POLICY BRIEF

Policy Briefs offer concise insights into emerging developments in the global health policy space that shape access, innovation, and affordability. Each Policy Brief will spotlight timely issues with relevance for the health economics and outcomes research (HEOR) community and beyond. The goal is to provide readers with a rapid overview of how policy shifts are influencing global markets and stakeholders. The Briefs present an overview of the issue and its implications for the HEOR field, followed by concise summaries that reflect key stakeholder perspectives.

US Drug Prices and the Medicare Drug Price Negotiation Program

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Overview: This inaugural column focuses on the evolving role of international reference pricing (IRP) and related mechanisms in the US Medicare Drug Price Negotiation Program. The column will also cover the ripple effects these reforms are having across the European Union. These policy shifts mark a pivotal moment in how governments, payers, and industry define "value" and balance cost containment with access and innovation.

US STAKEHOLDER PERSPECTIVES

Pharmaceutical Industry
As of October 2025, Pfizer, AstraZeneca, Amgen, AbbVie, Novo Nordisk, Lilly, Bristol-Myers Squibb, Sanofi, and EMD Serono have made announcements to lower select US drug prices, with some firms citing plans to remove third-party supply chain entities or reference to Most Favored Nation (MFN) international benchmarks. The announcement of several direct-to-consumer programs is viewed as pharma's response to MFN through sales channels that bypass the intermediaries (ie, payers and pharmacy benefit managers [PBMs]). PhRMA warns that international reference pricing-linked mechanisms could deter early US launches and delay or redirect research and development towards less-regulated markets. Lilly's CEO warned that importing foreign price controls would import the low productivity of Europe's biopharma sector without solving for high out-of-pocket costs of the US insurance market.

Payers and PBMs
CVS introduced a new pricing model called CostVantage that replaces traditional PBM-based systems with formulas reflecting actual drug acquisition cost, a fixed markup, and a standard dispensing fee. Express Scripts (Evernorth) issued a public statement defending the role of PBMs in drug affordability. They argued that removing PBMs is "oversimplified and shortsighted," and emphasized that PBMs help keep 93% of prescriptions under $20 out-of-pocket. Mark Cuban of CostPlusDrugs publicly endorsed Trump's MFN executive order.

Regulatory
The US Food and Drug Administration (FDA) announced that affordability will be incorporated as a consideration in the agency's new Commissioner's National Priority Voucher (CNPV) Pilot Program, which seeks to shorten review times from approximately 10-12 months to 1-2 months for selected products. FDA named the first 9 products eligible for priority review vouchers from Regeneron, Sanofi, Merck KGaA, Revolution Medicines, and Disc Medicine.

Academia and Research
Experts cautioned that MFN creates a prisoner's dilemma for pharmaceutical companies. If one company refuses to launch its drug in MFN-referenced countries to protect its higher US price, it risks losing international revenue while competitors who do launch abroad anchor the US benchmark price downward. If all companies launch abroad, they collectively suffer price compression in the United States, but if one defects, it gains short-term market share while triggering long-term losses for everyone.

Providers
Providers broadly support efforts to improve affordability but continue to raise concerns about transitional risks under the new Medicare Drug Price Negotiation framework. For hospitals and specialty practices operating under "buy-and-bill" models, sharper reimbursement controls could threaten financial stability and limit access to costly biologics or infusions without additional safeguards. Clinicians are calling for clear guidance on billing codes and transitional financing to maintain service continuity during implementation.

Patient Groups
Patient groups share the affordability goals of the Inflation Reduction Act but warn that negotiated price reductions must translate into lower out-of-pocket costs at the pharmacy

counter. Advocacy networks note that vulnerable populations, particularly Medicaid beneficiaries, dual-eligibles, and individuals with chronic or rare diseases, remain at risk of delayed access when drug manufacturers recalibrate launch strategies to manage international price referencing. Many groups also point to gaps in direct-to-patient platforms, which may not reach patients dependent on traditional provider networks.

EUROPEAN PERSPECTIVES

Brussels
European leaders voiced concerns over the US MFN policy, warning that it could lead to delayed drug launches and higher prices across Europe. Industry leader Alexander Natz (EUCOPE) and public health expert Helmut Brand noted that orphan drug companies may avoid launching in Europe to prevent setting low price benchmarks that could be referenced by US regulators.

United Kingdom
The United Kingdom is facing stalled pharmaceutical investment from Merck and AstraZeneca, which have paused or canceled major projects due to market uncertainty. In response, the government is considering raising the National Health Service's drug prices by up to 25% and revising the Voluntary Scheme for Branded Medicines to attract investment and align with international pricing standards. Finance Minister Rachel Reeves emphasized that the United Kingdom must remain competitive in pricing while securing more inward investment from global drug manufacturers.

France
French Prime Minister François Bayrou has requested the Economic Committee for Health Products (CEPS) to release a report in Q3 2025, outlining its drug pricing policy recommendations. Bayrou cited "changing geopolitical context" and "investment dynamics" for the European pharma sector. France is advancing reforms through its 2026 Social Security Finance Bill and CEPS pricing framework. These include price premiums for domestically manufactured drugs and lower discount ceilings for generics and biosimilars, aimed at improving financial viability and protecting local industry. The CEPS has also shown increased openness to price increase requests, signaling a more flexible stance amid global pricing pressures.

Central and Eastern Europe
Experts warn that MFN could disproportionately affect smaller Eastern European markets. Companies may delay or skip launches in these countries to avoid setting low price benchmarks that the Centers for Medicare and Medicaid Services could reference. The list prices of nonreferenced markets feed into the list prices of MFN-referenced markets, effectively pulling them into the MFN framework and thus risking delays or "no launch" strategies.

SUGGESTED READING:

- Application of International Reference Pricing Rules to Forecast Pharmaceutical Launch Prices in 5 European Countries
- Cost-Effectiveness of the 15 Drugs Selected for Initial Price Applicability Year 2027 by Centers for Medicare and Medicaid Services Drug Price Negotiation Program
- Integrating Price Benchmarks and Comparative Clinical Effectiveness to Inform the Medicare Drug Price Negotiation Program
- Referencing Drug Prices of Other Countries May Not Sustainably Lower Prices in the United States: Lessons From Europe
- Informing the United States Medicare Drug Price Negotiation for Apixaban and Rivaroxaban: Methodological Considerations for Value Assessments Many Years After Launch
- Estimated Savings From Using Added Therapeutic Benefit and Therapeutic Reference Pricing in United States Medicare Drug Price Negotiations
- Medicare Drug Price Negotiation in the United States: Implications and Unanswered Questions