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Trumps International Pricing Plan

June 2025

Trumps International Pricing Plan

President Trump's second attempt to get the US to adopt Most Favored Nation pricing is already off to a stronger start than the efforts that were quashed in court at the end of his first term. The situation offers some promise but mostly peril for the pharma industry, especially as the US FDA may be activated as never before to press an explicit pricing agenda. The Pink Sheet's globe-spanning staff offers reports of happenings in European capitals and the White House to help industry predict what might come next.

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Contents

HHS Negotiating With Manufacturers On Most Favored Nation Drug Pricing

Cathy Kelly
20 May 2025

Executive Summary

MFN policy would apply to all single source drugs in all insurance markets, according to HHS release. Secretary Robert F. Kennedy Jr. said the department is discussing the plan with drug sponsors.

The US Health and Human Services Department is discussing with pharma companies about voluntarily lowering drug prices to align with the lowest prices available in comparable developed nations, HHS Secretary Robert F. Kennedy Jr. said.

"The President announced an [executive order] on 'Most Favored Nation' status last week" and "we are already in negotiation with the drug companies to discern the ways that they're going to comply with that," Kennedy told the Senate Appropriations Labor, Health, Education and Related Agencies Subcommittee on 20 May.

The hearing focused on the HHS budget request for fiscal year 2026. Kennedy addressed the Most Favored Nation policy in response to a question from Sen. Jeff Merkley, D-OR.

Merkley is co-sponsoring a bill with Sens. Pete Welch, D-VT, and Bernie Sanders, I-VT, that would require manufacturers to market drugs in the US at no more than the lowest price

HHS Negotiating With Manufacturers On Most Favored Nation Drug Pricing

Key Takeaways

- HHS is talking with manufacturers about voluntarily complying with a Most Favored Nation policy to lower drug pricing in the US, Kennedy told a Senate committee.
- The department said manufacturers should align with "identified" prices.
- However, manufacturers are unlikely to agree to broad price reductions in all US insurance or non-insurance markets, meaning the administration may need to enact regulations.

per drug in 12 similarly developed countries: Australia, Austria, Belgium, Canada, France, Germany, Italy, Japan, the Netherlands, Sweden, Switzerland, and the UK.

The bill would extend the policy beyond Medicare and Medicaid and require drug companies to offer the established reference price to individuals enrolled in federal health programs, the uninsured and individuals covered by commercial insurance.

Sanders also has introduced a similar bill that would require US payers can be charged no more than the average price paid by a set of comparable countries.

Kennedy said lawmakers have his "enthusiastic partnership" on legislation that would align US prices with those abroad. He also said that if companies do not voluntarily lower prices, the administration is prepared to require lower drug prices.

The MFN policy has generated significant confusion and concern among stakeholders and policy experts.

Administration Has Identified Price 'Targets'

Prior to the hearing, HHS announced that it and the US Centers for Medicare and Medicaid Services "identified specific targets pharmaceutical manufacturers are expected to meet to satisfy the requirements of the executive order" and that the administration plans to "highlight" industry pricing commitments in the coming weeks.

"These commitments will ensure Americans no longer pay more for medications than patients in other economically comparable countries, relieving the unfair burden placed on hard-working Americans," the release states.

President Trump's 12 May executive order directed HHS, CMS and other officials to "communicate most favored nation price targets to pharmaceutical manufacturers to bring prices for American patients in line with comparably developed nations."

If "significant progress towards most-favored-nation pricing for American patients is not delivered to the extent consistent with law … the Secretary shall propose a rulemaking plan to impose most favored nation pricing," the EO states.

Absent legislation empowering HHS to implement broad price controls, the administration could establish a demonstration project through the Center for Medicare and Medicaid Innovation to test the approach in government insurance programs.

During his first term, Trump tried unsuccessfully to implement a Most Favored Nation demonstrationin Medicare Part B for a selection of drugs. The project was ultimately halted by the Biden Administration.

HHS Negotiating With Manufacturers On Most Favored Nation Drug Pricing

The HHS release offered a few details about the MFN policy, but leaves many questions unanswered:

- MFN would apply to all single source drugs without generic or biosimilar competition
- The policy would apply to the prices of eligible drugs in "all markets," presumably including private and government-sponsored insurance, as well as the uninsured
- The MFN target price would be the lowest price in an Organisation for Economic Co-operation and Development (OECD) country with a gross domestic product per capita of at least 60% of the US GDP per capita.

Manufacturers committing to voluntarily reducing prices seems unlikely, even if HHS has been able to collect confidential pricing information from other countries.

PhRMA Suggests Manufacturers Won't Comply Voluntarily

In a statement on the release, the Pharmaceutical Research and Manufacturers of America suggested manufacturers do not support an MFN approach but are interested in working on solutions to resolve the disparity between US and ex-US prices.

Trump has suggested that the US government could help "equalize" the disparity between US and ex-US prices by using trade policy, which manufacturers may support.

"To lower medicine prices for Americans, policymakers must address the real reasons we pay more:middlemen inflating prices and foreign countries not paying their fair share," PhRMA said.

Manufacturers are "committed to working with the Trump Administration to find policy solutions that lower medicine prices and protect the world's leading biopharmaceutical engine," the trade group continued. "As we've seen in other countries, socialist price controls could devastate America's leading ecosystem, putting investments, jobs and R&D at risk."

Most Favored Nation Policy 'Lazy, Misguided,' But US Price Reforms Politically 'Inevitable'

Cathy Kelly
15 May 2025

Executive Summary

Policy experts and pharma executives react to President Trump's executive order on"equalizing" drug prices between the US and comparable nations at the ISPOR 2025 conference.

MONTREAL – President Trump's most favored nation policy is a fundamentally flawed approach to lowering US drug prices, but it appeals to voters, policy experts said during the International Society of Pharmacoeconomics and Outcomes Research conference.

The MFN policy was included in an executive order Trump announced 12 May. A form of international reference pricing, MFN is framed as a fallback policy that will be implemented via rulemaking if manufacturers do not voluntarily bring US prices in line with those in comparable developed nations.

The policy is a favorite of Trump, who tried unsuccessfully to implement it for Medicare Part B drugs in his first term and reportedly tried recently to push Congress to implement the approach in Medicaid.

The executive order generated confusion, concern and some disbelief among stakeholders and policy experts.

The MFN policy "is lazy and misguided," University of Washington professor Sean Sullivan said during the 14 May conference's opening plenary session.

Most Favored Nation Policy 'Lazy, Misguided,' But US Price Reforms Politically 'Inevitable'

Key Takeaways

- President Trump's executive order establishing a most favored nation policy for drug pricing in the US is "lazy and misguided," University of Washington professor Sean Sullivan said during the ISPOR 2025 conference in Montreal.
- Experts agreed the order is unlikely to lower prices in the US while raising prices abroad top reserve global investment in innovation.
- But drug pricing reforms in the US are politically "inevitable" and "there will be blood" from manufacturers, USC's Darius Lakdawalla said.

Sullivan said the policy is lazy because "importing prices from other countries that have been determined through value assessments done by those countries' careful evaluations of drugs, applying social constructs … should not "replace the hard work we should do as a country [on] those same value assessments."

And it is "misguided because the view that other countries will raise their prices if we lower ours is naive and it shows a real lack of understanding of how other countries do [health technology assessments] and make decisions," Sullivan added.

Trump said that under the plan, Europe and other countries will pay more for drugs, the US will pay less, and manufacturers will make the same amount of money. He also said the US government will help drug companies negotiate higher prices outside the US, using leverage involving trade and tariff policies.

Manufacturers Have Little Chance Of Higher Prices Abroad

Two pharma company executives disputed the notion that manufacturers could persuade foreign nations to accept higher prices.

"It does seem to be a misconception that somehow pharma companies can strong-arm and negotiate higher prices with governments," said Greg Daniel, Eli Lilly global public policy VP. "There are real structural barriers in countries that have set prices. It's not that easy, in fact it's almost virtually impossible for a company to march in and say, 'You will pay a higher price'."

Virginia Lee Acha, Merck associate VP of science and regulatory policy, who is based in the UK, agreed.

"You've got contracts you've established under terms of agreement that have to be met or else you're in breach of contract," she said. "That's true in many countries, not only the UK."

"I would be curious about the company that can weather the storm that will follow in the press, on TV and in the rest of the outreach to our stakeholders," Acha added. "To be realistic, the premise in theory that I can go and say, 'My price is now 100% more than I told you yesterday' … How often does that happen in your life today?"

"I'm curious how the White House was briefed on that discussion," she said.

'Carrots And Sticks' From US Government

Graham Cookson, UK Office of Health Economics chief executive, said the US government could seek confidential data to help its companies negotiate.

"They've got trade and tariffs, the carrots and sticks, to try and get foreign governments, potentially almost to coerce them, to participate in reference pricing," he said. "At a complete extreme, you could see [US officials] trying to get access to net prices," which are confidential and the result of private negotiations between manufacturers and foreign governments.

Most Favored Nation Policy 'Lazy, Misguided,' But US Price Reforms Politically 'Inevitable'

One possible result of the executive order is that "global list prices go up, net … confidential prices stay the same." There might be "a political victory. But it's a pyrrhic victory. US prices don't fall."
UK Office of Health Economics Chief Executive Graham Cookson

Cookson suggested four "scenarios" that could result from the EO.

"The first one is … global list prices go up, net … confidential prices stay the same," he said. "There might be "a political victory. But it's a pyrrhic victory. US prices don't fall."

The second scenario "is what I guess [the Trump Administration] hopes will happen, which is that there is convergence of global net prices," Cookson said.

But a third "more realistic" scenario is that we would see "strategic behavior" by manufacturers, including "delays to new product launches, or a few products not launched in particular markets,"and "maybe even products being withdrawn. There would be huge patient consequences," he said.

Fourth, "maybe … countries would negotiate [higher prices] because of the trade relationships,"Cookson said. But that would involve "a cap on expenditure and a rebate claw back scheme … in which we would see a huge impact on industry, huge impact on innovation."

University of Southern California, Los Angeles professor Darius Lakdawalla said "the best scenario is this policy does nothing because it ends up producing artificially [high] list prices overseas with confidential rebates" that significantly lower actual net prices.

"There's a huge financial incentive to get the large confidential rebates," Lakdawalla said. "And financial incentives outrun politics every day of the week and twice on Sunday."

"Ultimately that is going to prevail in the end," he said.

The Trump Administration plan "really mischaracterizes and misunderstands" the realities involved, Lakdawalla said.

"Overseas countries are already walking away from drugs at … the current price range," he added. "So there's no reason to believe that if higher prices were demanded overseas that you wouldn't see even more countries walking away from drugs."

That "makes everyone a loser because global revenues fall, global innovation falls … and then prices in America don't come down because there's nothing to reference against," Lakdawalla said. "The best-case scenario is nothing happens. The worst-case scenario is that nothing good comes out of it."

More Government Price Controls 'Inevitable' In US

Lakdawalla also conceded that "some government price intervention is now politically inevitable" in the US.

"There has to be blood. That's the key point. That the political environment calls for some meaningful substantial revenue cut" for pharmaceutical manufacturers.
University of Southern California professor Darius Lakdawalla

"There has to be blood. That's the key point," he said. "That the political environment calls for some meaningful substantial revenue cut" for pharmaceutical manufacturers.

"The question is how to do it without doing damage to the innovation ecosystem," Lakdawalla added.

Lakdawalla also agreed "there has to be some kind of US HTA approach."

"We have to do it according to American values, and that means avoid discrimination against the disabled," he said. "It means accounting for the uncertainty in HTA processes so maybe proposing a band of prices that represent guidelines for negotiation."

The prospect amounts to a call to action for ISPOR members to engage in a national effort to promote a centralized HTA initiative in the US for prescription drugs, Rob Abbott, the organization's CEO, said during his opening remarks at the conference.

US 'Most Favored Nation' Pricing Could be Game Changer for Drug Access In Germany

Francesca Bruce
22 May 2025

Executive Summary

In this first in a series of articles looking at the potential impact of the MFN drug pricing policyon European pharmaceutical markets, EUCOPE's Alexander Natz tells the Pink Sheet why the USpolicy underscores the importance of confidential net pricing.

Access to medicines in Europe could be at stake if pharmaceutical companies delay or decide against launching there because of fears that lower prices may be adopted in the US in light of President Trump's "most favored nations" (MNF) policy, warned Alexander Natz, secretary general of EUCOPE, which represent small and medium sized companies in Europe.

The risk of such decisions is greater in Europe's biggest pharmaceutical market, Germany, because net prices there are widely available, unlike in other European countries where they are kept confidential, he said.

"Even Germany – where there is a good rate of access to innovative medicines – might face difficult situations if the German price is directly imported into the US," Natz told the Pink Sheet in an interview. If the US policy were to reference Germany prices, it would be a "game changer" for companies, he said.

US 'Most Favored Nation' Pricing Could be Game Changer for Drug Access In Germany

Key Takeaways

- Companies may not launch in some European markets if they think lower prices in the bloc may be adopted the US under President Trump's new most favored nations policy.
- Germany is particularly vulnerable to negative launch decisions because prices are not confidential and therefore easier to reference.
- However, the German market still offers benefits for companies, such as free pricing at launch.

On 12 May, Trump published his MNF executive order aimed at advancing a policy to reduce Medicaid drug prices, linking them to those in countries with lower drug prices.

A week later on 20 May, the US Department of Health and Human Services told companies that it was targeting a MFN price that is the lowest price in an OECD country with a GDP per capita of at least 60% of that of the US. Such countries could include Australia, Austria, Belgium, Canada, Czech Republic, Denmark, Finland, France, Germany, Iceland, Ireland, Israel, Italy, Japan, Korea, Lithuania, Luxembourg, the Netherlands, New Zealand, Norway, Slovenia, Spain, Sweden,Switzerland, and the UK. See also HHS Negotiating With Manufacturers On Most Favored Nation Drug Pricing, Trump's Rx Pricing Order: The Best-Case And Worst-Case Scenarios and HHS Intensifies Pressure On Pharma With MFN Pricing Benchmark.

Natz is calling on the new German government to take steps to better protect price confidentiality.

German Pricing

In Germany, rebated prices of new drugs are determined through negotiations between companies and the GKV-SV, which represents health insurers. These negotiations are informed by the results of AMNOG assessments that rate the additional benefit a new drug offers compared to an alternative treatment. The price for products that are awarded a non-quantifiable benefit or a minor added benefit cannot exceed that of the lowest-price comparator. Products that are deemed to have no added benefit must be priced lower than the comparator.

These rebates are made publicly available through the Lauer Taxe, a database that lists the prices of all medicines and medical devices. In addition, real prices, including discounts or rebates, are available to patients who access their medicines through private insurance. By contrast, in other European countries basic list prices may be made public, but "true"reimbursable prices, which might include rebates or discounts, are protected by confidentiality agreements.

Confidentiality

Limited attempts to introduce confidential pricing in Germany have been made, but much more needs to be done, according to Natz. Under the Medical Research Act that came into force on 1January 2025, companies that can show part of their R&D program was conducted in Germany can qualify for a confidential rebated price. Only the initial freely-set launch price will be made public (prices in Germany are freely set at launch and are valid for the following six months).

However, if companies opt for confidential pricing, they must pay an additional 9% rebate on the post-AMNOG price.

US ‘Most Favored Nation’ Pricing Could be Game Changer for Drug Access In Germany

The option has so far proved unpopular due to the added rebate and concerns about whether in practice the net price could actually be kept confidential. “We haven’t found a way to do it, we let the company pay for it,” said Natz.

He added that Germany “needs to continue in that direction… in a very rapid and speedy way,” because companies are already seeking advice on what a German launch might mean for them if a MFN policy comes to fruition.

Advice

EUCOPE is advising companies that Germany remains attractive as a launch market as there are three “safeguards” in place:

- Because prices in Germany are freely set at launch and are valid for the following six months,this means that companies can launch in Germany with the US price.
- If the company perceives the AMNOG benefit assessment and price negotiations will yield an unfavorable price, it can opt out of the system up to four weeks after the first price negotiations. This means there will be no price set in Germany.
- A better system for confidential pricing in Germany could be on the cards. The current attempts were introduced by the previous government, and according to Natz, there seems to be political willingness among the new administration to improve the system.

However, Natz acknowledged that confidentiality may have little impact if a new US policy were to force companies to reveal the details of agreements inked with foreign authorities, for example,through long-arm statutes.

“We really also need to start talking to the US government… if no one launches outside the US, they can’t import prices. So this is like a policy that in a way is shooting itself in the foot,” warned Natz.

US FDA's Familiar Drug Pricing To-Do List

Michael McCaughan

27 May 2025

Executive Summary

President Trump's new Executive Order on drug pricing reprises several policy themes from his first administration, including giving the FDA many tasks intended to increase competition in the marketplace.

The US Food and Drug Administration has an October deadline to deliver approaches to increase competition in the biopharma market, which should sound familiar to stakeholders.

President Trump's April executive order on drug pricing gives the agency 180 days to deliver a list of recommendations to "accelerate approval of generics, biosimilars, combination products, and second-in-class brand name medications."

The to-do list mirrors the agenda former FDA Commissioner Scott Gottlieb set for the agency during President Trump's focus on drug pricing during his first term. In his first address to FDA staff in 2017, Gottlieb declared that the FDA could and would pay a role in drug pricing by doing everything it canto "get lower cost alternatives to market." Gottlieb's remarks were a break from the agency's traditional posture that drug pricing issues are not part of its mission.

The FDA worked to prioritize generic and biosimilar drug approvals in the name of reducing costs, which continued after Gottlieb left in 2019 and through the Biden Administration. The notion of prioritizing "me too" brands has for the most part been rhetorical though there is perhaps inevitably an easier pathway for a second entrant going through the FDA.

US FDA's Familiar Drug Pricing To-Do List

Key Takeaways

- Agencies continue to work on approaches to increase competition in the biopharma market as President Trump ordered.
- A provision to clamp down on anti-competitive behavior seems mostly benign because only public listening sessions and a follow-up report are required.
- Trump's order to improve the drug import program also does not seem to agree with his tariff promises, but may be a small price to pay if it can limit their impact.

The new order adds an emphasis on encouraging over-the-counter (OTC) switches, a theme FDA Commissioner Martin Makary raised during his confirmation hearing. The FDA report must include ideas to "improve the process through which prescription drugs can be reclassified as over-the-counter medications, including recommendations to optimally identify prescription drugs that can be safely provided to patients over the counter."

Another provision in the order addresses industry "anti-competitive behavior," potentially a reference to perceived abuse of the patent process that can delay generic and biosimilar entry. However, only "public listening sessions" and a follow report on recommendations to reduce anti-competitive practices are required.

For biopharma companies, the order is generally non-threatening in the universe of potential pricing options and in keeping with what was a relatively benign set of policy proposals in the executive order. Innovator companies may not like easier pathways for biosimilars and generics, but the terrain is more comfortable compared to fighting against ideas like international reference pricing.

Any new initiatives by the FDA also would launch in the context of recent cutbacks that make it challenging to keep up with generic and biosimilar user fee goals, let alone accelerate reviews.

The order also states that the FDA has 90 days to "streamline and improve the Importation Program under Section 804 of the Federal Food, Drug, and Cosmetic Act to make it easier for states to obtain approval without sacrificing safety or quality," another recurring theme from the first Trump Administration and obviously less welcome to industry than some of the other topics.

The FDA already has announced one of the improvements, an opportunity for states and tribes to meet with FDA officials before sending an application in the hopes of avoiding mistakes that could delay a plan approval.

The silver lining may be that a viable importation program in the context of Trump's promised tariffs on pharmaceuticals is difficult to imagine. If the executive order means Trump drops the tariffs, or keeps them only for the short term, some use of the 804 import pathway would be a small price to pay.

Will International Prices Influence Medicare Price Negotiation?

Cathy Kelly
15 May 2025

Executive Summary

A former CMS official suggested the most likely way it could happen is through a Center for Medicare and Medicaid Innovation demonstration.

MONTREAL – The Trump Administration is unlikely to incorporate international reference pricing into the Medicare price negotiation program unless it is designed as a demonstration project, former US Centers for Medicare and Medicaid Services official Kristi Martin suggested.

A draft guidance on negotiated prices that will be implemented in 2028 includes new policies for Medicare Part B drugs, which will be subject to negotiated prices for the first time that year, and the process for price renegotiation.

The prospect that CMS could cite significantly lower prices abroad to justify a lower negotiated price in Medicare has persisted in policy circles since Trump was elected. He often complained about the disparity between drug prices in the US and abroad.

But Martin said during the ISPOR 2025 conference that adding international price considerations to the program would involve significant legal and operational challenges.

"The way the negotiation program has been laid out by statute is that there are nine factors that can be considered within the negotiation program," she said. "One of those factors that is very explicit is pricing and market volume data in the US."

Stakeholders wondered whether the guidance

Will International Prices Influence Medicare Price Negotiation?

Key Takeaways

- The Trump Administration likely will not incorporate international reference pricing into the Medicare price negotiation program because of operational and legal challenges, a former CMS official suggested.
- The policy more likely would be implemented as a demonstration project at the Center for Medicare and Medicaid Innovation.
- Some stakeholders are confident CMS will consider international pricing in the process to justify deeper price reductions.

would include substantive changes reflecting Trump Administration priorities, but it mostly retained the Biden Administration's key approaches to the basic program.

IRA Specifies US-Based Data In Negotiation Process

"If it didn't have, 'in the US' in the law, I think we'd maybe have [a] conversation," Martin said. "But it says, 'in the US.'"

Because CMS does not have the flexibility to waive legal requirements, the administration could use the Center for Medicare and Medicaid Innovation.

"If they wanted to think about international pricing, they'd have to use the Innovation Center authority to do it," Martin said. "That gives them a lot more room to do it. But it would require rulemaking, which most people know takes a little bit of time to do" and could be a deterrent.

President Trump attempted to launch a demonstration that would have reimbursed specific Medicare Part B drugs at a level equal to the lowest price available in comparable economies during his first term.

The effort failed in part because the administration attempted to take a short cut in the rulemaking process. The interim final rule was published after an advanced notice of proposed rulemaking. The proposed rule stage was skipped.

The program was blocked by the courts as violating the Administrative Procedures Act and later withdrawn by the Biden Administration.

Martin said the guidance came out almost simultaneously with President Trump's recently issued executive order on "equalizing" US and ex-US drug prices, but still does not mention applying international reference pricing to the negotiation process.

"I think it was really interesting that [Trump] talked about international reference pricing on Monday morning and then the guidance came out on Monday afternoon and there was no reference whatsoever" in the guidance, Martin said.

"I think it was because the negotiation program, it is very difficult, operationally it's complex, legally it's complex," she said. "So I anticipate if we see international reference pricing it will be in some other form, not in the negotiation program."

Ongoing Concern That CMS Will Find A Way

Other experts believe CMS still may use international prices in the negotiation process.

"In my opinion, it's not a risk, but a certainty," Avalere strategic advisor Lisa Joldersma said during a separate ISPOR session.

She predicted that even without a statutory change, CMS will make "lower initial offers" to manufacturers in the current price negotiation process "that may look like [most favored nation] prices."

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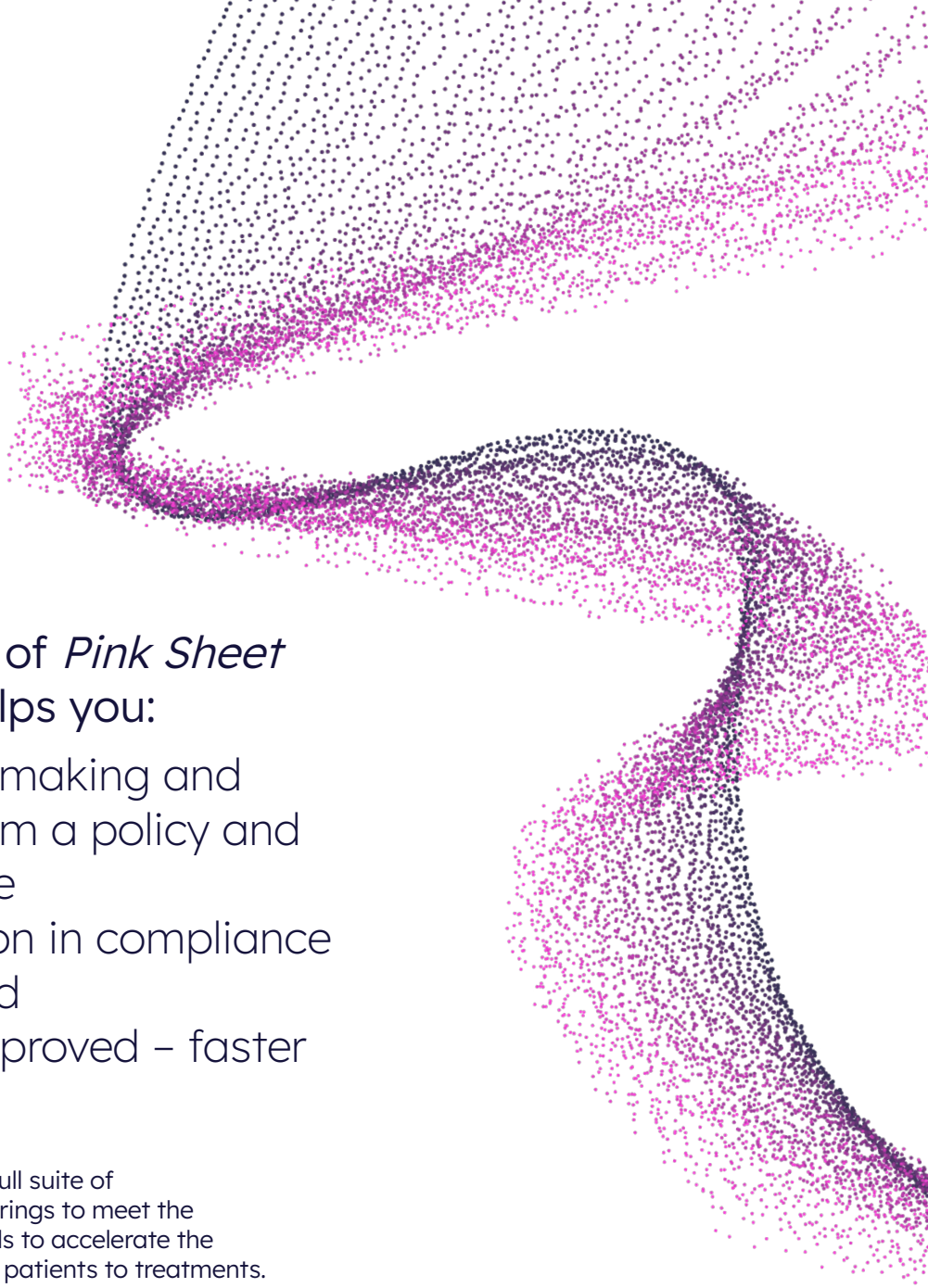

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