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International: Impact of MFN Drug Pricing on Transactions

Abstract: MFN policies are reshaping pharma deals, creating new pricing, launch and value risks. Companies should review agreements and build flexibility

In brief

Recent US efforts to introduce Most Favored Nation (MFN) drug pricing are creating new layers of uncertainty for transactions involving the commercialization of prescription medicines in the US. These policies - designed to align US drug prices with the lowest prices available in comparable countries - have the potential to reshape deal economics, launch strategies, and global pricing structures. Below, we outline the current MFN policy landscape and explore how these developments may affect both global and regional transactions.

As a reminder, these observations reflect the state of play today and may evolve quickly. To date, neither the US Department of Health and Human Services (HHS) nor the Centers for Medicare & Medicaid Services (CMS) has provided comprehensive guidance on how different commercial or licensing structures might be treated under an MFN framework.

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In more detail

I. What is MFN pricing?

US MFN drug pricing is a policy that aligns US prescription drug prices with the lowest prices available for the same products in certain other developed countries. A similar concept, known as External Reference Pricing (ERP), has long been used in Europe. Under this system, countries benchmark their drug prices against a selected basket of other countries. The details vary. Some countries apply strict rules, while others use the reference prices as negotiation points. They also differ in which countries they reference (so called reference baskets), how they calculate (average vs. lowest price), and when they apply the comparison (at launch or periodically). In this context we note that as of 1 January 2025, Germany has abolished the mandatory use of External/International Reference Pricing (ERP/IRP) in its drug-pricing system. The ERP/IRP concept gained formal traction in the US during President Trump's initial term.

During his first administration, President Trump issued an interim final rule targeting certain high-cost Medicare Part B and Part D drugs. The rule - later blocked by the courts and rescinded by the Biden Administration in December 2021 - would have linked Medicare Part B and Part D prices to the lowest prices paid by comparable countries, specifically OECD nations with at least 60% of US per-capita GDP.

After returning to office, President Trump revived this effort. In May 2025, he issued the "Delivering Most-Favored-Nation Prescription Drug Pricing to American Patients" executive order, directing drug manufacturers to offer US consumers the MFN price and laying the groundwork for a broader set of MFN-based initiatives.

First, in July 2025, President Trump sent letters to 17 of the leading pharmaceutical companies outlining the steps they would need to take to bring down US prescription drug prices.[1] The letters warned that failure to comply would result in strong measures. At the same time, the administration has directly engaged manufacturers in discussions to achieve MFN pricing. In April 2026, the Trump administration announced that it has reached voluntary MFN pricing agreements with each of the 17 leading pharmaceutical companies, representing 86% of the branded drug market, and expects to secure similar agreements with most manufacturers of sole-source brand-name drugs and biologics nationwide.[2]

Second, in November 2025, the Centers for Medicare & Medicaid Services (CMS) introduced a new Medicaid payment model called the GENEROUS Model (GENErating cost Reductions for US Medicaid).[3] Scheduled to begin in January 2026, the model is voluntary for both drug manufacturers and state Medicaid programs. Under the GENEROUS Model, for drugs included in the model, participating drug manufacturers will offer prices based on what other select countries pay for prescription drugs covered by the Medicaid program. Specifically, the MFN price will be based on the second-lowest net price reported for the drug in the G7 countries (excluding the US), Denmark and Switzerland, adjusted by gross domestic product per capita using a purchasing power parity method.

Third, a month after CMS introduced the GENEROUS Model, the agency released draft proposals for two additional payment models - GLOBE (Global Benchmark for Efficient Drug Pricing Model) and GUARD (Guarding US Medicare Against Rising Drug Costs) - to incorporate MFN pricing to Medicare Part B and Part D programs.[4] Under GLOBE and GUARD, CMS would require manufacturer rebates when the price of the drug exceeds that of an international benchmark based on what other comparable countries pay making the net cost to Medicare for certain Part B and Part D drugs similar to what other comparable countries pay. CMS plans to launch GLOBE in October 2026 and GUARD in January 2027. Unlike the voluntary GENEROUS Model, however, both GLOBE and GUARD would be mandatory for the Medicare drugs they cover. The notices of proposed rulemaking for these models were published on 23 December 2025, with public comment period closed on 23 February 2026.

These initiatives reflect the administration's policy objectives, which President Trump has framed as an effort to eliminate "global freeloading" and ensure Americans have access to affordable, lifesaving treatments. According to the White House, drug manufacturers benefit from substantial US government research funding and healthcare spending yet offer discounts in foreign markets, offsetting those lower prices by charging higher prices in the US. As stated in the 2025 Executive Order, "Americans should not be forced to subsidize low-cost prescription drugs and biologics in other developed countries, and face overcharges for the same products in the US. Americans must therefore have access to the most-favored-nation price for these products."[5]

While several major pharmaceutical companies have entered voluntary MFN agreements with the Trump administration, the industry continues to oppose mandatory price controls - especially efforts to codify MFN pricing in statute. That resistance reflects, in part, ongoing legal uncertainty over whether the federal government can implement MFN pricing broadly without explicit congressional authorization, particularly in Medicare.[6]

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[1] The White House, Fact Sheet: President Donald J. Trump Announces Actions to Get Americans the Best Prices in the World for Prescription Drugs (31 July 2025), https://www.whitehouse.gov/fact-sheets/2025/07/fact-sheet-president-donald-j-trump-announces-actions-to-get-americans-the-best-prices-in-the-world-for-prescription-drugs/.

[2] The White House, Fact Sheet: President Donald J. Trump Announces Deal with Regeneron to Bring Most-Favored-Nation Pricing to American Patients (23 April 2026), https://www.whitehouse.gov/fact-sheets/2026/04/fact-sheet-president-donald-j-trump-announces-deal-with-regeneron-to-bring-most-favored-nation-pricing-to-american-patients/; The White House, *Savings from Most-Favored-Nation Drug Pricing Policy* (6 May 2026), https://www.whitehouse.gov/research/2026/05/savings-from-most-favored-nation-drug-pricing-policy/.

[3] Centers for Medicare & Medicaid Services, CMS Announces New Drug Payment Model to Strengthen Medicaid and Better Serve Vulnerable Americans (6 November 2025), https://www.cms.gov/newsroom/press-releases/cms-announces-new-drug-payment-model-strengthen-medicaid-better-serve-vulnerable-americans.

[4] Centers for Medicare & Medicaid Services, CMS Proposes New Mandatory GLOBE Model (21 December 2025), https://www.cms.gov/newsroom/press-releases/cms-proposes-new-mandatory-globe-model; Centers for Medicare & Medicaid Services, CMS Proposes New Mandatory GUARD Model Administration (21 December 2025), https://www.cms.gov/newsroom/press-releases/cms-proposes-new-mandatory-guard-model.

[5] The White House, Delivering Most-Favored-Nation Prescription Drug Pricing to American Patients (12 May 2025), https://www.whitehouse.gov/presidential-actions/2025/05/delivering-most-favored-nation-prescription-drug-pricing-to-american-patients/.

[6] President Trump sought to address these concerns by unveiling his health-care roadmap in January 2026, which calls on Congress to codify the administration's recent MFN pricing deals into law to provide additional legal protections. See The White

II. Who is responsible for compliance?

President Trump's 2025 Executive Order and the accompanying White House fact sheets explicitly instruct the US government to target manufacturers for MFN compliance. The policies state, in relevant part:

> "My Administration will take immediate steps to end global freeloading and, should drug manufacturers fail to offer American consumers the most-favored-nation lowest price, my Administration will take additional aggressive action." Section 2 of 2025 Executive Order.
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> "To the extent consistent with law, the Secretary of [HHS] shall facilitate direct-to-consumer purchasing programs for pharmaceutical manufacturers that sell their products to American patients at the most-favored-nation price." Section 4 of 2025 Executive Order.
>
> "[The] Secretary shall . . . communicate most-favored-nation price targets to pharmaceutical manufacturers to bring prices for American patients in line with comparably developed nations." Section 5 of 2025 Executive Order.
>
> "Drug manufacturers benefit from generous research subsidies and enormous healthcare spending by the US Government. Instead of passing that benefit through to American consumers, drug manufacturers then discount their products abroad to gain access to foreign markets and subsidize those discounts through high prices charged in America. Americans are subsidizing drug manufacturer profits and foreign health systems, both in development and once the drugs are sold." White House fact sheets issued on 31 July 2025, and 6 November 2025.

As indicated above, the rationale behind the 2025 Executive Order is the view that US investment in pharmaceutical research and development (R&D) and healthcare justifies requiring manufacturers to offer American patients the same MFN pricing available to consumers abroad. Across these policies and subsequent initiatives, the consistent message is that manufacturers bear primary responsibility for MFN compliance. From a regulatory standpoint, the "point of compliance" is the manufacturer (particularly those receiving government R&D support or reimbursement through federal healthcare programs), not third-party intermediaries.

We also note that neither the 2025 Executive Order nor the accompanying White House fact sheets draw distinctions based on commercial or distribution arrangements, nor do they provide any carve-outs for commercial partners or distributors. In practical terms, this means that even when US pricing is set by a third-party partner - such as a licensee, licensor, distributor, or other commercial intermediary - the manufacturer may still be responsible for meeting MFN pricing obligations.

HHS and CMS have not yet issued MFN regulations, but existing Medicare and Medicaid statutes generally define a "manufacturer" as an entity involved in producing or distributing prescription drugs, excluding wholesale distributors.[7] Recent CMS guidance further interprets a manufacturer as the holder of a New Drug Application (NDA) or Biologics License Application (BLA), though this guidance is not legally binding. As a result, the precise definition of "manufacturer" under future MFN regulations remains uncertain, but agencies may ultimately rely on existing statutory definitions given that drugs sold at MFN pricing will continue to be reimbursable under the current Medicare and Medicaid framework.

III. How does MFN impact transactions?

For the purposes of this article, we use the term "transactions" to refer broadly to licensing, collaboration, distribution, and M&A deals involving the commercialization of pharmaceutical products.

a. Global deals and economics

MFN pricing has the potential to significantly reshape the pharmaceutical industry's business model. By tying US drug prices to lower international benchmarks, manufacturers may face reduced margins on patented products, tighter revenue streams, and ultimately a smaller pool of funding available for R&D.

Additionally, drug manufacturers may reassess global launch-sequencing strategies in response to MFN pricing, including by prioritizing higher-price markets before introducing new drugs in countries that could establish lower MFN benchmarks. Historically, manufacturers have often launched new drugs first in the US, followed quickly by Europe and other key markets, many of which are

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House, President Trump Unveils The Great Healthcare Plan to Lower Costs and Deliver Money Directly to the People (January 15, 2026), https://www.whitehouse.gov/articles/2026/01/president-trump-unveils-the-great-healthcare-plan-to-lower-costs-and-deliver-money-directly-to-the-people/; President Donald J. Trump, The Great Healthcare Plan, https://www.whitehouse.gov/wp-content/uploads/2026/01/The-Great-Healthcare-Plan.pdf.

[7] See 42 USC § 1396r-8(k)(5); 42 CFR § 447.502.

referenced for MFN pricing. However, launching too early in countries with lower prices can create a low MFN benchmark that depresses US margins. Importantly, US pricing under MFN-related arrangements is not necessarily fixed at launch. MFN pricing operates dynamically, with benchmark prices subject to recalculation or adjustment over time as foreign prices evolve or as new comparator markets are introduced. As a result, even if a drug launches in the US at an initially higher price, subsequent launches in lower-priced markets may trigger downward pressure on US pricing through MFN benchmarking, rebate reconciliation, or supplemental discount obligations. To manage this risk, manufacturers may choose to postpone - or even skip - launches in these markets until US pricing is firmly established or special pricing terms can be negotiated, potentially limiting patient access in those regions.

Moreover, the prices used for MFN referencing are typically list prices, even though governments and manufacturers frequently negotiate confidential discounts or rebates. Because these negotiated prices are not publicly available, some potential reference countries may shift away from list-price systems toward confidential, net-price agreements with manufacturers to avoid being benchmarked. They may even adopt retaliatory pricing measures in response to US MFN framework.

b. Pricing control in the US and reference markets

The language in the 2025 Executive Order suggests that MFN pricing is tied to the price of the drug product itself in other developed countries. The administration's stated goal is to ensure that Americans "have access to the most-favored-nation price for these products" because "Americans should not be forced to … face overcharges for the same products in the United States." This broad language implies that it is the reference market price - not the identity of the seller abroad - that matters. Whether a drug product is sold overseas by the manufacturer, a licensee, or a distributor, the price available in those markets could become the benchmark for US pricing under the MFN policy.

Specifically, neither the 2025 Executive Order nor the accompanying White House fact sheets draw distinctions based on commercial or distribution arrangements. This means MFN pricing could still apply even when a manufacturer retains US marketing authorization (e.g., NDA or BLA) but licenses commercialization rights outside the US to a third party. Under an MFN framework, the prices set by that ex-US licensee in foreign developed countries could directly influence the price for the same drug product in the US.

The 2025 Executive Order also omits any grandfathering protection for existing license agreements. Unless future rulemaking introduces such carve-outs, all current ex-US license agreements may be affected once the MFN policy is implemented. This creates additional complications for agreements with diligence obligations: a licensee could be required to launch in a foreign market - even if doing so triggers a lower MFN benchmark and negatively impacts US pricing - depending on how the diligence provisions were drafted.

IV. Mechanisms to mitigate MFN pricing impact in transactions

Against this backdrop, parties can adopt targeted contractual and strategic tools to reduce negative MFN exposure and preserve deal value. The discussion of mitigation strategies must first begin with a structural distinction, namely whether a transaction is structured as (i) a global deal, i.e., in which a single licensee or partner holds commercialization rights across substantially all territories (including both the US and the major ex-US markets, including the relevant reference markets), or (ii) a split territory deal, in which different parties hold rights in the US and in one or more key international markets. The nature, degree, and controllability of MFN risk differs between these two structures, and the appropriate mitigation tools likewise differ.

a. Global deals

MFN risk is more manageable in a global deal than a split-territory deal. The licensor does not retain any commercialization rights in any market and the licensee alone controls pricing decisions globally. Because the licensor's economic return is derived from royalties and milestones tied to the licensee's global revenues, both parties will be affected by MFN-driven erosion of US net prices. However, incentives may diverge depending on the specific financial terms (for example, if there are significant milestones tied to launch in reference countries), making contractual terms more relevant.

1. Risk-sharing in global deals

Licensees in global deals are starting to request risk-sharing arrangements, such as royalty and milestone threshold adjustments, to address potential MFN pricing.

These adjustments are more straightforward to allocate if launch occurs first in the US and there is a later launch in a reference country. The change in US price will be directly observable and can be used as a basis for a royalty rate adjustment (e.g., by having the royalty rate reduce in the same proportion as the sales price was reduced by MFN).

If launch occurs in a reference country first and then the US, there is no directly measurable change in the US price on which to base an adjustment. Adjustments could be made based on a fixed percentage that is intended to estimate the effective reduction in US price. However, MFN-driven rebalancing may lead to increases in pricing in Europe and other key ex-US markets (which is

illustrated by the Eli Lilly and Bristol Myers Squibb examples discussed above) and the manner in which MFN will be implemented remains uncertain. This makes determining a fair adjustment in advance very difficult. An alternative that we have seen suggested is to leave the adjustment (potentially within an agreed range) to future negotiation, potentially with "baseball" or another form of arbitration as a backstop if agreement cannot be reached.

Given the potential for other impacts on overall economics beyond MFN (such as tariffs or required supply chain shifts out of lower cost markets) and given the uncertainty of how MFN will impact prices, agreements could base adjustments on how global revenues and profitability compare to forecasts (e.g., to more closely align with the intended profit split that the upfront, milestones, and royalties were intended to simulate). This approach is much more difficult to reflect in agreements (and shifts additional risk to licensors) but could be useful if uncertainty continues.

2. Diligence obligations in global deals

License agreements often include commitments to use commercially reasonable efforts (CRE) to pursue regulatory approval or commercialization in the US and major ex-US markets.

A broad CRE obligation could, in practice, force the licensee to launch in markets even when doing so would create a low price that becomes an MFN benchmark for the US Licensees should therefore carefully consider whether they are willing to undertake CRE obligations in any potential reference countries. If they are willing to undertake these obligations, licensees should consider (a) using modified CRE definitions that expressly allow the potential impact of ex-US pricing decisions on US pricing to be taken into account or (b) having diligence obligations terminate with respect to an ex-US country if it would result in MFN pricing applying in the US.

Given there has tended to be alignment between ex-US CRE obligations and ex-US milestone payments, this shift in diligence obligations may lead to a change in milestone structuring.

b. Split-territory deals

The risks associated with MFN pricing are substantially higher in split-territory deals, where the split separates the US from one or more potential MFN reference countries. The ex-US licensee's pricing decisions are made entirely independently of the US rights holder's interests, and the US party has little or no natural leverage to prevent low prices outside the US from resetting the US MFN benchmark.

1. Should a split-territory deal be done at all?

The threshold question in any split-territory deal involving developed markets is whether the deal should be structured that way at all. Where the proposed split involves markets that are MFN reference countries (in particular G7 markets), the MFN risk for the US rights holder is particularly acute and structurally very difficult to mitigate by contract alone.

Parties contemplating such a structure should weigh whether the commercial rationale for splitting the territory justifies the MFN exposure that arises. In many cases, the preferable approach will likely be to keep developed country rights together. Either by structuring the transaction as a global deal or by grouping all major developed markets under a single licensed territory. This results in a structure so that a single party has both the incentive and the ability to manage pricing globally in a coherent and MFN-aware manner. Splitting off only territories that are not currently MFN reference countries (for example, China, markets in Southeast Asia or other developing regions) is considerably less problematic from an MFN perspective and may be a reasonable commercial compromise.

2. Split territory deal involving developed markets

If a split territory deal involving developed country markets must be done – for example because of pre-existing regional licensing commitments or strategic portfolio reasons – there are significant risks, as noted above. Parties may be significantly constrained by antitrust laws from coordinating pricing in the US and ex-US developed markets. Ensuring incentives are aligned, for example, by having the party with ex-US rights also have economic benefit from US sales, therefore becomes paramount. Assignment provisions may need to be modified so this alignment is maintained.

Conclusion

MFN pricing is set to change how innovative medicines are priced in the US and is already influencing pricing and launch strategies worldwide. The degree of impact will vary across portfolios. While the details are still evolving, the direction is clear: companies should start preparing for a more controlled and closely monitored pricing environment.

That preparation means reviewing existing agreements, checking ex-US pricing obligations that might set future MFN benchmarks, and building protective terms into new deals. Taking these steps now can help protect deal value, keep launch and pricing strategies flexible, and ensure companies are ready to adapt as MFN pricing policies take shape.

Contact us

Nadine Charrière
Associate
nadine.charriere@bakermckenzie.com

Shelly Kuo
Associate
shelly.kuo@bakermckenzie.com

Oren Livne
Partner
oren.livne@bakermckenzie.com

Julia Schieber
Partner
julia.schieber@bakermckenzie.com

Lois Liu Sheng
Counsel
loissheng.liu@bakermckenzie.com