



Executing under MFN: Commercialization choices for late-stage biotechs

Why smaller biotechs must reconsider their global path

Introduction

For smaller late-stage biotech companies, commercialization has always involved a series of high-stakes choices: where to invest, how much infrastructure to build, when to expand internationally, and whether to partner or go it alone. Most Favored Nation (MFN) pricing raises the stakes of each of these decisions.

Much of the discussion around MFN has focused on the risk of US price compression. That concern is real, but for smaller biotechs, it is not the full story. MFN does not simply threaten lower US prices; it rebalances global pricing logic. This may mean downward pressure in the US, upward pressure on ex-US pricing, delayed launches in lower-price markets, or more restricted access where price levels cannot be sustained.

For smaller organizations, the issue is therefore not just pricing pressure. It is how to preserve asset value in a world where decisions in one geography can shape global economics more directly.

Importantly, not all biotechs start from the same geographic position. While some companies are built around a US-first commercialization model, others (particularly those headquartered in Europe or Asia) historically anchored value creation in ex-US markets and approached US entry as a later or partnered step. However, because the US remains commercially the most important pharmaceutical market globally, even ex-US biotechs need to think “US first” much earlier in development and commercialization planning. MFN intensifies this dynamic by making global pricing interdependencies more visible and strategically consequential.



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Historically, smaller biotechs could often treat international expansion as a staged decision. While the US frequently served as the primary value driver, many ex-US pricing and access choices were made largely within local market dynamics, shaped by country-specific willingness to pay, national HTA frameworks, and budget realities.

MFN changes that logic. Price decisions across markets may now be more tightly interconnected, creating a more bi-directional relationship between geographies. A pricing outcome in one country may carry broader implications. Launch decisions in lower-price markets may influence value beyond that market alone.

To some extent, global pharmaceutical markets have always operated under international reference pricing (IRP) dynamics. What changes under MFN is that historically the most protected and commercially important market - the US - may itself become increasingly exposed to external pricing benchmarks. That creates a fundamentally different strategic challenge for biotech companies because US pricing has traditionally been the cornerstone of global asset valuation.

For large pharmaceutical companies, this is primarily a coordination challenge. For smaller biotechs, it is more fundamental. It forces a reassessment of whether the organization is equipped to operate across multiple geographies without taking on disproportionate cost, complexity, and strategic risk.

Rethinking the default path to globalization

For many smaller biotechs, there has long been an implicit assumption that success in one core market (often the US) should eventually be followed by broader international rollout. Under MFN, that assumption deserves closer scrutiny.

Building a global footprint has always required significant investment: market access capabilities, pricing strategy, regulatory coordination, launch planning, local expertise, and either direct infrastructure or strong partner management. MFN makes those investments harder to justify by increasing the strategic consequences of pricing and launch decisions.

At the same time, this dynamic is not uniform across all companies. For biotechs anchored outside the US, the question may not be whether to expand internationally, but how early to position for US value capture and whether partnering becomes more attractive earlier in the lifecycle.

As a result, globalization is no longer a default progression. It is a strategic choice that must reflect where value is created, how it is protected, and what the organization can realistically execute.

Narrower global price corridors, sharper trade-offs

If a small biotech chooses to operate across multiple geographies, it is likely to face a more constrained pricing environment. MFN is expected to narrow list and net price corridors between the US and ex-US markets, reducing the extent to which markets can remain commercially insulated from one another.

For smaller organizations, that pressure is especially acute because they have less room to absorb trade-offs. Preserving value in one market may require concessions in another. Pursuing higher prices may limit access. Prioritizing access may increase the risk of price spillover.

These trade-offs are not symmetric across companies. US-anchored biotechs may focus on protecting US pricing while managing ex-US exposure. Ex-US biotechs, however, will increasingly also need to optimize for US value creation much earlier than in the past, while simultaneously managing ex-US access and pricing expectations.

Importantly, the ability to sustain relatively aligned pricing across the US and ex-US markets is unlikely to apply equally to all assets. Products addressing high unmet need with substantial therapeutic differentiation may still be able to justify premium pricing globally. By contrast, products with limited incremental benefit are likely to face significantly greater pricing pressure and may ultimately struggle to sustain value across markets under MFN-linked dynamics.

The result is a sharper tension between price, access, timing, and organizational affordability, requiring more deliberate choices than in the past.

Launch sequencing becomes a value decision

Market launch sequencing has always been strategic. Under MFN, however, it becomes a value-defining decision.

Early-launch markets may do more to shape the effective global price corridor. Lower-price

countries may carry greater strategic weight than before. What once appeared to be a question of rollout speed now becomes a broader assessment of where early entry creates value versus risk.

For some companies, slower or more selective expansion can preserve optionality and protect value. For others, early access in strategically important ex-US markets may still be necessary to establish clinical credibility, generate real-world evidence, or strengthen the broader value narrative.

However, not all products will have equal flexibility. Therapies demonstrating major therapeutic improvement and addressing significant unmet need may be able to sustain more globally aligned pricing levels. Assets with limited differentiation, however, are more likely to experience meaningful downward pricing pressure and difficult trade-offs between access and value preservation.

The optimal sequencing strategy depends not only on geography, but also on the strength of the product's clinical differentiation and its ability to support a globally defensible value proposition.



Business model choice moves to the center

As a result, the choice between partnering, self-commercialization, and hybrid models becomes more consequential.

For biotechs seeking to partner

MFN introduces a new layer of uncertainty into deal-making. Potential partners are likely to scrutinize global pricing assumptions, launch sequencing, ex-US access strategy, and evidence readiness more closely than before. MFN-related risks may increasingly be reflected in valuation, deal structure, and contractual terms.

This dynamic applies in both directions. US-based biotechs must demonstrate how they will manage ex-US pricing and access without undermining overall value. Ex-US biotechs, in turn, may face greater scrutiny around their US strategy, including how early they assess US pricing potential, payer dynamics, and evidence requirements.

In that sense, MFN risk can become deal risk. Companies that cannot articulate a credible, scenario-based global pricing narrative may find that uncertainty is priced into transactions.

For biotechs planning to self-commercialize

For smaller biotechs considering self-commercialization, the implications are operationally demanding. Cross-market pricing implications are not entirely new. International reference pricing mechanisms have existed for years. Under MFN, the US itself may become increasingly influenced by global pricing benchmarks, creating direct pressure on the market that historically offered the greatest pricing freedom and commercial upside.

Building international capabilities now requires more than just local commercial readiness. It demands stronger list and net pricing governance, tighter cross-market coordination, and clearer decision rights than many smaller organizations have historically needed.

For ex-US biotechs, this challenge is particularly pronounced. Successful commercialization increasingly requires understanding US pricing opportunities, access dynamics, and evidence expectations much earlier in development than many organizations historically prioritized.

MFN does not point every company toward the same answer. But it does make the commercialization model decision more explicit, more strategic, and more analytically demanding.

How MFN changes the equation for ex-US biotechs

While MFN is a US-driven policy, its implications are global, and not all biotech companies are affected in the same way.

Ex-US biotechs may historically have relied more heavily on regional commercialization strategies or partnerships. However, in today's environment, many increasingly target the US early because it remains the largest and most commercially attractive pharmaceutical market globally. Capturing the full value of an asset therefore often requires US strategy, pricing, and evidence considerations to be integrated far earlier than in the past.

Their exposure to MFN may initially appear more indirect. Instead of facing immediate US price compression, they may be affected through changing partner expectations, evolving reference pricing dynamics, and increasing pressure to justify pricing consistency across geographies.

At the same time, narrowing global price differentials may alter relative competitiveness across assets. Products with strong differentiation and compelling clinical benefit may continue to command premium positioning globally. Less differentiated therapies, however, may find it increasingly difficult to sustain pricing power across both US and ex-US markets.

Strategic trade-offs are also evolving. Ex-US companies can no longer focus primarily on local HTA optimization while treating US



commercialization as a later-stage consideration. Instead, they increasingly need an integrated global pricing and evidence strategy that incorporates US value capture potential, launch sequencing, and global price rebalancing from an earlier stage.

These differences do not eliminate risk, but they change where risk sits and how it must be managed.

Evidence strategy becomes a precondition

One of the clearest implications of MFN is that evidence strategy moves even closer to the center of commercial decision-making.

A small biotech cannot credibly pursue global value creation without evidence that supports pricing and reimbursement in key markets. This includes comparative effectiveness data, patient-reported outcomes, tailored real-world evidence, and economic evidence relevant to HTA-driven systems.

For ex-US biotechs, this increasingly means generating evidence that supports US payer and access expectations much earlier. For US-based biotechs, it may mean expanding evidence generation to meet ex-US HTA requirements earlier in development.

In both cases, MFN raises the bar for what constitutes sufficient evidence package and increases the cost of getting it wrong.

Smaller biotechs still need an MFN-ready pricing strategy

Even for smaller companies, MFN increases the need for an integrated global pricing strategy. That means having a clear view on price corridors, launch trade-offs, evidence requirements, pricing governance, and – critically – US pricing opportunity much earlier in the product lifecycle.

Companies must evaluate how pricing decisions in one geography may affect the rest of the system. They need clear decision frameworks for when pricing or launch choices should be escalated, and they need the ability to model how different scenarios affect overall value.

For many companies, especially those headquartered outside the US, this represents a significant shift. Commercial strategy can no longer assume that US pricing optimization happens later, after ex-US positioning is established. Instead, US pricing potential and global price rebalancing considerations increasingly need to inform development and launch planning from the outset.

In short, beyond a pricing plan, MFN requires a pricing decision infrastructure.

Commercialization strategy must be redesigned around selectivity

Taken together, these shifts are likely to reshape commercialization models for smaller biotechs. Go-to-market strategy can no longer assume broad multinational rollout. Instead, it must reflect selective participation, stronger pricing governance, and a clearer view of where partnerships create more value than direct presence.

This affects operating model design, including where pricing authority sits, how decisions are governed across geographies, and which capabilities truly need to be built.

What smaller biotechs must do now

For smaller, late-stage biotechs, the right response to MFN is not to jump immediately into global launch optimization. Instead, they must reassess the commercialization model with greater discipline.

That starts with three practical decisions: where to participate directly, where to partner, and what level of evidence and infrastructure the chosen model will require. From there, companies need to evaluate whether the likely value justifies the investment and risk.

They should build explicit price corridor strategies, stress-test asset value across pricing and launch scenarios, and define market launch sequencing deliberately rather than by default.

Critically, they should also assess US pricing opportunity, payer dynamics, and global pricing implications much earlier than many organizations historically have, particularly if they are headquartered outside the US.

Finally, companies should monitor how MFN plays out in practice and use the signals to refine strategy over time.

The real differentiator will be disciplined selectivity

MFN raises the bar for smaller biotechs considering global commercialization. It makes strategy more interconnected, more resource-intensive, and less forgiving of weak evidence or diffuse execution.

The companies that succeed will choose the right geographic footprint early, align it with their capabilities, and translate that selectivity into pricing discipline, evidence prioritization, and partnership choices.

Importantly, companies with highly differentiated assets addressing meaningful unmet needs are likely to retain greater flexibility in sustaining global value. Companies with more limited differentiation may face significantly greater pricing pressure and more constrained strategic choices under MFN-driven dynamics.

In that sense, MFN may become a differentiator. It will separate companies that treat global expansion as an assumed next step from those that treat it as a strategic choice and execute accordingly.

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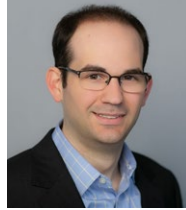
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