
and landscape



Strategic value of pricing
scenarios



AI-powered pricing
scenario tool



Key takeaways and close



Global pricing policy landscape



Neil Grubert, MA

Independent Global Market Access Consultant
Neil Grubert Consulting

Polling Question

What is the biggest challenge you face in global pricing policy today?

Three Most-Favored-Nation (MFN) deals negotiated to date



- Companies must provide every state Medicaid program with drugs at MFN prices, guarantee MFN prices on all new innovative medicines, repatriate increased foreign revenue on existing products, and offer deep discounts on direct-to-consumer distribution via TrumpRx starting in 2026.
- In return, companies will benefit from a three-year exemption from the 100% Section 232 tariff—on condition that they invest further in manufacturing in the United States.
- Deals with Eli Lilly and Novo Nordisk—which would reduce the cost of anti-obesity medications to \$149 per month—are said to be close to completion.
- MFN pricing will reportedly be based on prices after fees and rebates in Canada, Denmark, France, Germany, Italy, Japan, Switzerland, and the UK.

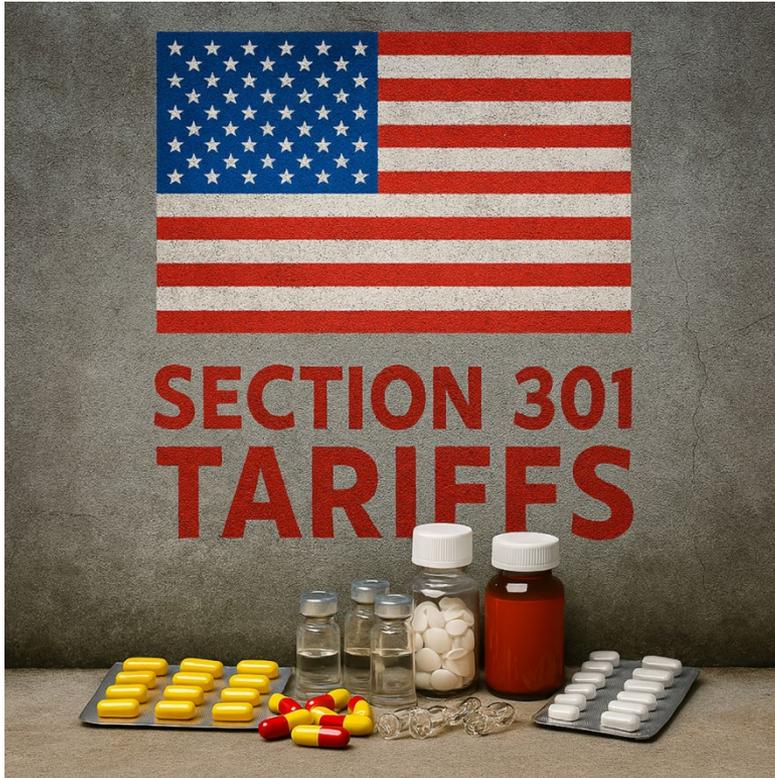
Nine drugs selected for FDA Commissioner's National Priority Voucher (CNPV) pilot program

Drug	Developer	Indication/use	Development status
DB-OTO (gene therapy)	Regeneron	Genetic deafness	Not yet licensed anywhere
Daraxonrasib (RMC-6236)	Revolution Medicines	Pancreatic ductal adenocarcinoma	Not yet licensed anywhere
Disc-1459 (bitopertin)	Disc Medicine	Porphyria	Not yet licensed anywhere
Pergoveris (INN-follitropin alfa and lutropin alfa)	EMD Serono	Infertility	Licensed in Europe and other markets
Tzield (teplizumab)	Sanofi	Treatment of stage 3 type 1 diabetes	Licensed in the US and UK for delaying the onset of stage 3 type 1 diabetes
Cytisinicline	Achieve Life Sciences	Nicotine dependence	Licensed in Europe for smoking cessation
Oxervate (cenegermin-bkbj)	Dompé Farmaceutici	Non-arteritic anterior ischemic optic neuropathy	Licensed in the US, EU, Australia, and Canada for neurotrophic keratitis
Ketamine	Phlow	General anesthesia	Commonly available
Augmentin XR (co-amoxiclav)	USAntibiotics	Broad-spectrum antibiotic	Commonly available

- A CNPV promises to slash review times from an average of 10-12 months to just 1-2 months.
- FDA Commissioner Marty Makary said of Regeneron's DB-OTO gene therapy: "We're hearing the company may make it available either at an extremely low price or for free, which of course is part of a national priority to make drugs more affordable."
- Makary disclosed that the FDA is inviting its reviewers to nominate drugs they believe "may potentially look amazing."

Key: FDA – Food and Drug Administration.

A whole new pharma tariff



- *The Financial Times* reports that preparations are under way for an “imminent investigation” under Section 301 of the Trade Act of 1974 into “whether any US trading partners are underpaying for drugs.” The probe would “lay the ground for a fresh barrage of tariffs.”
- Section 301 monitors whether another country’s trade practice violates trade agreements or “is unjustifiable and burdens or restricts United States commerce.”
- The 2025 Special 301 Report states that “pricing and reimbursement systems in foreign markets that do not appropriately recognize the value of innovative medicines and medical devices, present significant concerns. Such systems undermine incentives for innovation in the health care sector. It is important that trading partners contribute fairly to research and development for innovative treatments and cures.”

National differences over EU pharmaceutical package



- Malta rejected the latest version of the text because it opposed maintaining the baseline regulatory data protection period at eight years and considered the access obligations to be inadequate.
- Estonia and Cyprus were among countries that were uneasy about what they perceived to be undue concessions to the pharmaceutical industry.
- Portugal and Czechia criticised the lack of guarantees of improvements to equitable access to medicines.
- Germany, France, Italy, Denmark and Sweden—all home to leading pharmaceutical companies—opposed the idea of modulated data protection.
- Denmark aims to finalise the pharmaceutical package before the end of the year.

First confidential rebate in Germany



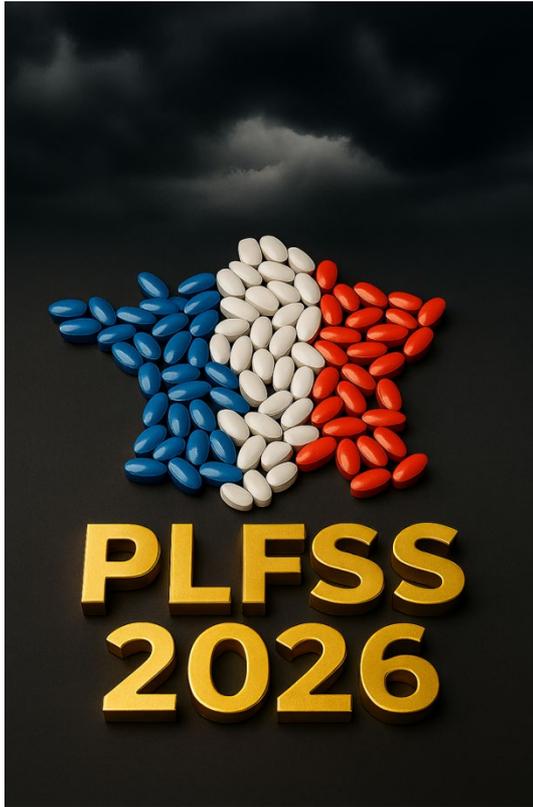
- Eli Lilly's Mounjaro (tirzepatide) is the first drug to use a new provision for rebated prices to be kept confidential.
- The company has reached agreement with the GKV-Spitzenverband on "the framework conditions for the contract on the reimbursement amount."
- The provision is intended to "give pharmaceutical companies more negotiating leeway without influencing pricing in other countries."
- In return for confidentiality, manufacturers must grant an additional price reduction of 9% on the rebated price.
- Lilly will notify physicians that the list price "does not play a role in their economic considerations," including the duty to ensure that their prescribing is "sufficient, appropriate and economical."

AMNOG and pricing reform will feature in the Pharma Dialogue



- Early benefit assessment and price negotiation will be “discussed and reviewed to see if reform is needed.” The review will be part of the Pharma Dialogue, which is set to resume in November.
- The Coalition Agreement pledged to continue the Pharma Dialogue and Pharmaceutical Strategy and further develop AMNOG in respect of the rebate guidelines and personalised medicine.
- The objective is to “enable access to innovative therapies and medicines while ensuring sustainable funding.”
- The Bundesrat (Federal Council) recently called for a swift reform of AMNOG that takes account of incentives for R&D, access and affordability, and the particular characteristics of ATMPs and personalised medicine.
- The health insurance funds are pressing for increased cost containment on pharmaceuticals.

Pharma alarm at PLFSS 2026



- The health insurance budget will be €270.4bn—an increase of only 1.6%.
- Companies will be required to pay a base contribution of 0.2% of their annual turnover plus 1.6% of their sales to the National Health Insurance system.
- Price cuts of €1.4bn will be imposed on medicines (including \$200mn on generics).
- The early access scheme will be limited and focused on drugs that lack sufficient clinical data. It will apply only to drugs that do not yet have a marketing authorisation. The emergency use criterion will be ended, and manufacturers will have to cover costs after 12 months.
- The direct access pilot will become permanent for drugs with an ASMR of I-IV.
- Tendering could be introduced for certain drugs—potentially changing the landscape of negotiation.
- CEPS will oversee a five-year experiment to boost the use of generics, biosimilars and hybrids, which might take account of environmental impact and economic and social sustainability.

Government help to drive the “Ferrari” of Italian pharma



- A Consolidated Pharmaceutical Legislation Act will seek to streamline regulation, improve access to medicines—particularly for rare, chronic and disabling conditions—incentivise domestic production of active ingredients for rare diseases, boost community-based medicine and review spending caps for payback.
- The government is committed to progressively cutting the payback rate for NHS drugs sold through the retail channel from 1.83% to 1.27% in 2026-27, saving companies around €100mn.
- More treatments for chronic conditions will be moved from direct distribution in the hospital sector to retail pharmacies.
- The pharma budget will be boosted by €1.2bn in return for pricing reforms.

“The country is sitting on a Ferrari, which is the pharmaceutical industry, and we are asking the government to help us drive this Ferrari.”

Marcello Cattani, President, Farindustria

UK is close to a drug pricing deal with the US and VPAG reform



- Negotiations with the US are being led by the Prime Minister’s office.
- There are “unique geopolitical overtones right now.” A US deal is “crucial for commercial confidence.”
- Pharmaceuticals’ share of healthcare expenditure needs to increase—potentially to around 12%.
- The new Single National Formulary will play a key role in boosting uptake of innovative medicines across the country.
- A future overhaul of NICE’s approach to HTA could take account of factors such as societal value, economic benefit, ability to work and avoiding reliance on the state.
- VPAG will be adjusted in line with the US deal, and a totally new scheme will be negotiated by the end of 2028: it is “not business as usual.”
- A future remuneration system could look beyond pricing at outcomes and investment into the UK.

Key: HTA – health technology assessment; NICE – National Institute for Health and Care Excellence; VPAG – voluntary scheme for branded medicines, pricing, access and growth.

Spain prepares for major HTA and P&R reform



- Pricing procedures for accelerated, conditional and provisional funding authorisations—including new payment models—will be developed.
- A 180-day timeline from marketing authorisation to reimbursement will be introduced.
- Coverage with evidence development will address uncertainty at launch.
- A framework for health economic evaluation and budget impact analysis will take account of financial uncertainty.
- Drugs that meet particular patient or public health needs could receive exceptional treatment.
- More than €2bn of public and private funding will be invested in a Cutting-Edge Health programme focused on the adoption of personalised medicine and the development and uptake of ATMPs and other innovative medicines.

Key: ATMP – advanced therapy medicinal product; HTA – health technology assessment; P&R – pricing and reimbursement.

Strategic value of pricing scenarios



Casper Paardekooper, MSc

Partner
Vintura

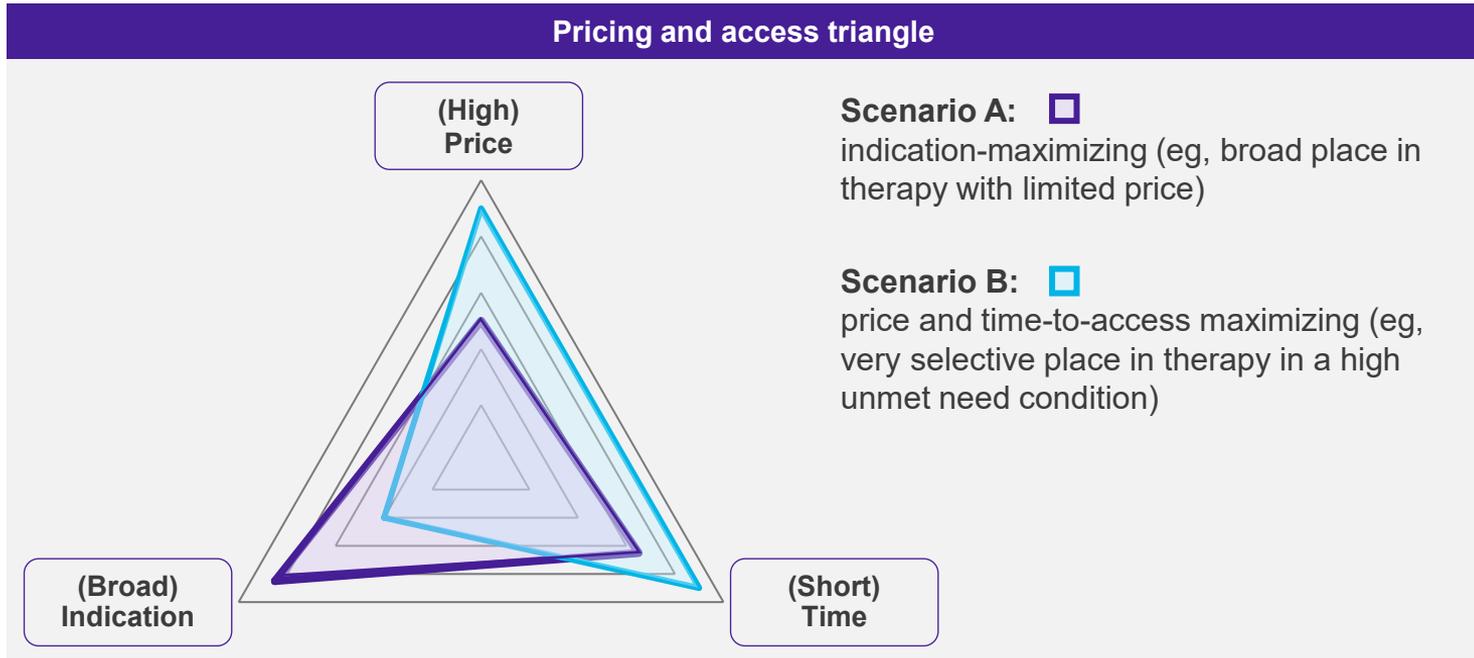
Polling Question

With global, regional, and national pricing policies in flux, how do you view the relevance of pricing scenarios today?

- a) They are no longer relevant
- b) They are relevant, but impossible to do
- c) They are relevant, but challenging to do
- d) They are relevant and still easy to do

Pricing strategy often impacts reimbursement conditions and time to patient access

- Delays in patient access frequently arise from a lack of **alignment between the available evidence, value proposition, and price**
- Long-term patient access requires a pricing strategy that models the influencing variables



Countries use distinct pricing mechanisms, but most also apply formal or informal IRP

Countries organized by pricing archetypes



A dynamic field that requires ongoing modeling and updating of the model is IRP



Country-specific IRP rules

- Country basket
- IRP calculation
 - Considered prices
 - Ex-manufacturing price
 - Wholesaler price
 - Exchange rates
 - **Discounts** (assumed and effective)
 - Referencing frequency
 - Formal vs **informal** practices
 - Practice **updates**



Product factors

- Drug's life cycle status (patented, branded, generic, biosimilar)
- Indication

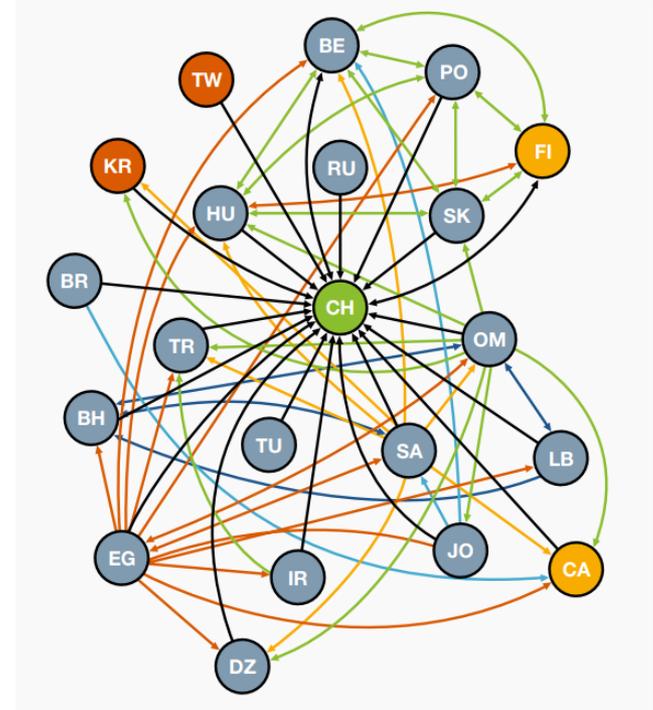
Unintended implications of IRP

- Influence launch sequence
- Market withdrawals to protect the pricing corridor
- Inhibit indication extension
- Focus on high drug price markets
- Increase drug prices
- Reduce transparency by hiding the net prices

Due to IRP, prices in smaller countries disproportionately impact revenue on a global scale

Based on a study from Interpharma and Novartis, in 2013:

- A Swiss price reduction of 10% would lead to a worldwide drop in turnover of almost 1.1 billion Swiss francs for the industry
- Around 515 million Swiss francs would be lost in Switzerland itself and the rest across the globe
- In other words, IRP **doubles the global revenue impact** of a price reduction in Switzerland

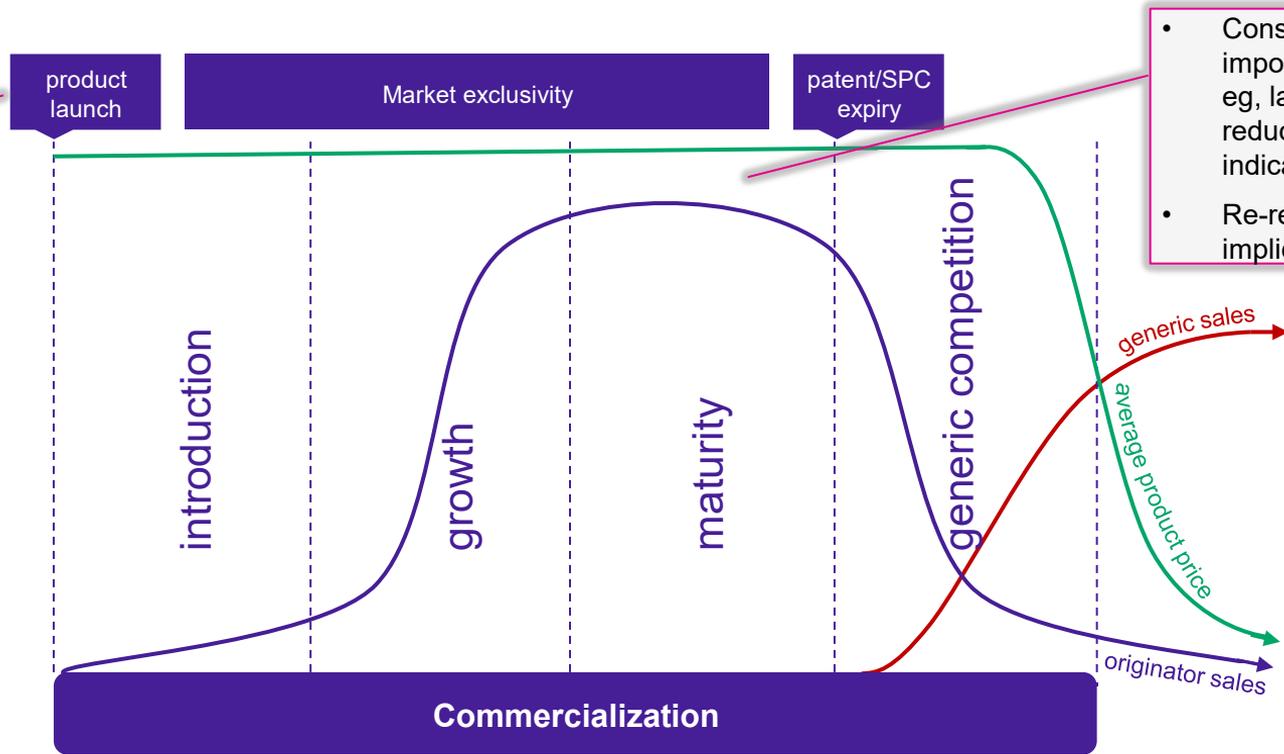


Key: BE – Belgium; BH – Bahrain; BR – Brazil; CA – Canada; CH – Switzerland; DZ – Algeria; EG – Egypt; FI – Finland; HU – Hungary; IR – Iran; IRP – international reference pricing; JO – Jordan; KR – South Korea; LB – Lebanon; PO – Portugal; RU – Russia; SA – Saudi Arabia; SK – Slovakia; TR – Turkey; TU – Tunisia; TW – Taiwan.

International impact of Swiss drug regulation. Charles River Associates. Interpharma. 2015. Accessed November 3, 2025. https://www.interpharma.ch/wp-content/uploads/2020/02/ly_iph.01.19.002_-_pharmamarkt_schweiz_2019_d_web-komprimiert.pdf

IRP is important throughout a product's life cycle

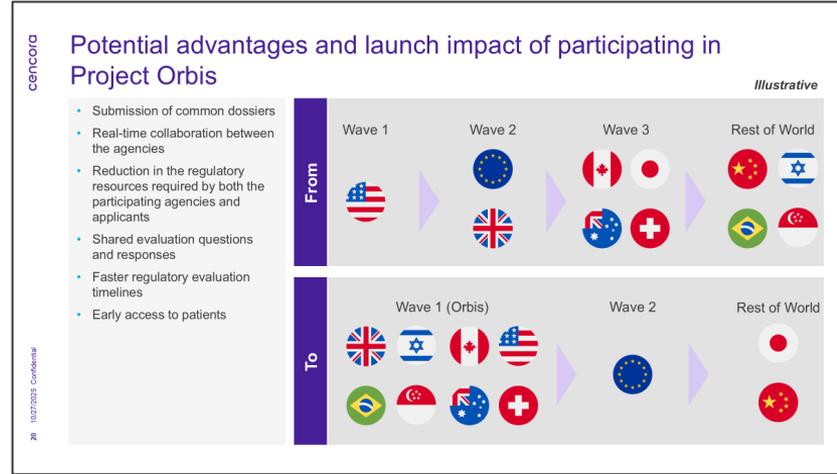
- Consider IRP during launch planning
- Balance the local pricing opportunity against the global pricing corridor



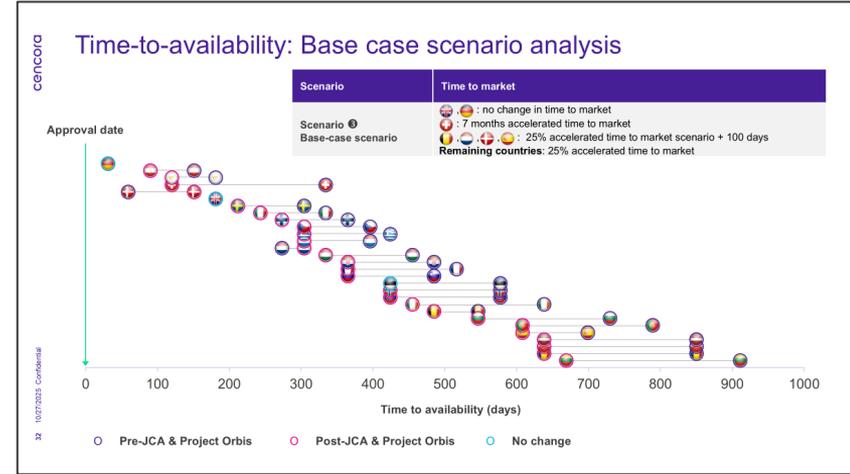
- Consider IRP at important events, eg, large price reductions, indication extension
- Re-referencing implications

Also changes to international regulatory and HTA initiatives are impacting pricing due to launch timeline shifts

Project Orbis



Joint Clinical Assessment (JCA)



As well as national initiatives are impacting pricing

Three Most-Favored-Nation (MFN) deals negotiated to date



- Companies are negotiating MFN deals for innovative pharmaceuticals to protect existing pricing and ensure consumer access.
- In return, companies will receive funding from the 11th investment round.
- Deals with the cost of said to be significantly lower than MFN prices in Switzerland.

Spain prepares for major HTA and P&R reform



- Pricing process and funding authority will be developed.
- A 180-day time limit will be introduced for coverage with launch.
- A framework for analysis will be developed.
- Drugs that receive exceptional reimbursement and other incentives.

First confidential rebate in Germany



- Eli Lilly's Mounjaro (tirzepatide) is the first drug to use a new provision for rebated prices to be kept confidential.
- The company has reached agreement with the GKV-Spitzenverband on "the framework conditions for the contract on the reimbursement amount."
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Case study: Rigorous analysis strengthens decision-making, ensuring we act rather than react

Situation

The context

A high-profile biotech startup is developing a first-in-class gene therapy for a rare and aggressive form of non-Hodgkin lymphoma.

To maximize its commercial potential, the company must define an effective launch sequence strategy.

The challenge

Due to significant pricing disparities across geographies, careful planning is essential to mitigate the risks of international reference pricing (IRP).

As the company's first product to be commercially launched, the company has no previous experience in launch sequencing.

The objectives

Develop launch sequence scenarios (fastest possible route to market). And evaluate the commercial opportunity associated with each scenario.

Identify markets that could threaten the global pricing strategy (e.g., low-price or highly referenced countries).

Test alternative launch sequences (e.g., delayed or excluded launches) and compare their commercial impact against the base case.

Our approach



Assess price potential: evaluating willingness to pay for the asset in Europe, with particular focus on EU4 + UK.



Evaluate countries' commercial opportunity: develop comprehensive financial forecasts to evaluate the commercial opportunity of each EU country.

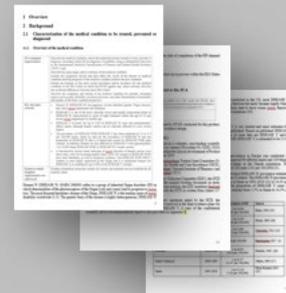


Develop launch scenario: develop launch sequences and apply IRP rules and P&R timelines to assess the corresponding EU commercial opportunities.



Strategic launch sequence analysis: Compare the commercial opportunities and associated risks of the different launch sequence scenarios to identify the most optimal sequence.

Initial results/ learnings



Thorough project planning: Even modest variations in product prices across countries can create significant differences in mid-term commercial opportunities



Improved decision making: The fastest-to-market sequence may set off a cascade of unintended effects that influence the product's pricing

In summary, continued modeling is crucial to maximizing a product's revenue

Do ✓

- Integrate robust modeling—such as early cost-effectiveness analysis, IRP, and pricing scenarios—into the product launch strategy, and update continuously throughout the lifecycle.
- Respect the complexity of national pricing frameworks to avoid oversimplification that can lead to inaccurate assumptions or flawed conclusions.
- Establish strong governance mechanisms to regularly assess pricing strategy and stay informed about regulatory and market changes.

Don't ✗

- Avoid relying on basic or superficial analysis—capturing country-specific nuances is critical for accurate pricing decisions.
- Don't overlook informal pricing regulations, which can significantly influence market dynamics.
- Don't focus solely on major markets—due to IRP, pricing decisions in smaller countries can disproportionately affect global price corridors.

AI-powered pricing scenario tool



Leanna Baker Williams, PharmD, MS

Manager, Value & Access Strategy
Cencora

Polling Question

Does your organization currently use AI in developing pricing scenarios?

- a) Yes
- b) No
- c) I don't know, let me ask ChatGPT

Polling Question

What is the biggest barrier your organization faces in adopting AI for pricing strategies?

Transforming data into strategy

AI-Powered Scenario Tool is positioned as a strategic layer that seamlessly unifies:

Analytics

Predictive modeling

Policy intelligence

Data-driven strategy



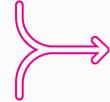
Synthesizes clinical, regulatory, and economic **datasets to model real-world pricing dynamics**



Leverages AI and ML algorithms to translate complex inputs into **actionable pricing recommendations**



Enables **scenario testing** under variable policy and market conditions (eg, MFN policy shifts, IRP ripple effects, biosimilar entry)



Provides a **unified interface** for real-time scenario adjustment and global alignment

Streamlined data-to-decision

Inputs

AI Engine

Scenario Simulator

Insights Dashboard

Data processing and analysis

Machine Learning Algorithms

Predictive Modeling (Supervised Learning)¹⁻⁵

- Forecast **list-to-net trends, rebate depth, reimbursement probability**
- Model **time-to-access timelines and payer decisions**
- *Example:* MFN or CNAM impact forecasting

Prescriptive Analytics (Reinforcement Learning)^{1,5-8}

- Recommend **optimal launch price/discount/rebate mix**
- Balance **ROI, access probability, and margin**
- *Example:* Optimize WAC discounts for EU5 + US markets

Unsupervised Learning^{1,9,10}

- **Cluster payers & markets** to tailor contracting
- **Detect anomalies** in competitor pricing or policy actions
- *Example:* Identify early biosimilar price undercuts

Generative AI + NLP¹¹⁻¹³

- Auto-create **scenario narratives & executive summaries**
- Summarize **HTA or policy updates** for real-time alerts
- *Example:* Generate global pricing scenarios across reforms

Hybrid/Ensemble Models^{1,11}

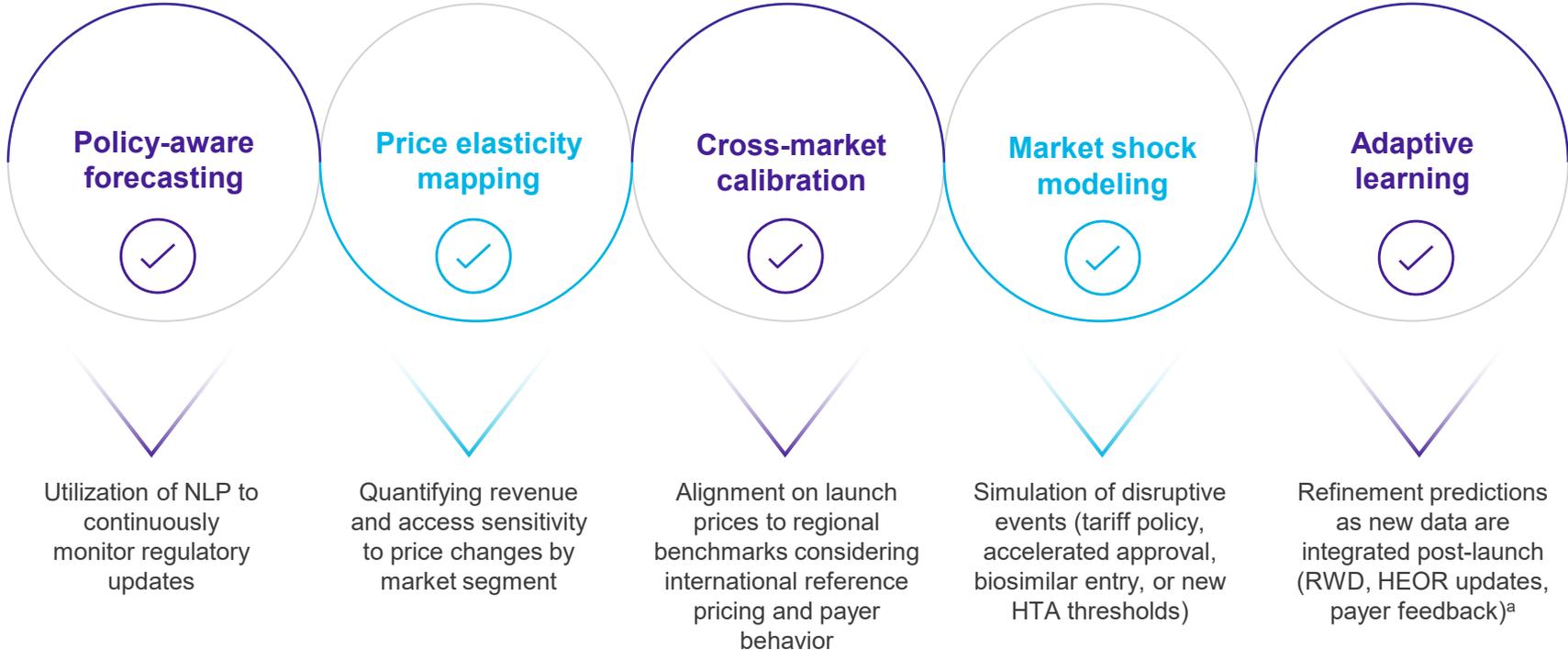
- Combine ML techniques for **greater accuracy & adaptability**
- Continuous learning from **RWD + payer feedback**

References: 1. Padula WV, Kreif N, Vanness DJ, et al. *Value Health*. 2022;25(7):1063-1080. 2. Academy of Managed Care Pharmacy (AMCP). *AMCP Format for Formulary Submissions 5.0*. *J Manag Care Spec Pharm*. 2024;30(4-B)(suppl). 3. NICE. Same-time decisions on licensing and value: What pharmaceutical companies need to know. *NICE Blog*. October 10, 2025. 4. Caisse Nationale d'Assurance Maladie (CNAM). *PLFSS 2026 overview and cost-containment measures*. Policy materials (French government publications), 2025–2026. 5. Centers for Medicare & Medicaid Services (CMS). *Most Favored Nation (MFN) Model—Fact Sheet and Model Overview*. 2020–2021. 6. Sullivan SD, Doyle JJ, Mühlbacher A, et al. *J Manag Care Spec Pharm*. 2022;28(8):908-916. 7. OECD. *Exploring the Feasibility of Sharing Information on Medicine Prices Across Countries*. Paris: OECD Publishing; 2024. 8. Mulcahy AW, et al. *International Prescription Drug Price Comparisons: 2022 Data*. Santa Monica, CA: RAND Corporation; 2024. 9. IQVIA. *The Impact of Biosimilar Competition in Europe 2024 (10th ed.)*. White Paper; 2025. 10. Association for Accessible Medicines (AAM). *U.S. Generic & Biosimilar Medicines Savings Report*. 2024. 11. Fleurence RL, Wang X, Bian J, et al. *Value Health*. 2025. 12. Fleurence RL, Dawoud D, Bian J, et al. *ELEVATE-AI LLMs Framework: An evaluation framework for use of large language models in HEOR*. arXiv; 2024. 13. Srivastava T, Lee S, Arora A, et al. *Pharmacoeconomics Open*. 2025;9(3).

Key: CNAM – Caisse Nationale d'Assurance Maladie; HTA – health technology assessment; MFN – most favored nation; ML – machine learning; NLP – natural language processing; ROI – return on investment; RWD – real-world data; WAC – wholesale acquisition cost.

What to look for in an AI-driven pricing & scenario modeling tool

AI Engine Functions



Key: HEOR – health economics outcomes research; HTA – health technology assessment; NLP – natural language processing; RWD – real world evidence.

^a Recognize that large, rapid data inflows can shift model behavior; requiring monitored retraining and governance to maintain accuracy and stability.

Integrated data ecosystems

Building a unified foundation of multi-source data to fuel predictive pricing intelligence

Market Data

- Historical pricing data of existing drugs to identify trends
- Competitor pricing strategies and market shares for benchmarking
- Market access data, including reimbursement rates and access policies affecting pricing

Regulatory Data

- Pricing regulations by country/region to ensure compliance
- Compliance requirements and historical changes in regulations to anticipate future shifts

Clinical Data

- Efficacy and safety profiles of products
- Comparative effectiveness data against competitors

Economic Data

- Cost-effectiveness analyses relative to alternatives
- Health economic outcomes and budget impact models

Patient Data

- Patient demographics and treatment patterns
- Patient access and adherence data

Decision support framework

Integrated Global Policy Intelligence



Centralizes **real-time policy feeds** from major health authorities and agencies (eg, AMNOG, HAS, CNAM, NICE–MHRA, FDA, CMS)

Uses **NLP-driven policy scanning** to identify and tag updates from pricing regulations, HTAs, and reimbursement frameworks

Automatically **refreshes pricing models** when new legislation, cost-containment measures, or HTA decisions are published

Interactive Simulation Workspaces

- ✓ Allow teams to **test price and access assumptions** under evolving regulatory conditions
- ✓ Facilitate **cross-regional scenario comparison** for strategic launch sequencing and contracting decisions



Advanced Visualization Tools



Heat maps display pricing alignment across global reference markets



Elasticity curves illustrate payer sensitivity under new HTA or reimbursement criteria



Waterfall charts break down the financial impact of regulatory adjustments by country or product line

Challenges in leveraging AI for predictive pricing & scenario planning

Barriers to AI Adoption

Data Complexity & Availability

Fragmented or proprietary datasets limit AI's ability to generate accurate pricing predictions.

Regulatory Uncertainty

Evolving policies (eg, price negotiation, transparency mandates, unwritten policies) disrupt model assumptions.

Confidentiality & Competitive Sensitivity

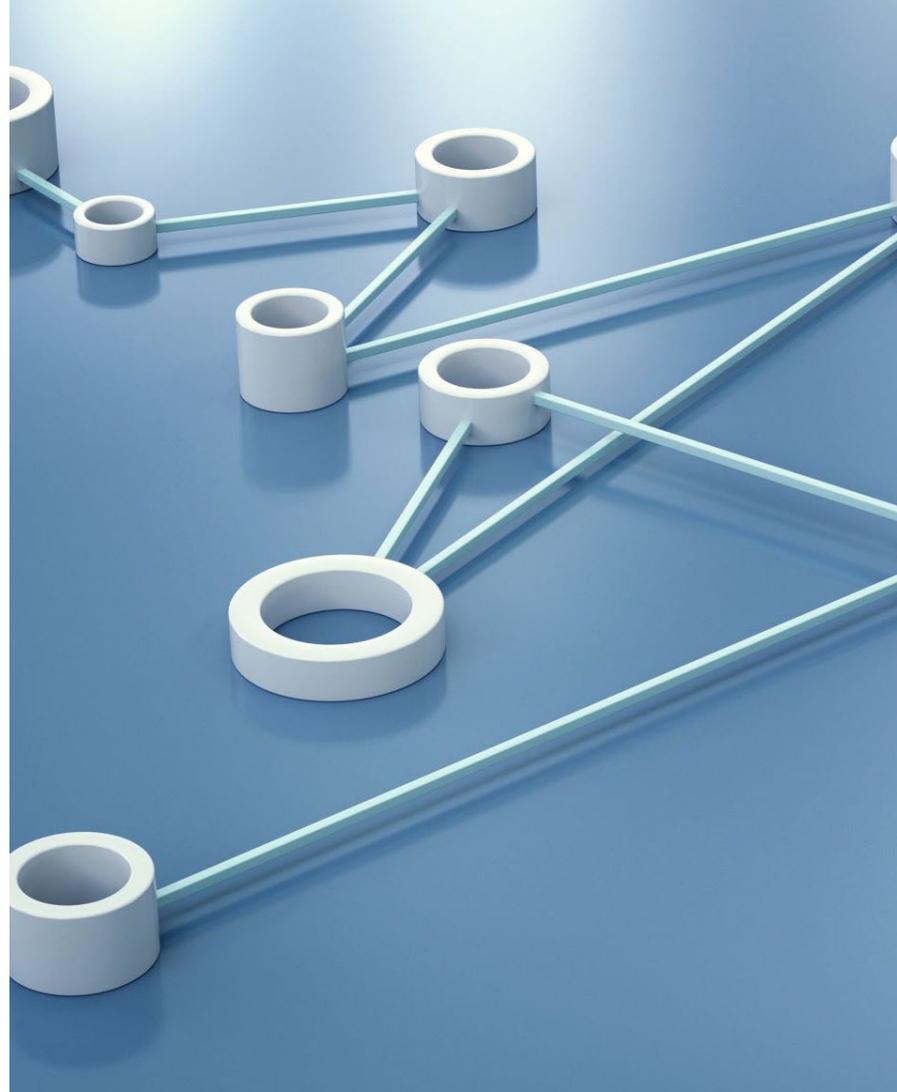
Companies may be unwilling or unable to share pricing strategies or pipeline data, restricting AI training and collaboration.

Ethical & Transparency Concerns

Black-box models can raise trust issues among regulators, payers, and internal stakeholders.

Market Dynamics

AI may struggle to anticipate competitor actions, payer negotiations, and global pricing variations.



Future opportunities

Smart Pricing Recommendations

Generate tailored pricing strategies designed to maximize ROI and market access potential



Market Insights

Identify pricing opportunities and potential risks to deliver valuable insights into competitor strategies and market dynamics

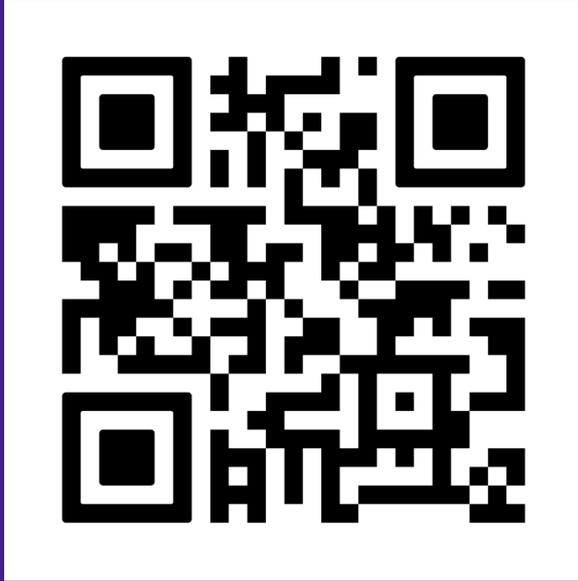


Comprehensive Reports

Create customizable reports summarizing scenarios, findings, and strategic recommendations for different stakeholders



Connect with Cencora at ISPOR EU



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