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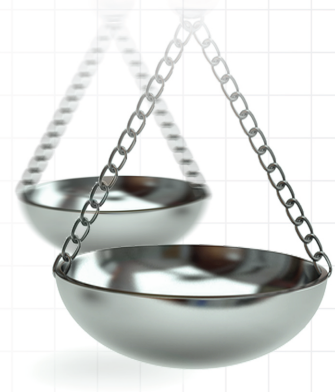

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Access in all areas? A round-up of developments in market access and health technology assessment: part 12

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In this update we cover the impacts of the US Most Favored Nation pricing policy and research evaluating drug availability and affordability in China as a result of the National Reimbursement Drug List negotiation policy.

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The financing of pharmaceutical innovation has long exhibited significant geographic disparities, with US patients paying substantially more for prescription medications than counterparts in other developed nations. This differential has generated persistent political pressure, culminating in President Trump's executive order in May 2025 directing alignment of US drug prices with the lowest prices paid by comparable nations through a Most Favored Nation (MFN) pricing framework, and contacting leading pharmaceutical manufacturers directly in July 2025 to bring down US medicine prices [1]. Concurrent with pricing demands, the administration launched the Commissioner's National Priority Voucher (CNPV) pilot program in June 2025, offering to reduce drug review times from 10–12 months to 1–2 months [2]. The program eligibility is tied to five priority areas: addressing US public health crises, providing transformative cures, meeting large unmet medical needs, onshoring manufacturing, and critically 'increasing affordability' through pricing aligned with MFN principles. The CNPV program represents a paradigm shift by explicitly linking pricing considerations to regulatory review timelines. Between September and October 2025, the administration announced agreements with three major pharmaceutical manufacturers: Pfizer (September 30) [3], AstraZeneca (October 10) [4] and EMD Serono (October 16) [5]. While differing in specific details, these agreements share common structural elements that reveal the practical implementation of MFN policy. Each agreement commits manufacturers to providing State Medicaid programs access to MFN drug prices, guaranteeing such pricing on future innovative medicines, repatriating increased foreign revenue from existing products for US patient benefit and offering deep discounts for direct-to-consumer sales. The Pfizer agreement, for example, specified discounts averaging 50% with maximum savings of 85% on select products, including 80% discounts on Eucrisa® (atopic dermatitis), 40% on Xeljanz® (rheumatoid arthritis) and 50% on Zavzpret® (migraines). In exchange, manufacturers receive exemption from Section 232 pharmaceutical tariffs, provided they invest in future biopharmaceutical manufacturing and research in the United States. The AstraZeneca agreement, for instance, includes commitment to invest $50 billion in US manufacturing and research by 2030, with a new facility in Charlottesville, Virginia, creating 3600 highly skilled jobs while producing active pharmaceutical ingredients for chronic disease and oncology pipelines. The EMD Serono agreement introduced novel features including collaboration with specialty pharmacies and inclusion in the CNPV pilot program for expedited review. The company committed to offer its complete portfolio of *in vitro* fertilization (IVF) therapies, including Gonal-F®, Ovidrel® and Cetrotide®, through direct-to-consumer channels at significantly reduced prices, with eligible patients receiving 84% discounts off list prices. Importantly, EMD Serono committed to manufacturing IVF drugs domestically for the first time, with implementation beginning January 2026.

Parallel to negotiated agreements, manufacturers have begun adjusting international prices in response to MFN pressures. Most notably, Eli Lilly announced in August 2025 that UK list prices for Mounjaro® (tirzepatide) would increase by up to 170% effective 1 September 2025, with the highest strength injection package rising from £122 to £330 [6]. The company explicitly stated this adjustment would "*address pricing inconsistencies compared with other developed countries*" and ensure "*fair global contributions to the cost of innovation*". Similarly, Bristol Myers Squibb announced plans to launch Cobenfy™ (xanomeline and trospium chloride) in the UK in 2026 at a list price equal to the US launch price, marking a departure from historical patterns where UK prices were substantially lower [7]. The company stated this approach would "*reflect the value of this medicine for patients and society*" while calling on the UK government to "*collaborate with the life sciences sector to increase investment in new medicines and fully recognize the value that innovation brings*". These price adjustments reveal a critical tension in MFN policy implementation. While manufacturers have raised list prices internationally, they have simultaneously negotiated confidential discounts with national health systems to maintain actual access. Lilly confirmed it had "*reached an agreement with the NHS to ensure continued supply and patient access*", suggesting NHS patients would see minimal impact after confidential rebates are applied. However, private patients lack similar protections, with an estimated 1.5 million UK patients accessing Mounjaro privately in March 2025 alone potentially facing substantial cost increases. Despite stated goals of reducing US drug costs, manufacturers have not yet publicly committed to substantive US list price reductions. Mounjaro remains priced at approximately $1080 in the US market, while Lilly has only stated it "*remains committed to working with the administration on drug pricing reforms that benefit patients*" without specifying price reduction timelines or magnitudes. The complexity of the US healthcare system, combining public and private providers, insurers, funders and multiple intermediaries, means that raising drug prices abroad does not automatically translate to lower domestic costs.

From a market access perspective, as previously discussed, the MFN policy implementation has generated several strategic implications. Manufacturers need to try to optimize global returns on investment [8] by: maintaining US pricing levels that support innovation financing, achieving list prices in reference pricing markets that satisfy MFN policy expectations and securing confidential discounts that enable market access in price-sensitive markets (as evidenced by Mounjaro) [1]. The MFN policy, however, creates incentives for manufacturers to focus development and launch strategies on the US market, potentially delaying or forgoing launches in markets with less favorable pricing dynamics. The negotiated agreements with Pfizer, AstraZeneca and EMD Serono establish templates for future manufacturer engagement, emphasizing direct-to-consumer distribution, domestic manufacturing commitments and integration with expedited regulatory review. If manufacturers wish to prioritize US speed to market, they should conduct comprehensive portfolio assessments to identify products that might qualify for CNPV program benefits and evaluate how development programs might be optimized to maximize expedited review eligibility. This requires early integration of pricing strategy considerations into development planning rather than treating pricing as a late-stage commercialization decision. Manufacturers should also evaluate opportunities to expand direct-to-consumer distribution models. The potential to reduce intermediary costs while improving patient access makes this an attractive strategic direction, though successful implementation requires careful evaluation of which products are suitable for direct distribution, development of required operational capabilities and navigation of regulatory requirements governing direct-to-consumer pharmaceutical sales. Finally, manufacturers should enhance health economics and outcomes research capabilities to support value-based pricing discussions with diverse stakeholders. As pricing debates intensify globally, the ability to demonstrate product value across multiple dimensions becomes increasingly important for maintaining pricing flexibility and securing reimbursement. We are seeing the ripple effects of MFN, with England's National Institute of Health and Care Excellence possibly considering increasing it's cost-effectiveness threshold [9]. The MFN policy debate reflects broader societal concerns about pharmaceutical pricing and access; manufacturers who engage constructively in these discussions will be better positioned for sustainable success.

While the US MFN policy seeks to reduce domestic drug costs by referencing international prices, other major pharmaceutical markets like China have developed alternative centralized approaches to balancing innovation incentives with population-level affordability and access. China's pharmaceutical market access landscape has undergone significant transformation since the implementation of the National Reimbursement Drug List (NRDL) negotiation policy, beginning in 2016. The Chinese government established the NRDL negotiation policy to address a fundamental challenge: the substantial gap between innovative drug prices and patient affordability. By 2018, patented originator drugs accounted for only 9% of prescription drug spending in China, compared with over 40% in Europe and the United States, highlighting significant disparities in access to innovative medicines.

The National Healthcare Security Administration, established in 2018, formalized and institutionalized these negotiations, leveraging China's position as the world's largest single-payer healthcare system to negotiate substantial price reductions in exchange for inclusion in the national reimbursement list.

Two recent comprehensive studies provide valuable insights into the multidimensional impact of this policy on drug availability, affordability and equity, offering important lessons for pharmaceutical manufacturers navigating this critical market. Qiu and colleagues conducted a cross-sectional analysis utilizing three drug databases covering 2018–2021, examining 233 negotiated drugs across six dimensions: availability (measured through proportion of procurement hospitals and defined daily doses), affordability (assessed via defined daily dose costs, reimbursement proportions and drug price indices), and equity (evaluated using Gini coefficients) [10]. Complementing this work, Hu and colleagues employed interrupted time series analysis on data from 698 hospitals, examining 155 negotiated drugs across six negotiation rounds from 2016 to 2021 [11]. The findings demonstrate substantial improvements in drug accessibility following policy implementation. Qiu *et al.* reported that defined daily doses showed remarkable growth with compound annual growth rates ranging from 25.21% to an extraordinary 26,700% across different drug categories. Hu and colleagues corroborated these findings, observing that average drug usage increased 3–12-fold after NRDL inclusion, with availability rising 1.5–4.5 times compared with pre-intervention levels. Both studies documented significant reductions in drug costs, with Qiu *et al.* reporting compound annual growth rates of defined daily dose costs ranging from -6.28 to -70.20%. Hu and colleagues found average defined daily dose cost decreases of up to 77.8%. Qiu *et al.* found that over 60% of Anatomical Therapeutic Chemical classifications demonstrated Gini coefficients below 0.4, indicating adequate equality in drug expenditure distribution across China's diverse provinces. Despite improvements, absolute medicine availability levels remain concerning, with Hu and colleagues reporting post-intervention availability ranging only from 19.4 to 33.6% – low by international standards according to the WHO/Health Action International.

For pharmaceutical manufacturers, these findings carry several strategic implications. The Chinese market offers substantial volume opportunities in exchange for significant price concessions, with the policy demonstrably expanding patient utilization. The geographic equity achieved suggests that successful NRDL inclusion provides relatively uniform national market access, reducing traditional regional disparities. Companies must prepare for transparent, value-based negotiations emphasizing clinical efficacy, cost-effectiveness and willingness-to-pay thresholds. The successful navigation of China's pharmaceutical market depends on acceptance of China's distinctive approach to balancing innovation incentives with population health objectives.

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