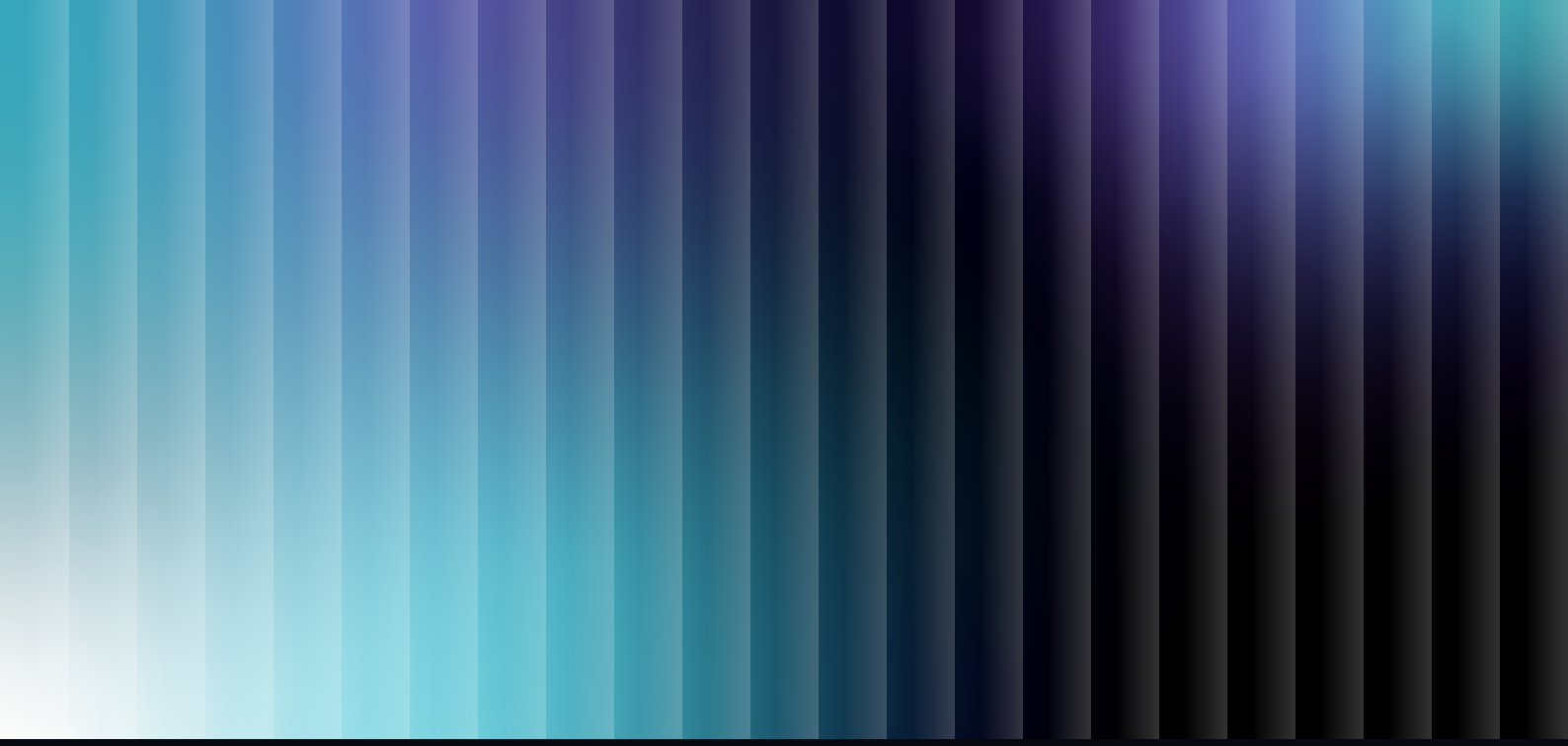

US MFN and Its Implications for Pharmaceutical Access

From a Multinational Expert Network

2026

Contents

United States (US) Most Favored Nation (MFN) and Its Implications for Pharmaceutical Access

0.1 Our multinational expert network

What is the purpose of this whitepaper?

0.2 Executive summary

01

To examine the potential implications of US MFN pharmaceutical pricing policies for pharmaceutical companies.

02

To provide guidance to pharmaceutical companies on how to operate effectively in this rapidly evolving environment, with expert input from each MFN country*.

What is MFN?

It is a series of policy proposals from the current US administration, in varying stages of development. The stated objective is "[To provide Americans with] low-cost pharmaceuticals on the same terms as other developed nations (1)."

- In the context of Medicaid policy, MFN will be implemented as a voluntary 5-year pilot program for outpatient drugs, using the GENErating cost Reductions fOr US Medicaid ("GENEROUS") model. This model will reference prices in relevant international benchmark countries (Section 1.2). The application period for manufacturers runs between November 10, 2025, and March 31, 2026.
- The Medicare MFN policy is less developed, currently undergoing a consultation period. A 7-year pilot is proposed, separated across Parts B and D, scheduled to start in October 2026 and January 2027, respectively. As per the GENEROUS model for Medicaid, these models (Global Benchmark for Efficient Drug Pricing (GLOBE) and Guarding US Medicare Against Rising Drug Costs GUARD)) will reference prices in relevant international benchmark countries (Section 1.2).

What are the implications of MFN?

- Staggered or differentiated indication launches
- Variant-based launch strategies (e.g., multiple doses, formulations, contracts)
- Alternative channel strategies (i.e., private market launches)
- Evolution of international reference pricing (IRP) and launch sequencing tools
- Delayed and/or more targeted ex-US launches
- Narrowing of global pricing corridors
- Critical importance of confidential net prices outside the US
- Increased importance of lifecycle price discipline

What value does this multinational expert network bring?

- The multinational network of separate consultancies that has developed this whitepaper provides country-level understanding from each MFN country* combined with a summarized global viewpoint.
- The network can identify pricing and access opportunities in each MFN country, while continuously monitoring how different countries adapt their MFN-related policies and implementation approaches over time.

* As defined by the GENEROUS model under the current Medicaid MFN policy.

This paper presents an analysis of the potential implications of US MFN pharmaceutical pricing policies from the perspectives of pharmaceutical manufacturers and country-specific public agencies responsible for health financing, pricing, and access. The views and data presented are intended to support technical understanding and policy dialogue and do not constitute official positions, policy recommendations, or binding statements of any government, agency, or international organization.

Nothing in this paper should be interpreted as legal advice, regulatory guidance, or an endorsement or rejection of any specific policy proposal. References to US policy initiatives, statutes, regulations, or executive actions are provided for analytical context only and may evolve over time. Readers should not rely on this paper as a substitute for consultation with legal, regulatory, or policy experts.

The analysis reflects the information available at the time of writing. Policy design, implementation details, and enforcement mechanisms related to MFN proposals remain subject to change, legal challenge, and administrative interpretation. As such, conclusions regarding impacts on pharmaceutical pricing, access, and market behavior should be understood as conditional and illustrative rather than predictive or definitive.

1. Introduction

1.1 Background on US MFN and global pharmaceutical pricing

- US drug prices are recognized to be significantly higher than those in other developed markets. List prices from 2022 in the US were reported to be 422% of prices in a selected group of 33 Organization for Economic Co-operation and Development (OECD) countries for brand-name originator drugs (2).
- The US holds less than 5% of the global population, and yet funds around three-quarters of global pharmaceutical profits (1).

- The current US administration states the objective of MFN as: "[To provide Americans with] low-cost pharmaceuticals on the same terms as other developed nations" (1).
- Below is an abbreviated timeline of MFN policy events:

01 → **02** → **03** → **04**

2020

An MFN model was originally proposed in the first Trump administration (2020) that would link Medicare Part B payment limits to the lowest prices paid in similar OECD countries. This policy was never implemented due to legal challenges (3).

2021

The Biden administration removed regulatory text to support the launch of an MFN model in 2021, citing concerns about access and broader impacts (4).

may 2025

In May 2025, President Trump signed an Executive Order titled "Delivering MFN Prescription Drug Pricing to American Patients". The order directed the Centers for Medicare & Medicaid Services (CMS) and other US government agencies to develop rules linking US drug prices to the lowest prices in a set of economically comparable countries, with the aim to reduce US drug prices (5).

late 2025

In late 2025, the CMS released detailed proposals that would implement MFN-style pricing in Medicare Parts B and D (GLOBE and GUARD models), along with a voluntary Medicaid MFN framework (GENEROUS) (6).

The MFN proposals have separate scopes across US government healthcare programs:

01

Medicaid: MFN will be implemented as a voluntary 5-year pilot program only for outpatient drugs that (6):

- Will include supplemental rebates informed by international price benchmarks using the GENEROUS model. Specifically, the following international price benchmarks: the United Kingdom (UK), France, Germany, Italy, Canada, Japan, Denmark, and Switzerland. CMS will select the 2nd-lowest net price and adjust it for purchasing-power parity.
- Will require manufacturers to report international prices to CMS for each covered outpatient drug within 30 days of entering into a participating agreement.

02

Medicare: There are two MFN models currently in the consultation period, GLOBE and GUARD, which, unlike the GENEROUS model, are proposed as mandatory for manufacturers (6):

- GLOBE: A 7-year pilot proposed to start in October 2026, for Medicare **Part B**, using prices from 19 potential countries to set a benchmark. CMS will calculate the standard inflation rebate and the international benchmark rebate, and then require manufacturers to pay the greater rebate as a supplemental amount.
- GUARD: A 7-year pilot proposed to start in January 2027, for Medicare **Part D**, using prices from the same 19 potential countries to set a benchmark. Under the model, international reference-based benchmarks would be used to calculate manufacturer rebate obligations for selected Part D drugs when the Medicare net price exceeds the benchmark.

When referring to "MFN countries", it is often the eight countries from the GENEROUS (Medicaid) model that are being referenced, and as such are the focus of this whitepaper. A summary of the MFN countries proposed as references across Medicaid and Medicare is illustrated below.

Medicaid — 8 countries proposed by CMS:

- UK
- France
- Germany
- Italy
- Canada
- Japan
- Denmark
- Switzerland

Medicare (Part B and D) — 19 potential countries proposed by CMS:

- Australia
- Austria
- Belgium
- Canada
- Czech Republic
- Denmark
- France
- Germany
- Ireland
- Israel
- Italy
- Japan
- Netherlands
- Norway
- South Korea
- Spain
- Sweden
- Switzerland
- UK

2. United States perspective

2.1 Baseline: How US pharmaceutical pricing and access function today

35.5%*

of the US population is covered by key government healthcare programs (7).

The two largest government healthcare programs are:

Medicare (coverage for 65 years or older and/or disabled):

- Part B (physician-administered drugs) – Coverage is national once a drug achieves US Food and Drug Administration (FDA) approval and coverage is deemed by CMS to be "reasonable and necessary". Payments are historically based on average selling price (ASP) plus an add-on (e.g., 6.0% statutory rate, but due to sequestration, the effective rate has been ASP plus 4.3% for extended periods since 2013) (8).
- Part D (outpatient prescription drug) – Coverage decisions are made by private Part D plans. These plans use formularies, tiers, and utilization management to control drug usage. CMS sets minimum coverage rules. Rebates are negotiated with plans and pharmacy benefit managers (PBMs) and can be subject to the Inflation Reduction Act (IRA) price negotiation, depending on the level of spend.

Medicaid (coverage for low-income populations):

- Mandatory coverage of FDA-approved drugs. Manufacturers must provide statutory rebates. The base rebate for brands is 23.1%. Prices are set by the "Best Price Rule" – Medicaid must get the lowest net price in the US.

53.8%*

of the US population is covered by employer-sponsored or other group-purchased plans administered by private insurers (7), and 10.7%* are covered by private individual direct-purchase insurance (9).

- PBMs design formularies on behalf of insurers and employers. While manufacturers are free to set list prices, they will have to negotiate rebates, formulary positioning, and any volume guarantees with PBMs. The formulary placement determines patient co-pay and potential volume uptake. PBMs can also control uptake with various levers, such as "prior authorization", step therapy, and quantity limits.

8.0%*

of the US population are uninsured (7).

*These figures reflect point-in-time coverage status and may overlap, as individual can hold more than one coverage type simultaneously.

2.2 What MFN aims to change from a US perspective

01

The current US administration states the objective of MFN as: "[To provide Americans with] low-cost pharmaceuticals on the same terms as other developed nations" (1).

02

The Department of Health & Human Services (HHS) aims to align "US pricing for all brand products across all markets that do not currently have generic or biosimilar competition with the lowest price of a set of economic peer countries" (10).

03

The White House has shared that MFN policy is intended to influence the US commercial healthcare market (1).

04

It is important to understand that MFN is not merely a health policy, but also a trade policy.

2.3 Implications for access, coverage, and manufacturer behavior in the US

01

Direct-to-consumer (DTC) pathways are likely to become more prevalent in the US, partially due to new government policies. These programs will only be accessible to a small percentage of patients due to insurance coverage status, ability to pay cash, and digital literacy.

02

As MFN pilots are implemented, there will be **disproportionate impacts on providers and patients** depending on the numerous variations in the pilots (e.g., drugs included, geography, and type of Medicaid/ Medicare enrollment). Patient access in the affected areas should be monitored.

03

The MFN pricing pilot models for Medicare (GLOBE and GUARD) are still being finalized. As they are currently constructed, the impact on patients' out-of-pocket costs will vary by product and geography eligibility. It is difficult to predict whether this will lead to lower beneficiary cost sharing (out-of-pocket expenses for patients).

04

Global launch sequencing will change, and the US launch success will be increasingly critical for companies within covered therapeutic areas due to changing revenue margins. **Manufacturers will need to tighten focus on new product launches regarding payer mix and site of care dynamics in the US.**

3. MFN reference-country chapters

3.1 United Kingdom

01

Healthcare across England, Scotland, Wales, and Northern Ireland is funded through general taxation, with national budgets set by His Majesty's (HM) Treasury.

02

National Institute for Health and Care Excellence (NICE), the health technology assessment (HTA) agency in England, assesses cost effectiveness & determines national coverage decisions.

03

NICE-approved technologies must be funded by the National Health Service (NHS) within set timelines.

04

Integrated care boards (ICBs) commission services; providers are reimbursed via national payment mechanisms.

05

Managed access agreements/ commercial arrangements address uncertainty and affordability.

06

The Scottish Medicines Consortium (SMC) and All Wales Medicines Strategy Group (AWMSG) are devolved HTA bodies that independently appraise medicines for Scotland and Wales, respectively. SMC and AWMSG consider NICE decisions but conduct independent, faster appraisals.

07

There is one national list price under the UK commercial framework, which applies across England, Scotland, Wales, and Northern Ireland.

08

Prices are set by manufacturers under a voluntary scheme for branded medicines pricing, access, and growth (VPAG) or statutory rules; list prices are public, net prices often confidential.

09

As part of the US-UK Economic Prosperity Deal, the UK has secured arrangements to continue access to innovative medicines and encourage early drug launches in the UK, in exchange for making changes to NHS pricing structures and rebate schemes (11).

10

Pilots or soon-to-emerge processes (non-exhaustive): Medicines and Healthcare products Regulatory Agency (MHRA)–NICE Accelerated Aligned Pathway pilot; Innovative payment model pilots for advanced therapies and VPAG.

Key MFN-related facts	
Are confidential discounts possible? If yes, what prerequisites need to be fulfilled?	Confidential discounts via Patient Access Schemes apply to NICE-appraised medicines not cost-effective at list price, supported by evidence, administratively simple, and reflected in final guidance.
Is it possible to withdraw from negotiations (including point in time)?	Yes. Manufacturers can withdraw from negotiations any time before final NICE guidance, during scoping, evidence submission, committee review, or commercial discussions—typically terminating the appraisal process.
Is it possible to negotiate only for a subpopulation?	Yes, NICE can restrict recommendations to a defined subpopulation. The subgroup must have clear clinical/economic evidence & the restriction appears in the final guidance.
Is international price referencing part of the negotiation? If yes, please state the relevant mechanisms.	No, not directly.
What are triggers for renegotiations?	New clinical or economic evidence, comparator changes, updated NICE guidance, international pricing shifts, NHS budget constraints, or modified patient access requirements.
Is free pricing possible, if the product is not reimbursed?	Yes, but uptake is typically limited to private prescriptions or self-pay patients.
Are innovative reimbursement agreements possible on the national level?	Yes, outcome-based schemes or managed access via Patient Access Schemes, are possible, contingent on NICE appraisal, NHS England approval, and operational feasibility.
At what time point is the public list price published relative to the HTA submission?	At or just before MHRA approval, around the time of NICE HTA submission.

01

The national health insurance system (Caisse Nationale de l'Assurance Maladie (CNAM)) provides coverage for all residents.

02

Value-based pricing approach.

03

Prices are negotiated at the national level with the Economic Committee for Health Products (Comité économique des produits de santé (CEPS)).

04

Prices negotiated are valid for the outpatient setting. For inpatient setting, there are 2 possibilities:

- Drug funded specifically on top of the diagnosis-related group ((DRG) budget "liste en sus"): price negotiations with CEPS.
- Drug funded within DRG budget: no price negotiation with CEPS (negotiations at hospital level), but this generally means the drug will not be selected/used by the hospital.

Key MFN-related facts

Are confidential discounts possible? If yes, what prerequisites need to be fulfilled?	Yes, pre-requisites are: • At least moderate clinical added value (Amélioration du Service Médical Rendu III (ASMR III)). • Or a minor clinical added value (ASMR IV) + some additional criteria (e.g., orphan status). • No clinical added value (ASMR V) only in exceptional cases.
Is it possible to withdraw from negotiations (including point in time)?	Yes, it implies the drug will not be reimbursed if commercialized by the company. This withdrawal can be made up until a final ministerial decision is issued.
Is it possible to negotiate only for a subpopulation?	No, unless the French National Authority for Health (Haute Autorité de Santé (HAS)) has specifically concluded to a different clinical added value in that population.
Is international price referencing part of the negotiation? If yes, please state the relevant mechanisms.	International pricing is generally not used for negotiation of the net price. For the list price (publicly available), it should not be lower than the lowest price observed in the UK, Germany, Italy, and Spain.
What are triggers for renegotiations?	Mainly re-evaluations by HAS in case of new data available. Price decrease planned after some time (or if generics).
Is free pricing possible, if the product is not reimbursed?	Yes.
Are innovative reimbursement agreements possible on the national level?	Yes (but limited and with strict rules).
At what time point is the public list price published relative to the HTA submission?	This price is published after the HTA evaluation, and subsequent price negotiation with CEPS has been completed.

01

Statutory health insurance (SHI) provides coverage for all residents.

02

Value-based pricing approach.

03

Prices negotiated at the national level with the GKV-Spitzenverband (GKV-SV).

04

Prices negotiated are valid for outpatient as well as inpatient settings.

Key MFN-related facts	
Are confidential discounts possible? If yes, what prerequisites need to be fulfilled?	Yes, bound to conditions (research activity in Germany) and an additional rebate of 9% necessary. If conditions are no longer fulfilled, a new negotiation followed by a publicly visible price.
Is it possible to withdraw from negotiations (including point in time)?	Yes, opt-out only within 14 days after the first negotiation date.
Is it possible to negotiate only for a subpopulation?	No, pricing and reimbursement (P&R) according to label (different indications or subpopulations lead to a mixed price).
Is international price referencing part of the negotiation? If yes, please state the relevant mechanisms and the reference countries.	No.
What are triggers for renegotiations?	The Federal Joint Committee (Gemeinsamer Bundesausschuss (G-BA)) resolution and price negotiation: Extension of indications, new scientific knowledge, Orphan Drugs: € 30-Mio-turnover. Only price negotiation: End/termination of contract between the GKV-SV and the company.
Is free pricing possible, if the product is not reimbursed?	No. There is an obligation to negotiate a reimbursement price.
Are innovative reimbursement agreements possible on the national level?	Yes, but are more the exception.
Minimum and average time from HTA approval to public price listing.	With launch, the price becomes a public price for 6 months with free pricing for the pharmaceutical company, and within 12-15 months on average, the negotiated reimbursement price becomes a publicly visible price.

01

Italy operates a tax-funded, decentralized National Health Service (Servizio Sanitario Nazionale (SSN)).

02

The system is divided into 21 territorial entities (19 Regions + 2 Autonomous Provinces).

03

Since 2001, Regions have concurrent legislative powers and direct responsibility for organizing and managing healthcare delivery through their Regional Health Services (Servizio Sanitario Regionale (SSR)).

04

The State, through the Ministry of Health, defines the Essential Levels of Care (Livelli Essenziali di Assistenza (LEA)) that must be guaranteed nationwide.

05

Pharmaceutical policy is centralized at the national level, although delivery and implementation occur regionally.

Key MFN-related facts

Are confidential discounts possible? If yes, what prerequisites must be met?	Yes, confidential discounts are extensively used.
Is it possible to withdraw from negotiations (including point in time)?	Yes, and withdrawal is possible and is not time-bound.
Is it possible to negotiate only for a subpopulation?	Yes, this is commonly done in practice.
Is international reference price part of the negotiation? If yes, please state the relevant mechanisms and the reference countries.	Yes, applies external reference pricing. International prices are requested but generally not used for negotiation of the net price at launch. Relevant countries include: the United Kingdom, Germany, France and Spain.
What are triggers for renegotiations?	New indications or label extensions; clinical or emerging real-world evidence; and the expiration or expiry or revision of managed entry agreements (MEAs).
Is free pricing possible, if the product is not reimbursed?	Yes, but only for non-reimbursed medicines (Class C).
Are innovative reimbursement agreements possible on the national level?	Yes, Italy is one of the most experienced markets for these agreements.
Minimum and average time from HTA approval to public price listing.	The public list price becomes visible once the product is reimbursed. The average time to reimbursement is typically 12-18 months from European Medicines Agency (EMA) approval.

01

Decentralized, publicly funded healthcare system: Outpatient drugs are covered through a combination of provincial/territorial/federal drug plans, private drug plans (employer funded) and out-of-pocket costs for patients.

02

HTA recommendations from Canada's Drug Agency (L'Agence des médicaments du Canada; CDA-AMC) (formerly the Canadian Agency for Drugs and Technologies in Health; CADTH) or Quebec's National Institute of Excellence in Health and Social Services (Institut national d'excellence en santé et en services sociaux; INESSS) are generally required before pan-Canadian Pharmaceutical Alliance (pCPA) negotiations; most recommendations are conditional on significant price reductions.

03

Each province has different eligibility criteria, with most public drug plans covering seniors and those on social assistance (~42% of prescription spending); hospital drugs are publicly funded through provincial budgets.

04

Private drug plans (primarily employer-sponsored, ~38% of spending) also negotiate confidential net prices directly with manufacturers.

05

Canadian manufacturer ex-factory list prices for patented medicines are subject to price-ceiling regulation by the federal Patented Medicine Prices Review Board (PMPRB), which uses IRP against the PMPRB 11 basket of countries (Australia, Belgium, France, Germany, Italy, Japan, Netherlands, Norway, Spain, Sweden and the UK). Canadian prices may also be used as reference points in some other countries' pricing systems.

06

Actual net reimbursement prices are negotiated confidentially through the pCPA and listing decisions are made by provincial/territorial/federal drug plans through Product Listing Agreements (PLAs).

Key MFN-related facts

Are confidential discounts possible? If yes, what prerequisites need to be fulfilled?	Yes, confidential discounts are implemented through PLAs following pCPA negotiations with public drug plans. Prerequisites: Health Canada approval (NOC) a pCPA decision to engage, and a successful negotiation resulting in a Letter of Intent (LOI). Confidential rebates are not disclosed to PMPRB or HTA bodies.
Is it possible to withdraw from negotiations (including point in time)?	Yes, the manufacturer can withdraw at any point in the process. Consequence: the drug is typically not listed on public formularies. Re-entry possible via unsolicited offer, at pCPA discretion.
Is it possible to negotiate only for a subpopulation?	Yes. Only 0.9% of CDA recommendations are unconditional; 84.6% include utilization management criteria that are narrower than the Health Canada-approved indication. Sub-populations can be negotiated if supported by the HTA and the evidence.
Is international price referencing part of the negotiation? If yes, please state the relevant mechanisms.	PMPRB implements international list price referencing.
What are triggers for renegotiations?	Generic/biosimilar entry; indication expansion (new HTA review required); PMPRB price-ceiling reductions; volume or budge- cap exceedance; entry of new comparators (therapeutic review); PLA term expiration.
Is free pricing possible if the product is not reimbursed?	No for patented medicines. PMPRB regulates excessive pricing for all patented medicines regardless of reimbursement status. Unsuccessful pCPA negotiation typically results in loss of the public market (on average ~33%) and private plans often follow public coverage decisions.
Are innovative reimbursement agreements possible on the national level?	Yes, although these agreements are not common.
At what time point is the public list price published relative to the HTA submission?	The list price is set by the manufacturer prior to Health Canada approval (Notice of Compliance (NOC)) and is published before pCPA negotiations begins. HTA submission can begin up to 180 days before anticipated NOC (pre-NOC submission).

01

Universal healthcare coverage through a statutory national health insurance (NHI) system.

02

Centralized pricing and reimbursement are set by the Ministry of Health, Labour and Welfare (MHLW).

03

Uniform national reimbursement prices apply in both inpatient and outpatient settings.

04

Prices are set via cost-based or comparator-based methods at launch, followed by mandatory annual price revisions (semiannual reviews are increasingly common).

05

Multiple post-listing price adjustment mechanisms apply (e.g., market expansion repricing, dosage/regimen change repricing).

Key MFN-related facts

Are confidential discounts possible? If yes, what prerequisites need to be fulfilled?	No. Prices are publicly listed and nationally uniform, with no formal mechanism for confidential rebates or managed entry discounts. Effective price reductions occur only through mandatory price revisions.
Is it possible to withdraw from negotiations (including point in time)?	Yes. Companies may withdraw prior to NHI listing and Chuikyo price decision. Once listed, participation in price revisions is mandatory.
Is it possible to negotiate only for a subpopulation?	Generally, no. A single national price applies across the approved label. Premiums (e.g., innovation, orphan, pediatric) may apply but do not constitute indication-based pricing.
Is international price referencing part of the negotiation? If yes, please state the relevant mechanisms.	Yes. Japan applies Foreign Average Price (FAP) referencing at launch and during repricing, typically referencing the US, the UK, Germany, and France.
What are triggers for renegotiations?	Annual price revisions; market expansion beyond initial assumptions; new indications or dosage changes; loss of exclusivity; and policy-driven repricing reforms.
Is free pricing possible, if the product is not reimbursed?	Limited. A small non-reimbursed private market exists, but most innovative medicines seek NHI listing, where free pricing is not permitted.
Are innovative reimbursement agreements possible on the national level?	Very limited. Formal outcomes-based or confidential agreements are rare; value recognition is handled through premiums and pricing rules rather than contracts.
At what time point is the public list price published relative to the HTA submission?	At the time of NHI listing, following Chuikyo approval.

01

Tax-funded, decentralized healthcare system providing universal coverage to all residents.

02

List (public) prices in Denmark are widely referenced by other European countries.

03

List prices in Denmark are set freely by pharmaceutical companies.

04

The incremental cost-effectiveness ratio (ICER) from cost-effectiveness modeling is highly influential in decision-making for hospital-based medicines.

05

For hospital-based medicines, the net price is negotiated nationally with Amgros at based on the preliminary assessment from Danish Medicines Council (DMC) submission. For outpatient medicines, an abbreviated submission is assessed by the Danish Medicines Agency (DMA).

06

The private market for hospital-based medicines is very limited.

Key MFN-related facts	
Are confidential discounts possible? If yes, what prerequisites need to be fulfilled?	Yes, confidential discounts are possible via an agreement with Amgros.
Is it possible to withdraw from negotiations (including point in time)?	Yes, the applicant can withdraw the application at any time prior to the decision.
Is it possible to negotiate only for a subpopulation?	Yes.
Is international price referencing part of the negotiation? If yes, please state the relevant mechanisms.	No.
What are triggers for renegotiations?	Entry of a generic or biosimilar; policy or guideline changes; expansion of the reimbursed population; exceeding any agreed budget or volume cap; and entry of a new branded comparator.
Is free pricing possible, if the product is not reimbursed?	Yes.
Are innovative reimbursement agreements possible on the national level?	Yes.
At what time point is the public list price published relative to the HTA submission?	List price is published prior to DMC/DMA submission.

01

Solidarity-based, mandatory health insurance system providing universal coverage to all residents. Additional private health insurance is optional.

02

Public list prices are negotiated at the national level with the Swiss Federal Office of Public Health (FOPH), and formal price setting and review processes are anchored at the federal level.

03

For hospital-based medicines, access and net pricing are largely negotiated at the cantonal or hospital level.

04

Single case reimbursement is possible in specific cases with defined discounts on the international reference price average.

05

The private market plays a limited but growing role, with rising interest in supplementary or alternative access pathways.

Key MFN-related facts

Are confidential discounts possible? If yes, what prerequisites need to be fulfilled?	Yes. List price is defined by IRP, net price ≥25% below list price to be confidential. Net price agreed with the Ministry of Health.
Is it possible to withdraw from negotiations (including point in time)?	Yes, at any time.
Is it possible to negotiate only for a subpopulation?	Yes, if clinical data support efficacy in a subpopulation. Often, the FOPH uses cohort-limited reimbursement to contain costs.
Is international price referencing part of the negotiation? If yes, please state the relevant mechanisms.	Yes. Arithmetic mean of published prices of nine European reference countries with similar economic structure/wealth (AT, BE, DE, DK, FI, FR, NL, SE, the UK).
What are triggers for renegotiations?	Renegotiations occur regularly, every 1.5 - 3.0 years, with every label change, loss-of-exclusivity (LoE), etc.
Is free pricing possible, if the product is not reimbursed?	Yes.
Are innovative reimbursement agreements possible on the national level?	Yes.
At what time point is the public list price published relative to the HTA submission?	List price published after reimbursement decision. Time point varies based on indication and disease area, and can take up to 300 days post marketing authorization or even longer. No defined negotiation timelines.

4. How pharmaceutical companies can operate effectively in an MFN environment

4.1 Strategic implications for global pricing and launch sequencing

The emergence of MFN style pricing represents a structural shift in how pharmaceutical value is translated into price, particularly in the US. While pharmaceutical companies have long operated under IRP systems across Europe and other ex-US regions, MFN fundamentally alters the equation by explicitly integrating US pricing into global reference dynamics. This weakens the historical separation between the US and ex-US markets on price, and materially increases the consequences of pricing decisions made outside the US.

Historically, pharmaceutical companies have used IRP strategically to manage prices both globally and within the European Union (EU). A well-established example is Germany, which has often been treated as a priority launch because the initial free-pricing period is used as a strong price anchor for referenced markets. In practice, some companies have deprioritized or delayed launches in other European markets to protect or optimize the German price. Under MFN-style pricing, a similar but more consequential logic emerges: pricing decisions outside the US can no longer be allowed to jeopardize the US price. The US effectively becomes the new anchor market in global pricing strategy.

Pricing decisions outside of the US can no longer be optimized in isolation. Instead, pharmaceutical companies must adopt a proactive, globally coordinated pricing and access strategy that explicitly accounts for MFN exposure, reference chains, and lifecycle price erosion, for resilient and risk-adjusted access across interconnected systems over the full therapy lifecycle.

The following implications have been consolidated from our multinational expert network, with insights from each of the currently considered MFN countries.

Delayed and/or more selective launches outside the US

Manufacturers are likely to become more selective and deliberate in ex-US launches. We expect increased prioritization of "non-MFN" countries (i.e., those not referenced by the US) ahead of MFN countries that were historically prioritized, due to reference pricing risks. This may materially rebalance traditional global launch sequences across the industry.

Narrowing of global pricing corridors

The width of global pricing corridors is expected to narrow significantly, reducing the ability to independently optimize pricing across US and ex-US markets. Manufacturers will face pressure to reduce the gap between US list and net prices, potentially through lower US launch list prices or tighter global net price discipline.

Critical importance of confidential net prices outside the US

Confidential discounting mechanisms outside the US will become increasingly important. Manufacturers must have a clear and early understanding of where confidential agreements are feasible, under which conditions they can be negotiated, and how they are treated in reference pricing frameworks. This understanding must be established well before P&R submissions.

Increased importance of lifecycle price discipline

Beyond launch prices, price discipline over the full product lifecycle becomes materially more important. Average price erosion over time, including through renegotiations, indication expansions, and competitive dynamics, now carries greater global risk.

Cautious approach to indication expansions

Manufacturers may hesitate to launch additional indications or label expansions if these trigger price renegotiations that introduce new downside risks, including indirect effects on the US price through MFN mechanisms.

Alternative channel strategies

Manufacturers may explore more creative approaches to channel management, including private channel launches or restricted access pathways in MFN reference countries, where public pricing would pose unacceptable reference risks.

Evolution of IRP and launch sequencing tools

Existing IRP and launch sequencing tools must be updated to explicitly incorporate MFN policies and evolving country-specific implementation rules.

01

Targeted population strategies in ex-US MFN markets

- To support relatively higher price points outside the US, manufacturers may increasingly target more specific, high-value patient populations in relevant MFN markets. This approach requires early alignment between pricing strategy and clinical development teams.

02

Early trial design implications

- Clinical trial programs must be planned early to allow for pre-specified subgroup analyses or separate targeted trials. This enables flexibility to pursue differentiated pricing and access strategies across MFN and non-MFN markets at launch.

03

Staggered or differentiated indication launches

- Manufacturers may explore launching different indications in different ex-US MFN markets as part of a broader global pricing strategy, where regulatory and access frameworks allow.

04

Variant-based launch strategies

- For therapies with multiple doses, formulations, or administration routes, manufacturers may consider developing variant-specific evidence packages that support independent launches. This could mitigate direct MFN referencing effects but requires a deliberate and well-resourced evidence generation strategy.

Role of innovative pricing agreements under MFN

While it remains unclear how many innovative pricing agreements will be formally incorporated into MFN frameworks, these agreements are likely to play a critical role in practice. Outcome-based agreements, indication-specific pricing, budget caps, and volume-based arrangements can materially complicate cross-country price comparisons.

Creation of pricing non-transparency

Innovative agreements can be used strategically to create non-transparency in net prices across countries, making direct international price comparisons more difficult. This non-transparency can be an important risk-management tool under MFN, if agreements are structured in a way that limits the ability to reference.

Early capability and expertise requirements

It is critical that pharmaceutical companies have the internal resources, expertise, and governance structures to fully understand which innovative pricing agreements are legally and operationally feasible in each MFN country.

Indirect reference risks from non-MFN countries

Countries that are not formally included in MFN reference lists may still influence US prices indirectly if they are referenced by MFN countries. Manufacturers must therefore map not only direct MFN exposure but also second-order reference chains.

Private market supply as a strategic option

Where public market access would create unacceptable MFN or IRP risks, manufacturers may consider supplying products through private markets. While not feasible in all countries or therapy areas, this option should be systematically evaluated as part of a global access strategy.

01

- Build a comprehensive understanding of strategic launch options and requirements in ex-US markets included in MFN reference lists. Our multinational expert network of MFN countries can provide this service.

02

- Ensure that evidence generation strategies allow for flexibility to pursue targeted, higher-value populations at higher price points, where feasible. This requires an early understanding of country-specific evidence requirements.

03

- Extend evidence generation plans beyond launch to support long-term value defense, particularly in markets with established post-launch price renegotiation mechanisms.

04

- For MFN list countries, assess alternative access channels, including private markets, and explicitly incorporate these options into launch sequencing and IRP calculations.

05

- Establish or strengthen a centralized global pricing function with the authority to coordinate pricing corridors and risk management across all key markets, including the US.

06

- Identify relatively high-price markets that are excluded from current MFN lists and ensure that these markets are incorporated into early launch sequence planning, even if this requires deviation from historical commercial practices.

07

- Evaluate not only launch prices but also historical price erosion patterns across therapy areas when assessing launch sequencing. Markets with greater price stability may become more valuable under MFN dynamics.

08

- In markets that require price renegotiation upon indication expansion, consider delaying launches to allow clustering of indications within a single submission, where feasible, to reduce lifecycle price erosion risk.

01

Currently proposed MFN policies apply pressure to an already highly competitive pharmaceutical market. Within this evolving environment, pharmaceutical companies must understand their ex-US markets even better than they do today, to ensure that they are prepared to seize opportunities before competitors and avoid unnecessary risks of price erosion in key markets.

02

Pricing & access departments must be ready to engage even earlier with their clinical development and commercial counterparts to articulate the value of optionality for a newly emerging pricing environment. These options could unlock access that would otherwise remain closed to patients until late in the product lifecycle.

03

Along with impacts on manufacturers, we also anticipate ex-US decision-making authorities to indirectly feel this pressure. These ex-US reimbursement decision-makers will have to manage manufacturers that are more likely to walk away from negotiations. Expect ex-US reimbursement decision-makers to offer new access pathways for manufacturers in the next few months, as MFN policies materialize. Manufacturers must keep up to date on these new access pathways or risk falling behind the competition. On this and other related aspects of MFN, our multinational expert network can be a valuable resource to ensure opportunities and risks are understood.

5. Multinational Expert Network: Company descriptions

Cogentia (UK)

Cogentia®

Founded in 2010, Cogentia helps pharmaceutical and healthcare companies bring their products to market and drive patient uptake.

- Clients trust us as a long-term partner in launching new innovations and expanding patient access, whether for strategic, ongoing, or ad-hoc projects.
- From assessing the potential of early-stage discoveries to optimizing the pricing of mature products, our teams deliver insight across the product lifecycle. Based in Cambridge, we are recognized as one of the UK's leading market access consultancies, working across all major therapeutic areas and global markets.
- We support established pharmaceutical, device, and diagnostic firms as well as biotechs, start-ups, and investors. With deep experience across the public sector, industry, and consulting, we offer robust research and actionable insight that empower our clients to make confident, informed decisions.

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CEMKA is a consultancy specializing in medical products (medicines, vaccines, devices), health programs, and organization evaluations. CEMKA was created in 1990 as a French National Institute of Health and Medical Research (Institut National de la Santé et de la Recherche Médicale (INSERM)) spin-off and is located in the suburbs of Paris.

- CEMKA's activities cover a wide range of fields: health economics (Patient Reported Outcome Measures (PROMs), Patient Reported Experience Measures (PREMs), modelling, efficiency dossiers etc.), production and analysis of primary and secondary data, market access, HTA and pricing, strategies and dossiers (early access, P&R). CEMKA provides its expertise of French health system for local and European projects (as part of a network of national consultancies).

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Ecker + Ecker GmbH, based in Hamburg, Germany, is a market leader in national and international market access, including P&R consulting as well as support in price negotiations for pharmaceutical and medical devices.

- Ecker + Ecker has focused on the German Act on the Reform of the Market for Medicinal Products (Arzneimittelmarktneuordnungsgesetz (AMNOG)) since its inception in 2011. In recent years, this focus has expanded to include EU HTA. By providing support for EU HTA procedures and offering numerous training courses on the subject, Ecker + Ecker has also established itself as an expert in this new field.
- An interdisciplinary team of around 90 specialists from the fields of life sciences, pharmacy, health economics, and biostatistics ensures a holistic, evidence-based approach to complex issues in the healthcare market. This ranges from early strategic planning and successful market launch to complete life cycle management.

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More Than Access (MTA) S.r.l. Società Benefit is a boutique consulting firm headquartered in Milan, Italy, specializing in providing services that facilitate market access for healthcare technologies. MTA is founded upon the idea of building healthy partnerships with scientific societies, institutions, academia, patient associations, and companies offering complementary services, and is oriented to the European context through the development of strategic collaborations with consultancies in other countries.

- Based on the deep knowledge of the target market and the analysis of its continuous evolution, beyond a huge network of contacts, MTA intends to offer customized solutions to support all stakeholders in the drug supply chain and in particular pharmaceutical companies - whether Big Pharma or start-ups - in order to optimize the access of health technologies up to the patent, in an effective, timely and sustainable way, from national access and P&R, to strategy definition, Health Economics and Outcomes Research (HEOR) support and regional access management.

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MORSE Consulting is a pharmaceutical market access and reimbursement strategy consultancy headquartered in Canada, with offices in Toronto and Ottawa. It leverages strategic market access, HTA, pricing, and pCPA negotiation expertise to support patient access to innovative medicines across Canada.

- Established in 2017, MORSE (Mani & O'Quinn Reimbursement Strategy Experts) has built a reputation for honesty, integrity, and collaboration within the market access community. The MORSE team brings unique perspectives from public drug programs, industry, HTA agencies, and the pCPA, enabling us to bridge the gap between stakeholders and to deliver tailored strategies that drive meaningful outcomes for patients and the healthcare system.

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Vista Health is a global value-based healthcare agency founded in the Asia-Pacific region in 2015. We offer strategic consulting and tech-enabled solutions to our clients across all corners of healthcare. We believe in building lasting, meaningful partnerships with payers, providers, patients and industry players to drive positive change and innovation.

- Rigor, integrity and creativity are core to our work. We take a bespoke approach to solving and executing our clients' critical business and strategic needs using technology, with total commitment to delivery excellence.
- Members of our seasoned senior leadership team oversee all solution delivery – translating decades of experience into impact. Our regional experts and global affiliate network drive the local knowledge needed to deliver results for our clients across Asia-Pacific (APAC), Europe, and Emerging Markets.

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Zealth

Zealth is a Market Access and Health Economics consultancy headquartered in Copenhagen, with offices in Sweden and Norway. We leverage strategic market access, HTA, and pricing expertise across the Nordic region to support patient access to innovative medicines.

- Zealth operates as part of Zealth Group, an integrated healthcare consulting group offering end-to-end strategic, analytical, and creative solutions for life sciences companies. Zealth Group includes, in addition to Zealth, Ijovi Strategy, Ijovi Creative, and Ghintell. Zealth Group is headquartered in Copenhagen, Denmark, has a US office in Boston, and operates a medical and analytical Center of Excellence in Bangalore, India.

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SICOMED is a leading Market Access boutique consultancy in Switzerland, guiding pharmaceutical and biotech companies through the full complexity of Swiss, P&R, and life-cycle management. SICOMED delivers integrated Market Access solutions, working hand in hand with trusted Swiss partners across legal, policy, negotiation, communication, and evidence generation, ensuring that every strategic, policy, and stakeholder need is covered, from early access to long-term value realization. SICOMED stands for strategic excellence, reliability, and results.

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Established in 2016, we are a woman and minority-owned company with seasoned biopharma industry professionals in the US, Canada, and Europe. Our diverse team is passionate about delivering transformative market access strategies and innovative digital communication solutions to our clients.

- AESARA is a digital-forward value and access consulting agency with a focused purpose to impact healthcare decision-making and improve people's lives. We partner with life science and biopharmaceutical organizations to develop and deliver transformative market access, value strategy, and evidence-generation solutions that optimize patient access and payer engagement across the product lifecycle. Aesara's services span comprehensive market access strategy, payer research and advisory boards, value proposition development, integrated evidence planning, economic modeling, value communication tools, and HTA support.

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