

Impact der Most-Favoured-Nations & Referenzpreise: wie geht es weiter?

PCMA Impuls

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Agenda

- Introduction
- U.S. Pricing Models (GENEROUS / GLOBE / GUARD)
- Potential Implications for Patient Access and Business in the EU
- Potential Solutions to Address MFN-Policies in the Europe
- Latest Developments & Outlook

Introduction

MFN – Timeline + Priorities

Trump I

Trump II



DONALD J. TRUMP (1ST TERM)

45th President of the United States: 2017 - 2021

**Executive Order 13948—
Lowering Drug Prices by
Putting America First**

September 13, 2020

Executive
Order

Letters /
Individual
Deals with
Companies

GENEROUS /
GUARD /
GLOBE

Codification
?

MFN – Effects intended for the U.S. ...

FINANCIAL TIMES

US trade + Add to myFT

Donald Trump sparks race for trade deals to counter US tariffs

Nations turn to tactic used in US president's first term when more bilateral agreements were signed



Containers at a port in Shenzhen, China. Beijing has recently clinched trade deals with Serbia, Cambodia, Nicaragua and Ecuador © Jade Gao/AFP/Getty Images





 Save

Andy Bounds in Brussels

THE WHITE HOUSE
WASHINGTON

NEWS GALLERY LIVESTREAM CONTACT >

- The agreements ensure foreign nations can no longer use price controls to free ride on American innovation by guaranteeing MFN prices on all new innovative medicines the nine companies bring to market.
- The agreements require the nine companies to repatriate increased foreign revenue on existing products that they realize as a result of the President's strong America First U.S. trade policies for the benefit of American patients.
- The agreements require the nine companies to offer medicines at a deep discount off the list price when selling directly to American patients through *TrumpRx*.

... and in other countries



DELIVERING ON PROMISES TO PUT AMERICAN PATIENTS FIRST: President Trump is delivering on promises to ensure American patients no longer pay high prices to subsidize low prices in the rest of the world, something the political establishment did not believe was possible.



- On December 1, 2025, the Office of the United States Trade Representative, the Department of Commerce, and the Department of Health and Human Services announced an agreement with the United Kingdom (U.K.) that will increase the net price of new prescription drugs by 25% in the U.K., helping ensure they pay their fair share for innovative medicines.

MFN is back - why it matters now

MFN = linking US drug prices to lower prices in a set of comparable countries

- **US** policy developments have revived “**lowest-price**” international benchmarking.
- This creates a global incentive to **avoid being** the lowest comparator price (especially on visible list prices)
- **Europe is in scope**, increasing the global impact of European prices on launch strategy.
- The role of confidentiality depends on the design of MFN programs

MFN spillover

Implications for Europe

Negotiations increasingly reflect global benchmarking exposure

- Avoiding the lowest-priced position becomes a practical launch consideration

Launch sequencing may shift

- Greater risk of delayed availability in smaller and/or lower-priced markets to protect reference baskets

Contracting becomes more structured

- Beyond simple discounts: rebates, conditionality, outcomes-based agreements to impact direct comparability

Disproportionate impact on SMEs and mid-caps

- Limited capacity for multiple bespoke evidence requests and country-specific contracting → risk of delays and uneven access

U.S. Pricing Models:

GENEROUS (Medicaid) | **GLOBE** (Medicare Part B) | **GUARD** (Medicare Part D)

Pricing Models at a Glance

Model	Program	Mandatory	Drugs Covered	Proposed Effective Date	Upcoming Deadlines	Proposed Price Adjustment
Proposed GLOBE Model	Medicare Part B	Mandatory	Drugs with Part B spend over \$100M Selected USP categories	October 1, 2026	Comments Due February 23, 2026	Lowest country-level price based on existing data sources OR Across country average based on manufacturer reported net prices OR Domestic inflation penalty
Proposed GUARD Model	Medicare Part D	Mandatory	Drugs with Part D spend over \$69M Selected USP categories	January 1, 2027	Comments Due February 23, 2026	Lowest country-level price based on existing data sources OR Across country average based on manufacturer reported net prices OR Domestic inflation penalty
GENEROUS Model	Medicaid	Voluntary	All covered outpatient drugs for Medicaid participating manufacturers	January 1, 2026	Applications accepted through March 31, 2026	Second-lowest manufacturer reported country-level net price

Reference Price Calculation

Proposed GLOBE Model (Medicare Part B)

- **Benchmark Calculation:**

Method 1: lowest individual country-level average price (as determined by CMS), adjusted upward by 2%

Method 2: across-country average net price self-reported by manufacturers, adjusted upward by 5%

GLOBE benchmark - products that “align with a GLOBE Model drug’s HCPCS Level II code long descriptor”

Proposed GUARD Model (Medicare Part D)

- **Benchmark Calculation**

Method 1: lowest individual country-level average price (as determined by CMS), adjusted upward by 2%

Method 2: across-country average net price self-reported by manufacturers, adjusted upward by 5%

GUARD benchmark - for “international analogs” that align with the GUARD Model drug across identifying characteristics, including “active ingredient(s), route of administration, dosage form, and strength”



International Pricing Data

- For the **GLOBE and GUARD** models, CMS identified three potential data sources for information about international pricing for the relevant reference countries:
 - **IQVIA’s MIDAS**
 - **GlobalData Pharmaceutical Prices**
 - **Eversana NAVLIN’s Price & Access database**
- Other data sources could be identified by CMS
- Additionally, for both models, manufacturers may voluntarily submit international pricing data about their drug products.

GENEROUS Model (Medicaid)

- **Benchmark:** 2nd-lowest manufacturer-reported net price across reference countries (at NDC-9), net of all concessions.
- **Source:** Manufacturer self-report only (no international price databases).
- **Rebate:** Supplemental rebate = WAC – Guaranteed Net Unit Price (benchmarked to the MFN price).

Potential Implications for Patient Access and Business in the EU

Copenhagen Economics Study for EUCOPE, January 2026

Pharmaceutical products face U.S. import tariffs and Most Favoured Nation pricing

We asked EUCOPE members how they are likely to respond to...

Most Favoured Nation pricing

- 12 May Executive Order on MFN pricing for prescription medicines, whereby **U.S. prices would be tied to the lowest price available in any OECD country with a GDP per capita of at least 60% of that in the U.S.**
- Many implementation details remain uncertain
- Several individual deals

15% import tariffs on pharmaceutical products

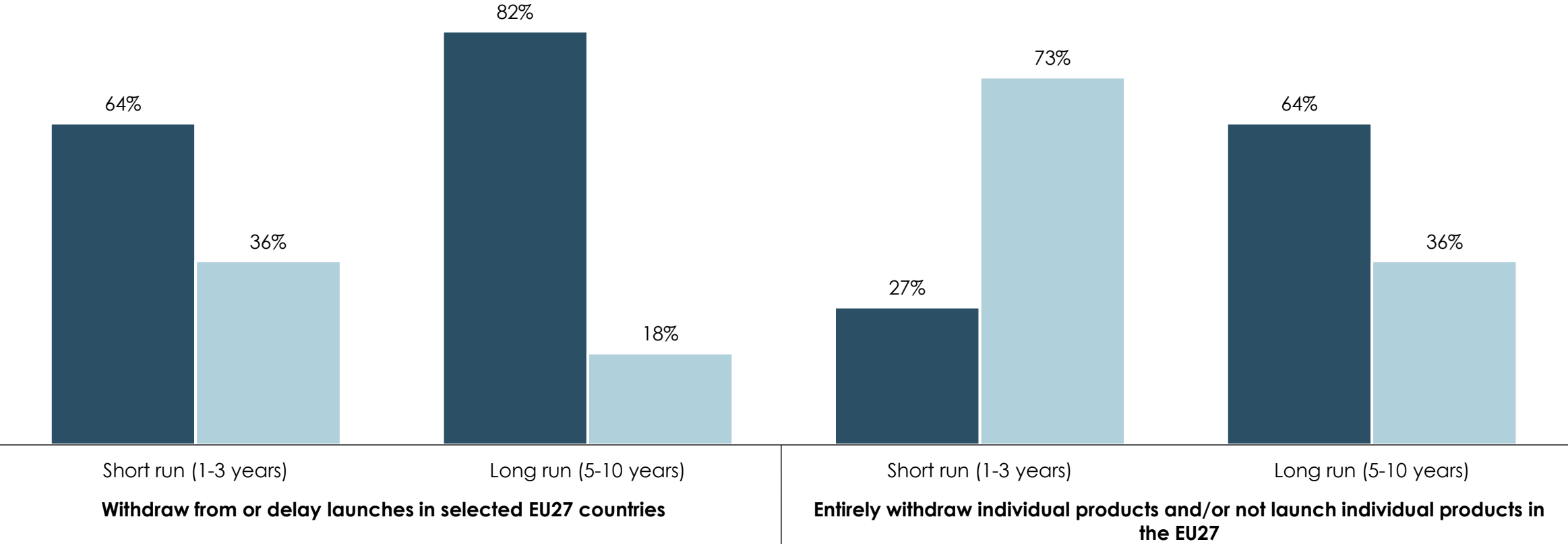
- 21 August Agreement on Reciprocal, Fair and Balanced Trade established a **15% maximum tariff** on most EU27 goods, including **branded pharmaceuticals**

Companies are likely to delay or withdraw from launching in selected EU27 countries when faced with MFN pricing

Figure 5. Distribution of launch responses to MFN pricing in both the short and long run

Share of respondents

■ Likely ■ Unlikely



Note: "Unlikely" combines the response categories "Very unlikely" and "Unlikely," while "Likely" combines "Very likely" and "Likely." The number of responses is 11. Source: Copenhagen Economics.

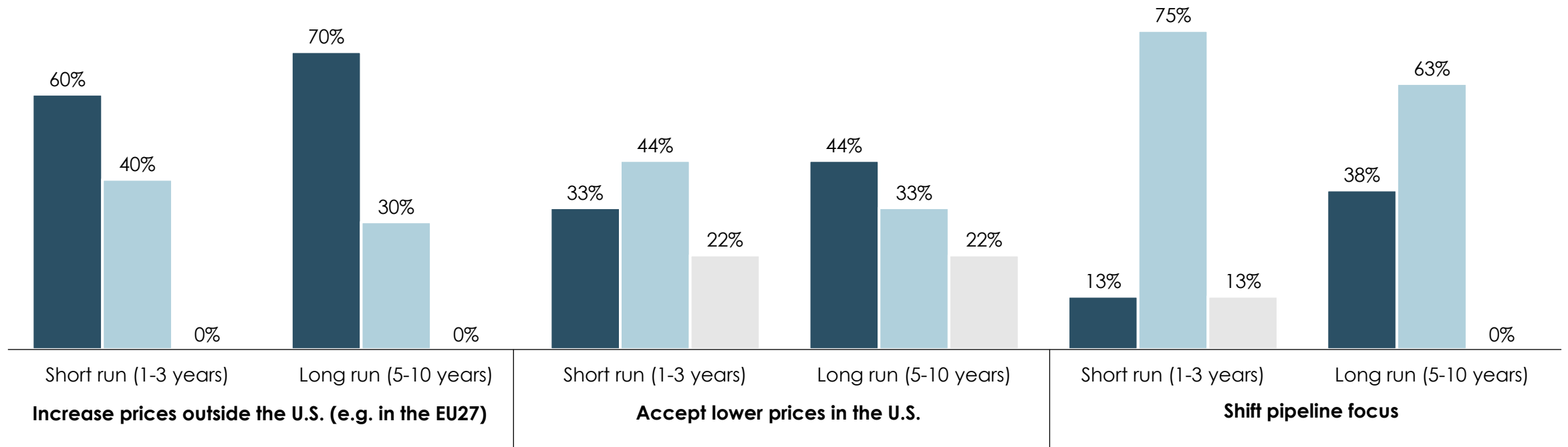
Companies are likely to increase prices outside the U.S. when faced with MFN pricing

Figure 6. Distribution of pricing responses to MFN pricing in both the short and long run

Share of respondents

■ Likely
 ■ Unlikely
 ■ Neither likely nor unlikely / not relevant

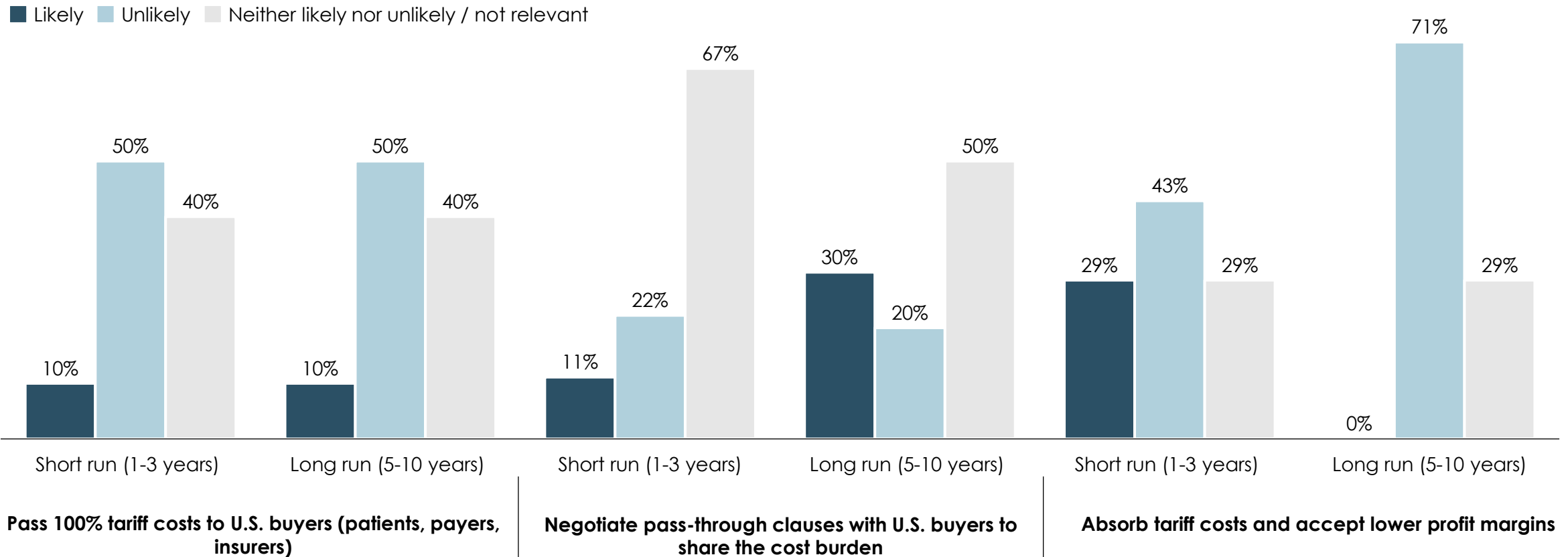
In interviews, companies emphasised the difficulty of predicting precise outcomes, and responses vary widely depending on factors such as current geographic presence, development stage, pipeline composition, existing trade flows, and company size



Note: "Unlikely" combines the response categories "Very unlikely" and "Unlikely," while "Likely" combines "Very likely" and "Likely." The number of responses per question ranges from 8 to 10. Source: Copenhagen Economics.

U.S. import tariffs are unlikely to be directly felt in the U.S. and more likely impact markets outside

Figure 7. Distribution of pricing responses to a 15% tariff on pharmaceutical products
Share of respondents

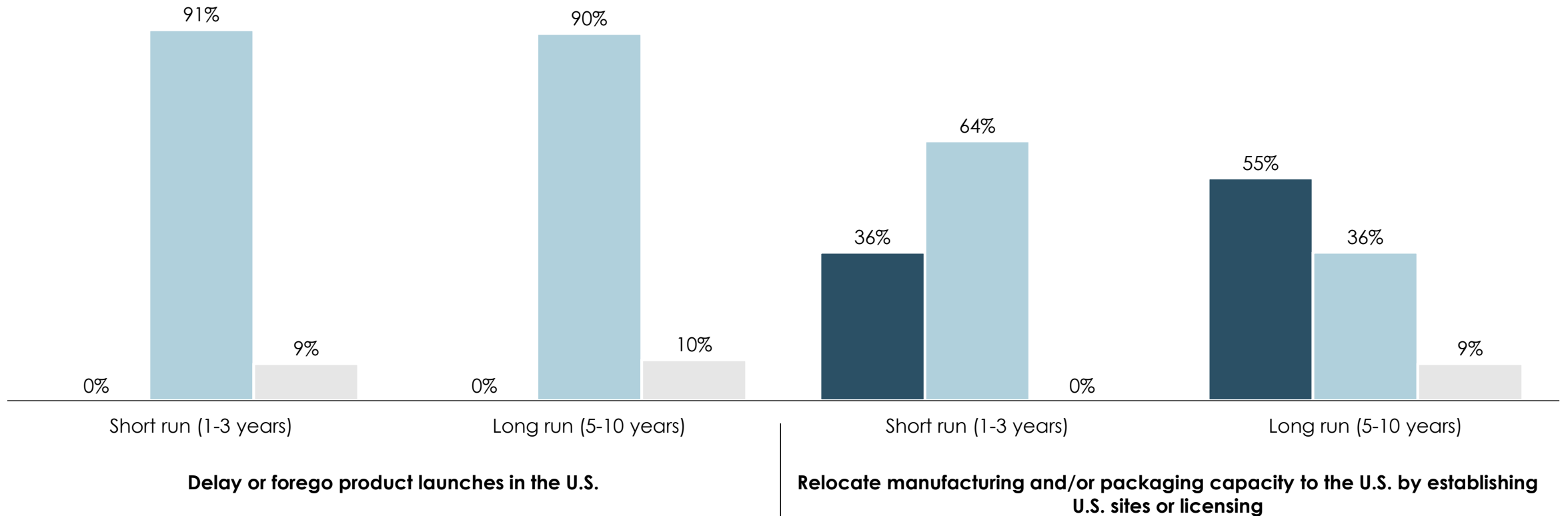


Note: "Unlikely" combines the response categories "Very unlikely" and "Unlikely," while "Likely" combines "Very likely" and "Likely." The number of responses per question ranges from 7 to 10. Source: Copenhagen Economics.

U.S. import tariffs will not see the industry deprioritise the U.S.

Figure 8. Distribution of U.S. launch responses and relocation responses to a 15% tariff on pharmaceutical products
Share of respondents

■ Likely ■ Unlikely ■ Neither likely nor unlikely / not relevant



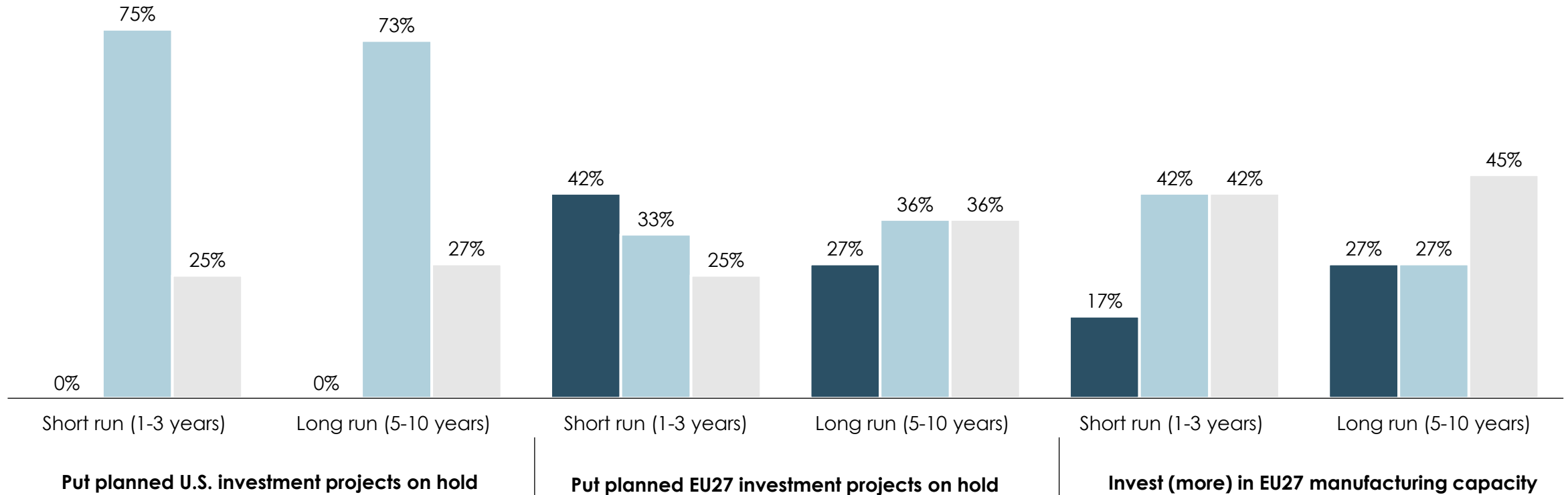
Note: "Unlikely" combines the response categories "Very unlikely" and "Unlikely," while "Likely" combines "Very likely" and "Likely." The number of responses per question ranges from 7 to 12. Source: Copenhagen Economics.

U.S. import tariffs may lead to investment hesitation in the EU27 in the short run

Figure 9. Distribution of investment responses to a 15% tariff on pharmaceutical products

Share of respondents

■ Likely ■ Unlikely ■ Neither likely nor unlikely / not relevant

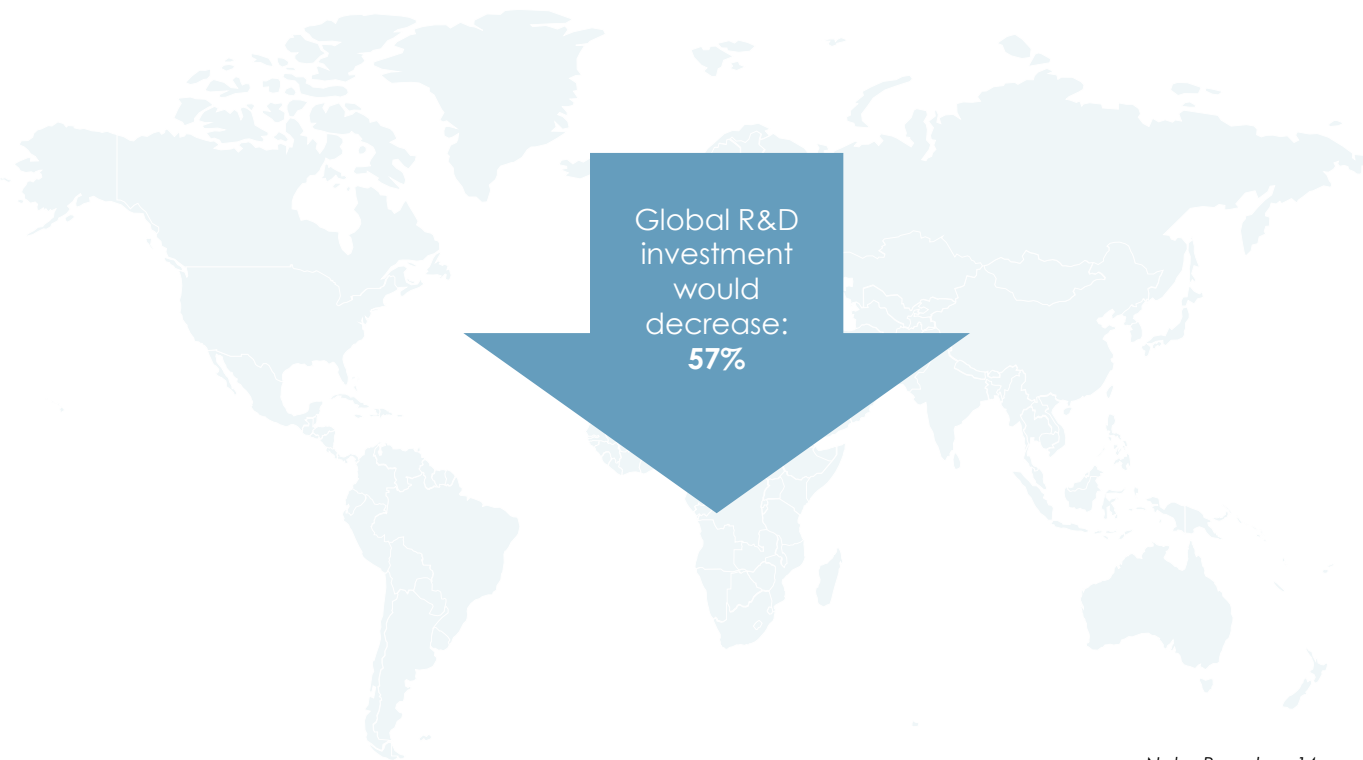


Note: "Unlikely" combines the response categories "Very unlikely" and "Unlikely," while "Likely" combines "Very likely" and "Likely." The number of responses per question ranges from 11 to 12. Source: Copenhagen Economics.

U.S. tariffs and MFN pricing may put global, and therefore European, R&D activity at risk

- Faced with MFN pricing policies and/or tariffs on pharmaceutical products and absent any policy changes in the EU27, 57% of respondents anticipate a decrease in global R&D expenditures, and no respondent expects an increase.
- A scenario with MFN pricing and/or tariffs on pharmaceuticals may therefore, inadvertently decrease global pharmaceutical R&D expenditures and ripple effects throughout the pharmaceutical value chain may ultimately lead to a lower GDP contribution from the industry, fewer jobs, and potentially fewer new treatments many years down the road.

Figure 10. Change in global R&D expenditures following MFN pricing and/or tariffs
Share of respondents



Note: Based on 14 survey responses.
Source: Copenhagen Economics.

Potential Solutions to Address MFN Policies in Europe

Solution Objectives

What a good European response must deliver



PROTECT PATIENT ACCESS
(esp. in smaller markets)



**PRESERVE AFFORDABILITY
/ BUDGET PREDICTABILITY**



**MAINTAIN INNOVATION
INCENTIVES** (incl. SMEs)



**BE WORKABLE IN EU
PRACTICE** (doesn't rely on
unrealistic legal/political leaps)

Potential Solutions

Value-based net pricing beyond list-price signals

Net price as the primary lever

Confidential discounts/rebates with clear governance

Managed entry to address uncertainty

Early access; evidence generation; reassessment

Price–volume agreements (PVAs)

Volume/uptake thresholds; paybacks / tiered rebates
Utilisation caps; budget predictability

Implementability (incl. SMEs)

Standard MEA templates; minimal outcomes dataset

Differential pricing and small-market launch timelines

Differential pricing (ability-to-pay)

With practical safeguards against arbitrage/parallel trade

External reference pricing (ERP) modernisation

“lowest-of-basket” anchoring avoidance
One-off tender / outlier prices exclusion (as appropriate)

Small-market access pathway

Requirements simplification + staged payments
Rapid reassessment once evidence matures

Evidence portability across Europe (EU HTA + RWE)

EU Joint Clinical Assessments (JCAs) as the clinical baseline

Duplication reduction across Member States

Evidence expectations (PICO)

Early alignment; rework minimisation; SME relevance

Reassessment and adjustment pathways

Initial access; real-world evidence; price/value update schedule

Outcomes-based access at scale

Interoperable registries; common data standards

Latest Developments & Outlook

Supreme Court Ruling on Tariffs

(Slip Opinion)

OCTOBER TERM, 2025

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Syllabus

NOTE: Where it is feasible, a syllabus (headnote) will be released, as is being done in connection with this case, at the time the opinion is issued. The syllabus constitutes no part of the opinion of the Court but has been prepared by the Reporter of Decisions for the convenience of the reader. See *United States v. Detroit Timber & Lumber Co.*, 200 U. S. 321, 337.

SUPREME COURT OF THE UNITED STATES

Syllabus

LEARNING RESOURCES, INC., ET AL. *v.* TRUMP,
PRESIDENT OF THE UNITED STATES, ET AL.

CERTIORARI BEFORE JUDGMENT TO THE UNITED STATES
COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 24–1287. Argued November 5, 2025—Decided February 20, 2026*

The question presented is whether the International Emergency Economic Powers Act (IEEPA) authorizes the President to impose tariffs. See 91 Stat. 1626. Shortly after taking office, President Trump sought

- **Supreme Court struck down IEEPA-based reciprocal tariffs** on 20 February 2026.
- This is a **legal setback**, not the end of U.S. tariff pressure.
- The White House is expected to pursue **alternative tariff authorities**.
- Net effect: **continued uncertainty and volatility** in the U.S. trade environment.
- EU message remains: **predictability, stability, lower tariffs**.

Government change unlikely to result in policy change

Congress of the United States
Washington, DC 20515

March 5, 2026

President Donald J. Trump
The White House
Office of the President
1600 Pennsylvania Avenue NW
Washington, DC 20500

Mr. President:

As Ranking Members of the committees with jurisdiction over health care, we write to request copies of the most-favored-nation agreements that you struck with pharmaceutical companies and have kept hidden from Congress and the American people. While there is no evidence that you have meaningfully reduced health care costs for Americans—and substantial evidence that your policies have increased those costs—you continue to boast about these deals as the solution to Americans' prescription drug costs. For example, you have repeatedly claimed

Potential next developments

EU:

- Today, biggest groups in European Parliament discuss whether to put US-EU trade deal back on the agenda for Plenary Meeting in two weeks
 - New negotiations?
 - Countermeasures from EU? Counter tariffs (thousands of products concerned / worth 93 bln dollars, already agreed). Plus, new anti-coercion measures, e.g. withdraw licenses from US, limit export licenses, exclude from public procurement processes.

US: Proposal of “Template” for mid-size companies to agree on deals

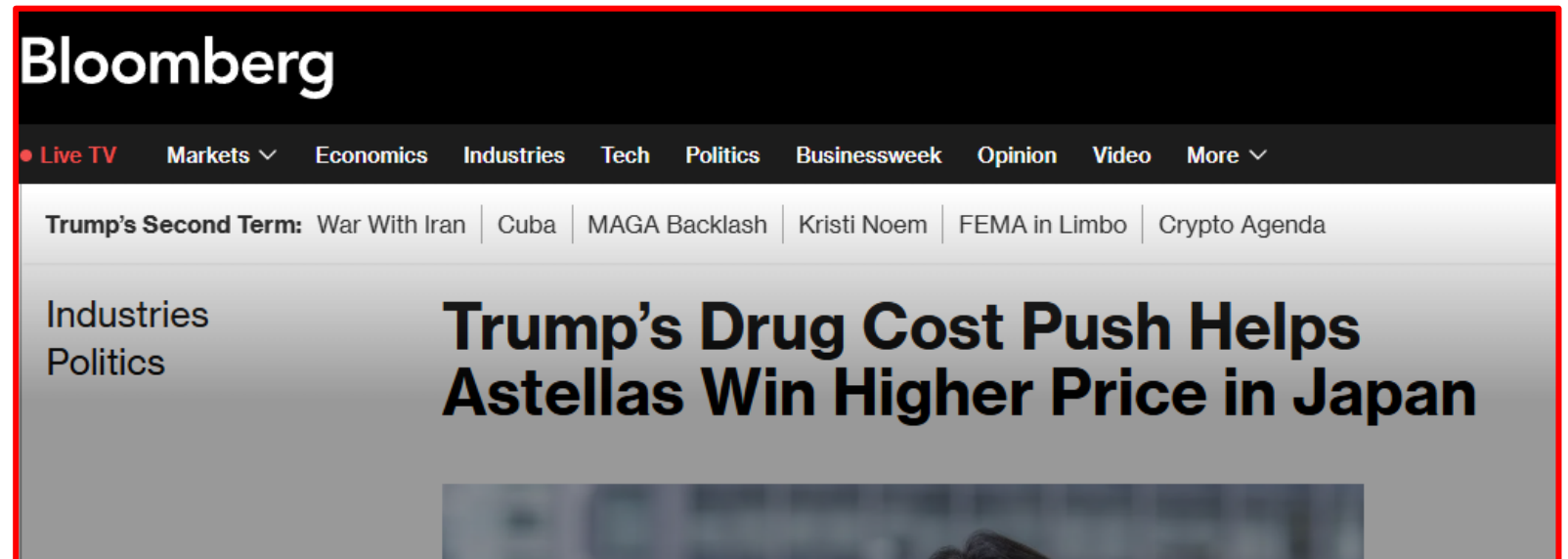
Impact on other countries' healthcare systems

News from past 5 days



Earlier this month, Amgen pulled Repatha from the Danish market, as Euractiv Advocacy Lab [reported](#), potentially the first case in the country driven by the U.S.'s MFN policy.

“Due to significant changes in the market, the current tender conditions mean that Amgen is no longer able to supply Repatha to Denmark,” a company spokesperson told news outlet Euractiv at the time. “The price offered does not adequately reflect the value of this innovative medicine, making continued supply commercially unsustainable.”



Considerations for Discussion

- The U.S. will continue shaping global MFN norms; Europe must adapt now.
- EU Member States control the price levels and frameworks (Confidentiality?)
- The priority is developing **MFN-compliant pathways at Member State level** to protect access, innovation, and differential pricing.
- **EU-level** action should support Member States, ensure legal clarity, and maintain Europe's competitiveness and attractiveness as an early-launch region.
- **MFN policies — wherever they originate —** must not jeopardise Europe's ability to deliver timely, equitable access to innovative therapies.



QUESTIONS



COMMENTS



ANSWERS

Contact: heck@eucope.org