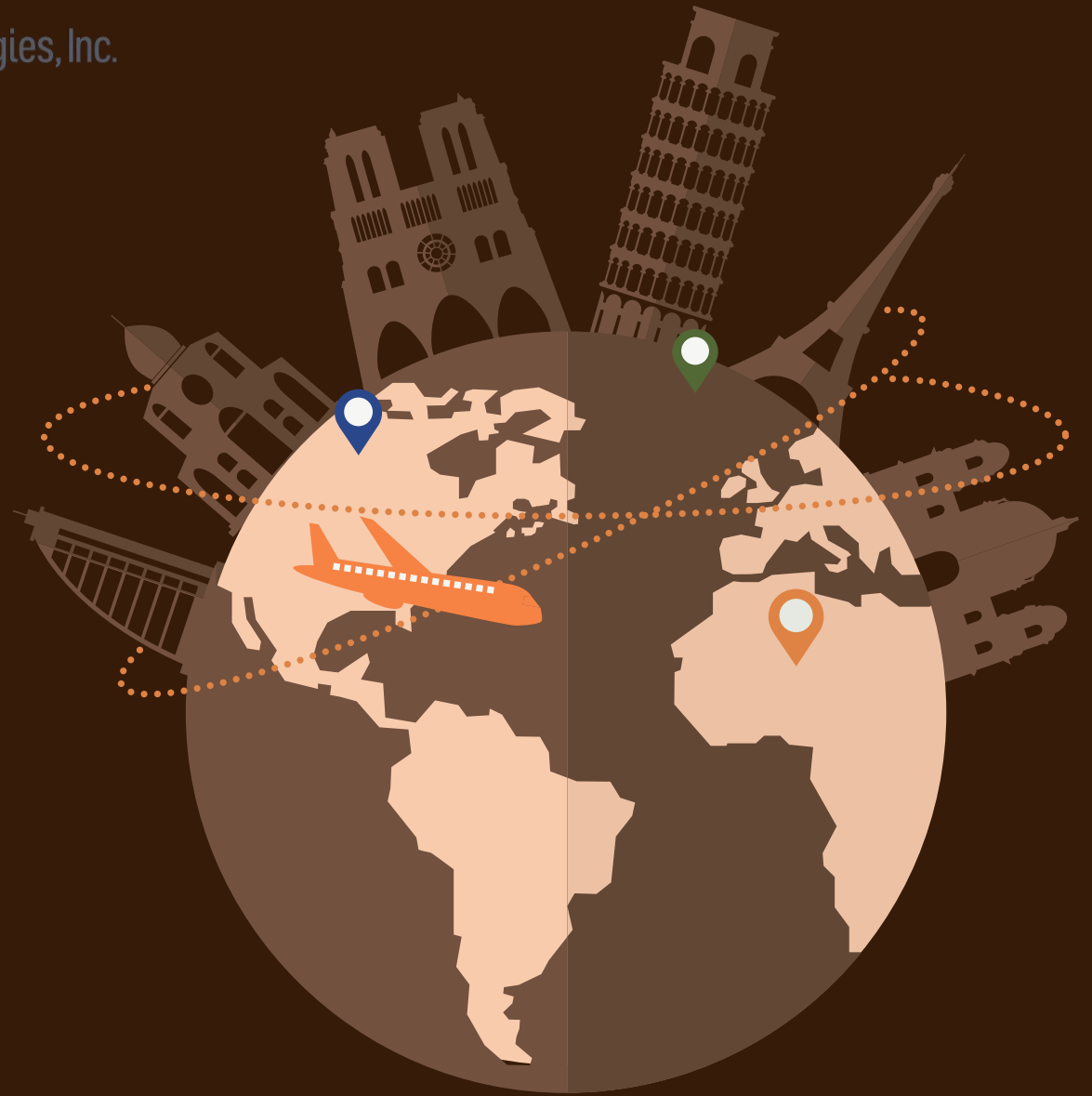


Beyond US Borders: What do global drug prices really mean for MFN?

30th June 2025



Webinar objectives

OBJECTIVES



Set the scene:

Recap the Most Favored Nation (MFN) policy, including latest developments and what it may mean for the US



Discuss how ex-US pricing works:

Introduce how medicines are priced outside the US and explain why these mechanisms matter for the MFN



Assess global pricing implications:

Discuss how ex-US pricing dynamics are likely to influence the practical impact, potential implementation and viability of the MFN Policy



Today's agenda



INTRODUCTION TO THE MFN POLICY



Ex-US PRICE SETTING & ITS CONSEQUENCES



POTENTIAL GLOBAL MFN IMPLICATIONS



AUDIENCE Q&A



Why are we here today?



May 20, 2025



PRESIDENTIAL ACTIONS

DELIVERING MOST-FAVORED- NATION PRESCRIPTION DRUG PRICING TO AMERICAN PATIENTS

“

Americans are overcharged for prescription drugs and “must therefore have access to the most-favored-nation price...”

The EO directs multiple federal agencies to take specific actions to lower drug prices in the United States in a manner comparable with other “developed nations.”

”

What do we know as of now?



May 20, 2025



“

*HHS expects each [drug] manufacturer to commit to aligning [United States] 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.*

”



Single-source drugs



Lowest price



**OECD with >0.6 GDP
per capita vs. US**

Today's agenda



INTRODUCTION TO
THE MFN POLICY



**Ex-US PRICE SETTING
& ITS CONSEQUENCES**



POTENTIAL
GLOBAL MFN
IMPLICATIONS

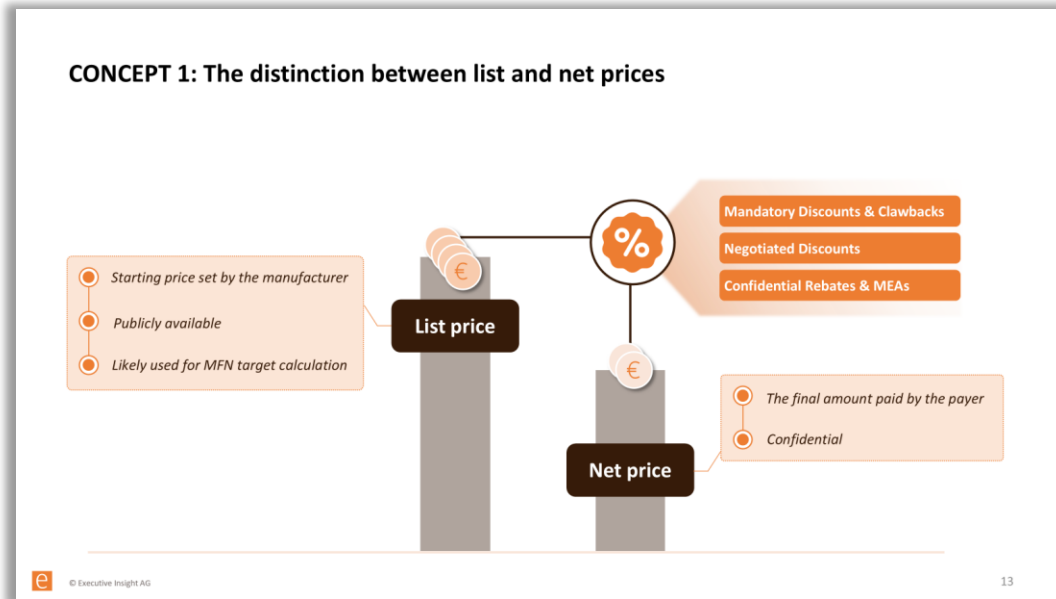


AUDIENCE Q&A



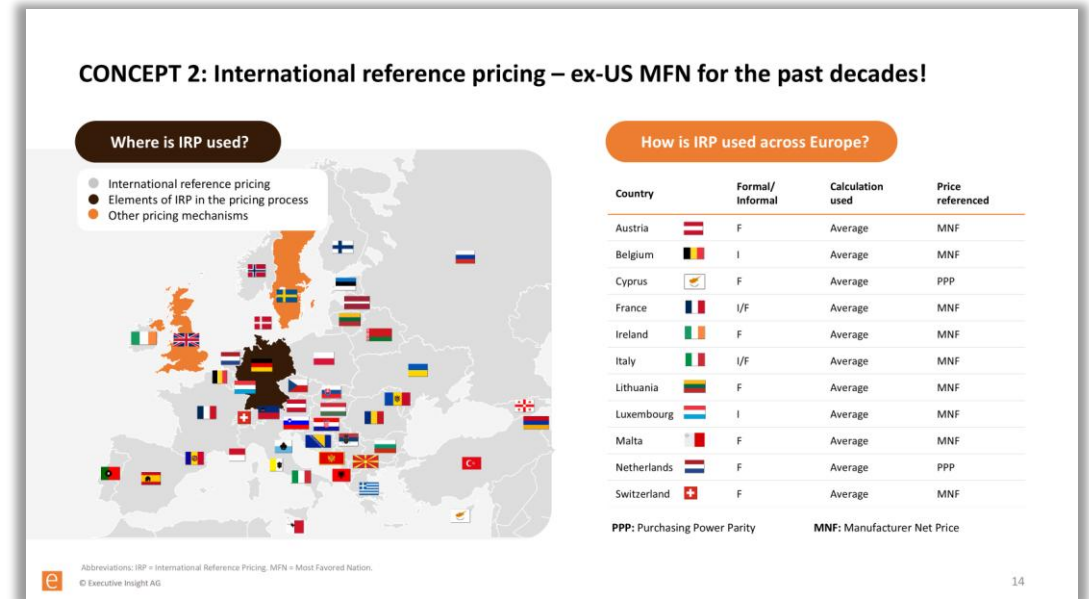
Before we begin, there are two background concepts we would like to introduce

Concept 1 The distinction between list and net



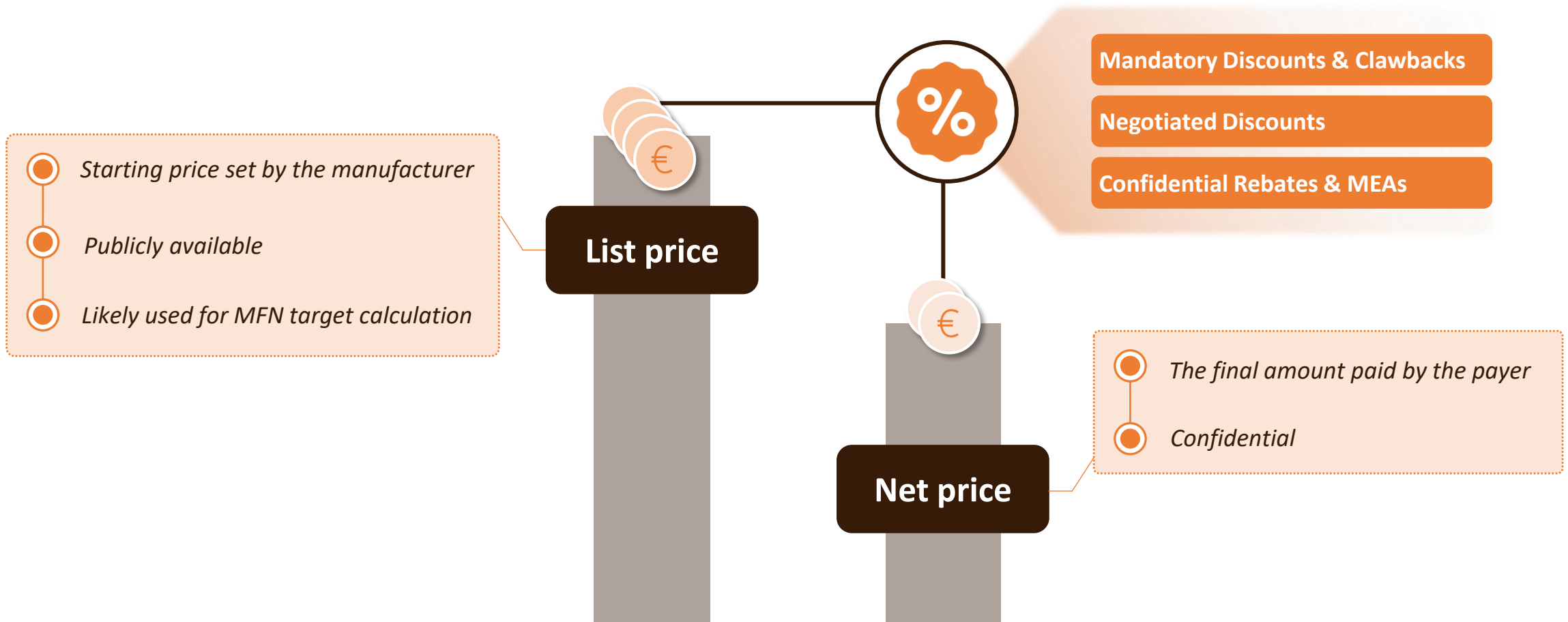
It's the same in the US!

Concept 2 International Reference Pricing



New concept!
And it impacts prices at launch,
and price evolution over time

CONCEPT 1: The distinction between list and net prices














CONCEPT 2: International reference pricing – ex-US MFN for the past decades!

Where is IRP used?

- International reference pricing
- Elements of IRP in the pricing process
- Other pricing mechanisms



How is IRP used across Europe?

Country		Formal/ Informal	Calculation used	Price referenced
Austria		F	Average	MNF
Belgium		I	Average	MNF
Cyprus		F	Average	PPP
France		I/F	Highest or lowest*	MNF
Ireland		F	Average	MNF
Italy		I/F	Average	MNF
Lithuania		F	Average	MNF
Luxembourg		I	Average	MNF
Malta		F	Average	MNF
Netherlands		F	Average	PPP
Switzerland		F	Average	MNF

PPP: Purchasing Power Parity




MNF: Manufacturer Net Price

* for ASMR I to III the price is either the highest or the lowest in the 4 reference countries, depending on whether the product is manufactured in France

CONCEPT 2: International reference pricing – ex-US MFN for the past decades!



IRP is a regulatory method used to set drug prices by referencing the prices of the same product in other countries

Parameter	Description
Reference Basket	Set of countries used for comparison (e.g. OECD, similar markets)
Calculation Method	<div>Common methods include:</div> <ul style="list-style-type: none">• Lowest price in basket (e.g. Greece) • Average of lowest 3 (e.g. Portugal) • Median or average (e.g. Poland) 
Exchange Rate Policy	Static or regularly updated currency conversion; some use fixed annual rates



Challenges & Considerations

- Launch delays due to pricing impact on other countries
- IRP typically uses list prices, which does not include confidential / negotiated discounts
- Prices may spiral downwards since countries reference each other cyclically
- Public price data may be outdated or inconsistently reported

To understand MFN implications, we first need to unpack...

US vs. ex-US LIST PRICE TENSION



**How do OECD and US
list prices branded
drugs compare?**




**What are the
lowest-priced
OECD markets?**



**How do OECD
list prices evolve
over time?**

OECD reference countries have different approaches to pricing of branded drugs – but overall, countries fall under one of three archetypes

Key archetypes and drivers




Primarily Negotiated Price

Negotiations are informed by



Clinical benefit assessment




Cost-effectiveness



Budget impact




Primarily Regulation-Based Price




IRP-based



Formula-based



Manufacturer-Set (at Launch) Price



Free pricing*

**Germany is free-priced for the first 6 months after launch.*

Abbreviations: IRP = International Reference Pricing. OECD = Organisation for Economic Co-operation and Development.

In many markets, prices can be set through direct negotiation between the manufacturer and health authorities, typically reflecting the drug's clinical benefit, cost-effectiveness & budget impact



Primarily Negotiated Price

Prices* are set through negotiations between the manufacturer and national authorities or public payers. This process considers multiple criteria to determine a fair and sustainable price

KEY CHARACTERISTICS

- Prices* are negotiated through structured processes within legally defined frameworks that set clear boundaries for the negotiation
- Emphasis on value-based pricing
- Typically involves HTA bodies

PRICE-SETTING CRITERIA

Clinical benefit
assessment

Evaluation of therapeutic
advantage over existing options


Germany (post-HTA), France

Cost-effectiveness

Value for money relative to
health outcomes (e.g., QALYs)


UK, Canada, Sweden

Budget impact

Financial feasibility
within the healthcare system


Italy, Spain

*Negotiated prices can be either list or net, depending on the country.

Abbreviations: HTA = Health Technology Assessment. QALY = Quality-Adjusted Life Years.

For regulation-based prices, government bodies determine the price using predefined methods, incl. international reference pricing, price caps or statutory pricing frameworks



Primarily Regulation-Based Price

Countries under this model regulate drug prices* directly using fixed rules or benchmarks. These can be based on international prices or predefined formulas

KEY CHARACTERISTICS

- Less flexible but ensures pricing predictability
- Strong government control over pricing

SUBTYPES

IRP-based

Price benchmarked against other countries


Turkey, Greece, Poland

Formula-based

Price derived from production costs, mark-ups or comparators


Japan

* Prices can be either list or net, depending on the country.

In some markets, incl. the US, manufacturers set the initial list price independently at launch, based on internal pricing strategy, market expectations and perceived therapeutic value



Manufacturer-Set (at Launch) Price

Manufacturers freely set drug prices at launch without upfront governmental controls, however public / private payers may later negotiate reimbursement conditions

KEY CHARACTERISTICS

- No formal price regulation at launch whereby high initial launch prices are common
- Market forces and payer negotiations influence sustainability of higher prices

COMMON METHODOLOGIES

Although there is no formal methodology for free pricing, manufacturers often apply internal strategies and benchmarks to guide pricing decisions

Value-based pricing

Aligned to
outcomes or cost-
effectiveness

Premium pricing

Set high to reflect
breakthrough status
or unmet need

Anchor pricing

Set with
reference to
analogues or
future impact

EXAMPLES



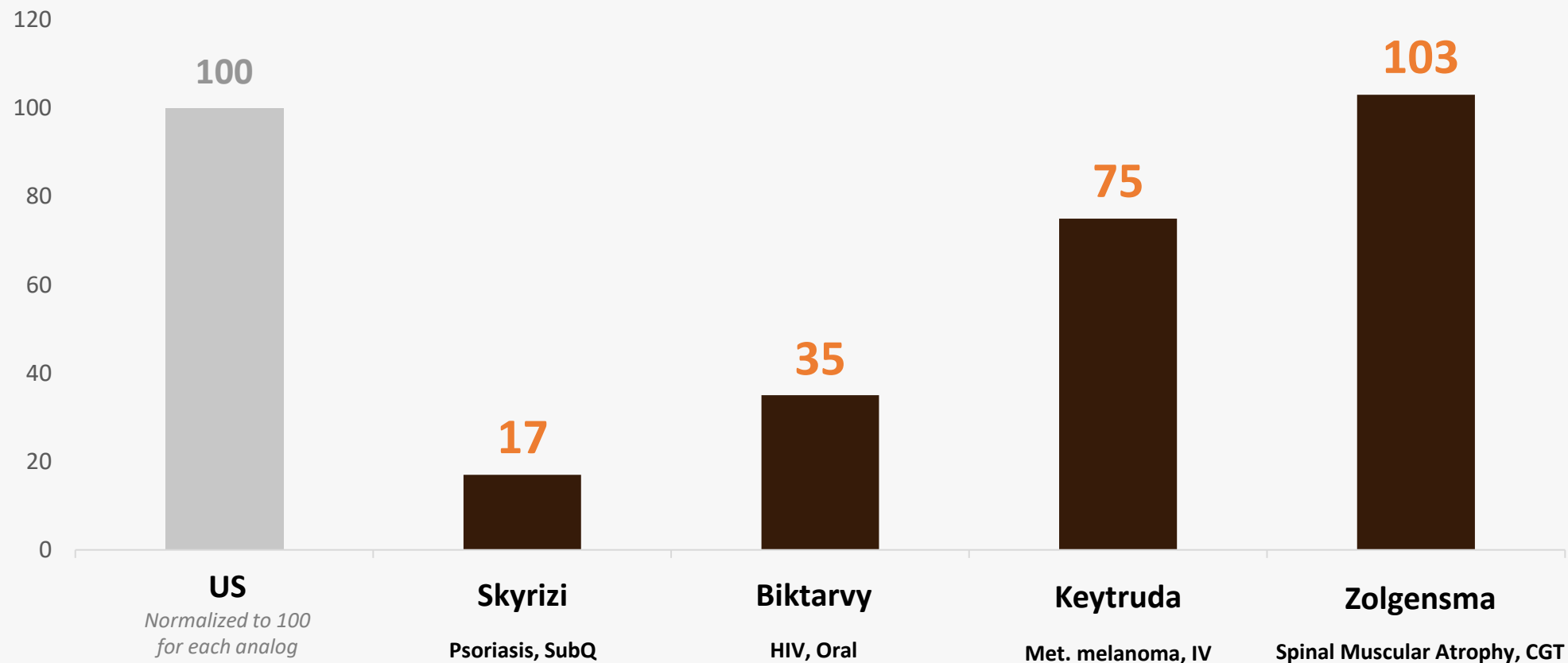
United
States



Germany
(initial 6-
months)

Ex-US list prices vary significantly vs. US prices, and in some instances can even be higher

Average OECD list prices at launch, US WAC at launch = 100

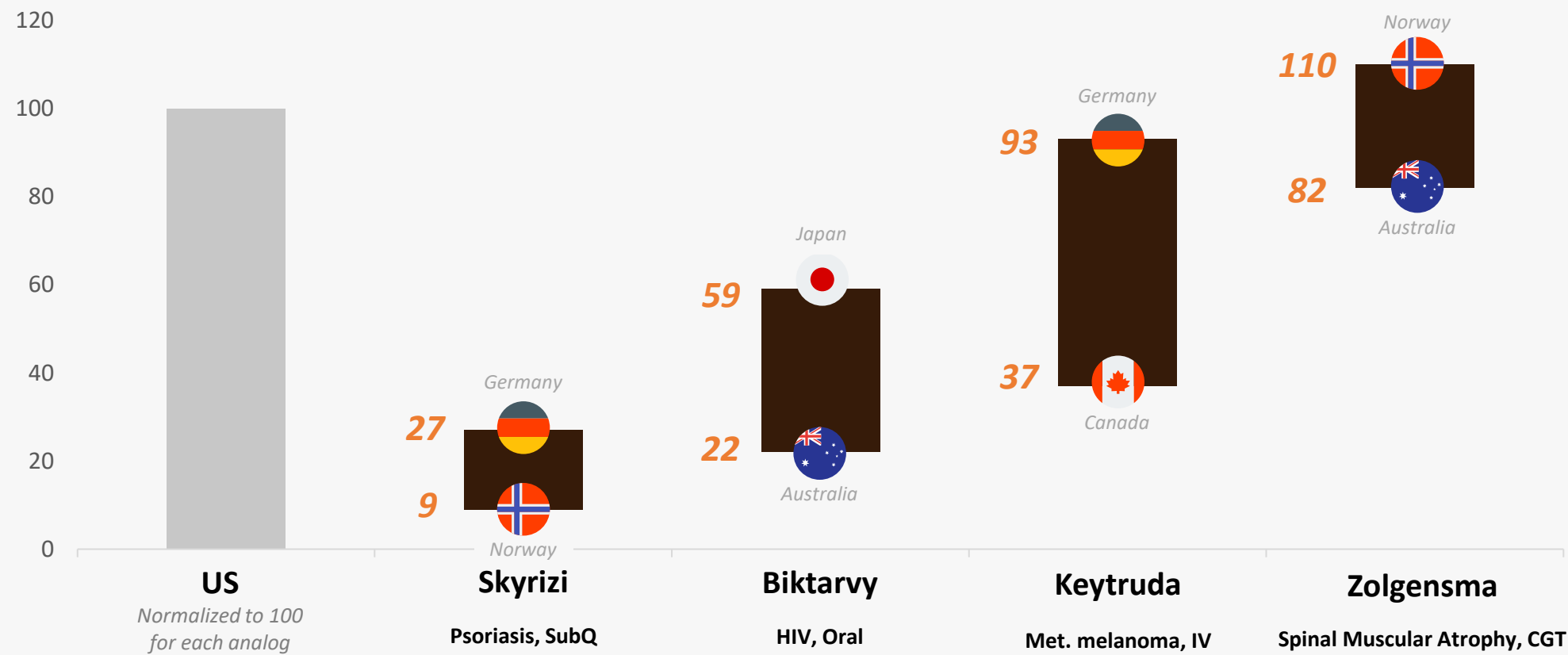


Source: Navlin. Notes: Ex-factory (WAC) list prices are used, converted to USD at the average quarterly rate at launch reported by the IMF. Germany's prices are at launch prices post the P&R process; price of Zolgensma in Germany is hospital price as the ex-factory price was not reported.

Abbreviations: CGT = Cell & Gene Therapy. HIV = Human Immunodeficiency Virus. IV = Intravenous. SubQ = Subcutaneous. WAC = Wholesale Acquisition Cost.

The spread of list prices within OECD is diverse as well...

Range of OECD list prices at launch, US WAC at launch = 100

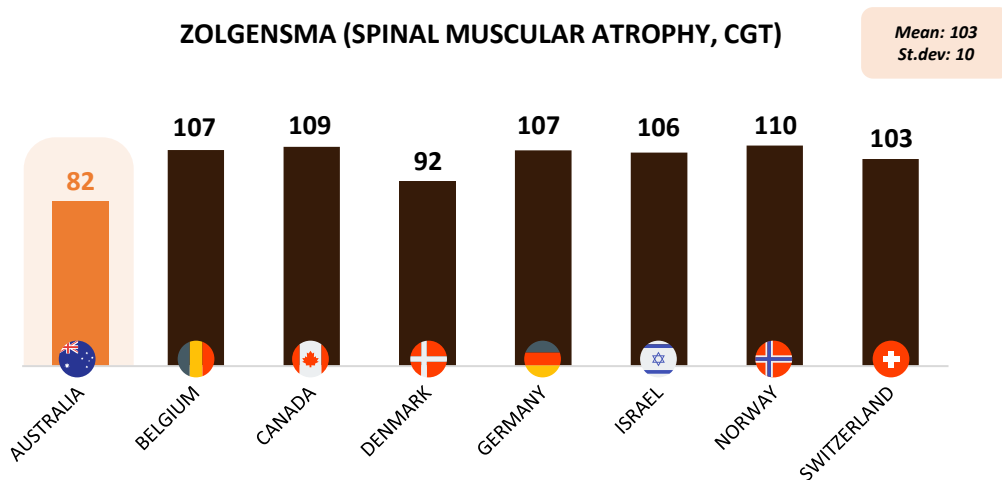
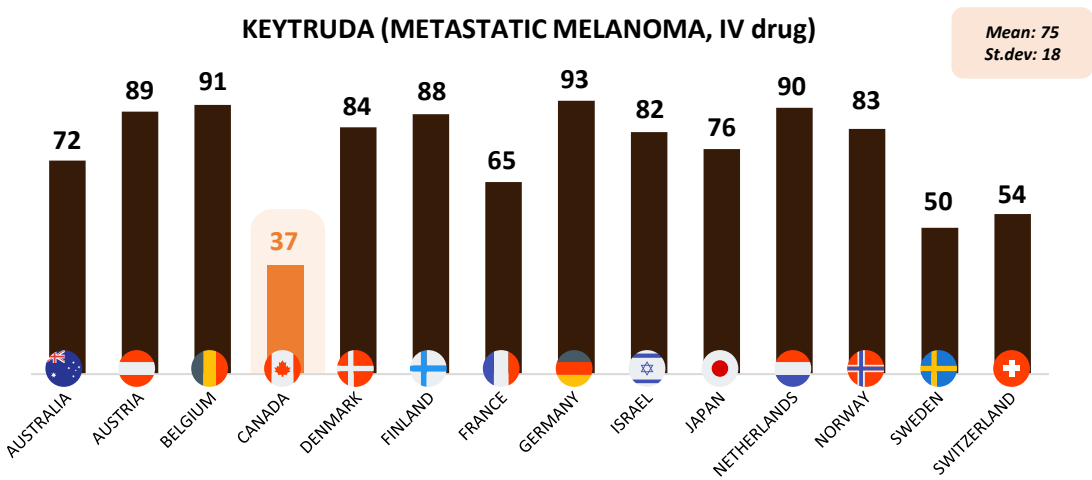
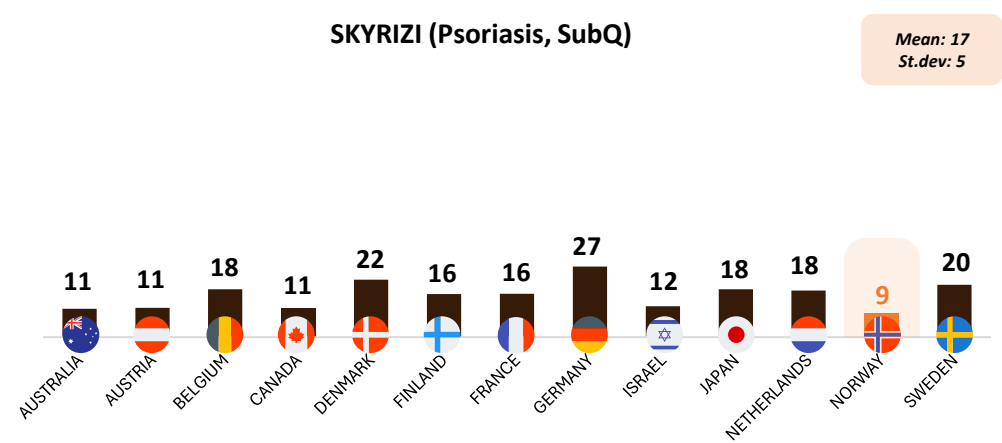
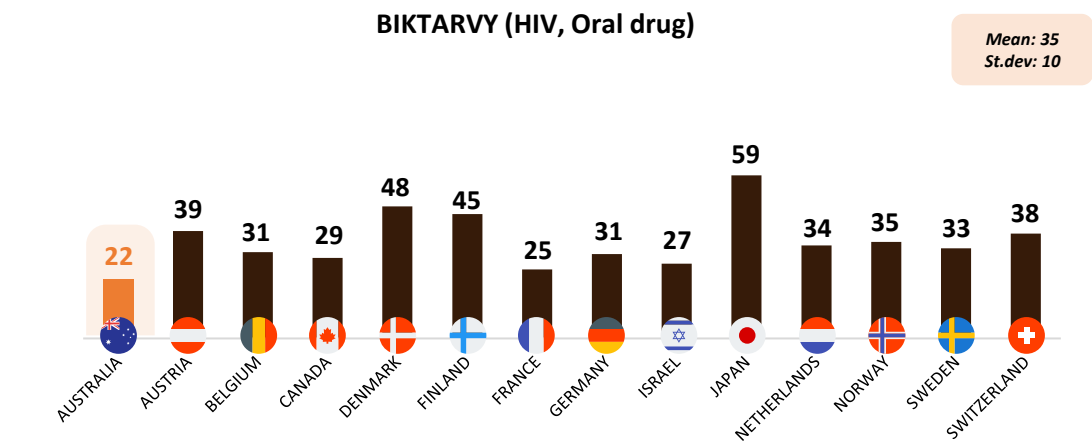


Source: Navlin. Notes: Ex-factory (WAC) list prices are used, converted to USD at the average quarterly rate at launch reported by the IMF. Germany's prices are at launch prices post the P&R process; price of Zolgensma in Germany is hospital price as the ex-factory price was not reported.

Abbreviations: CGT = Cell & Gene Therapy. HIV = Human Immunodeficiency Virus. IV = Intravenous. OECD = Organisation for Economic Co-operation and Development. SubQ = Subcutaneous. WAC = Wholesale Acquisition Cost.

Both the size of the US-to-ex-US price gap and the lowest-priced country vary significantly by product

OECD list prices at launch, US WAC at launch = 100

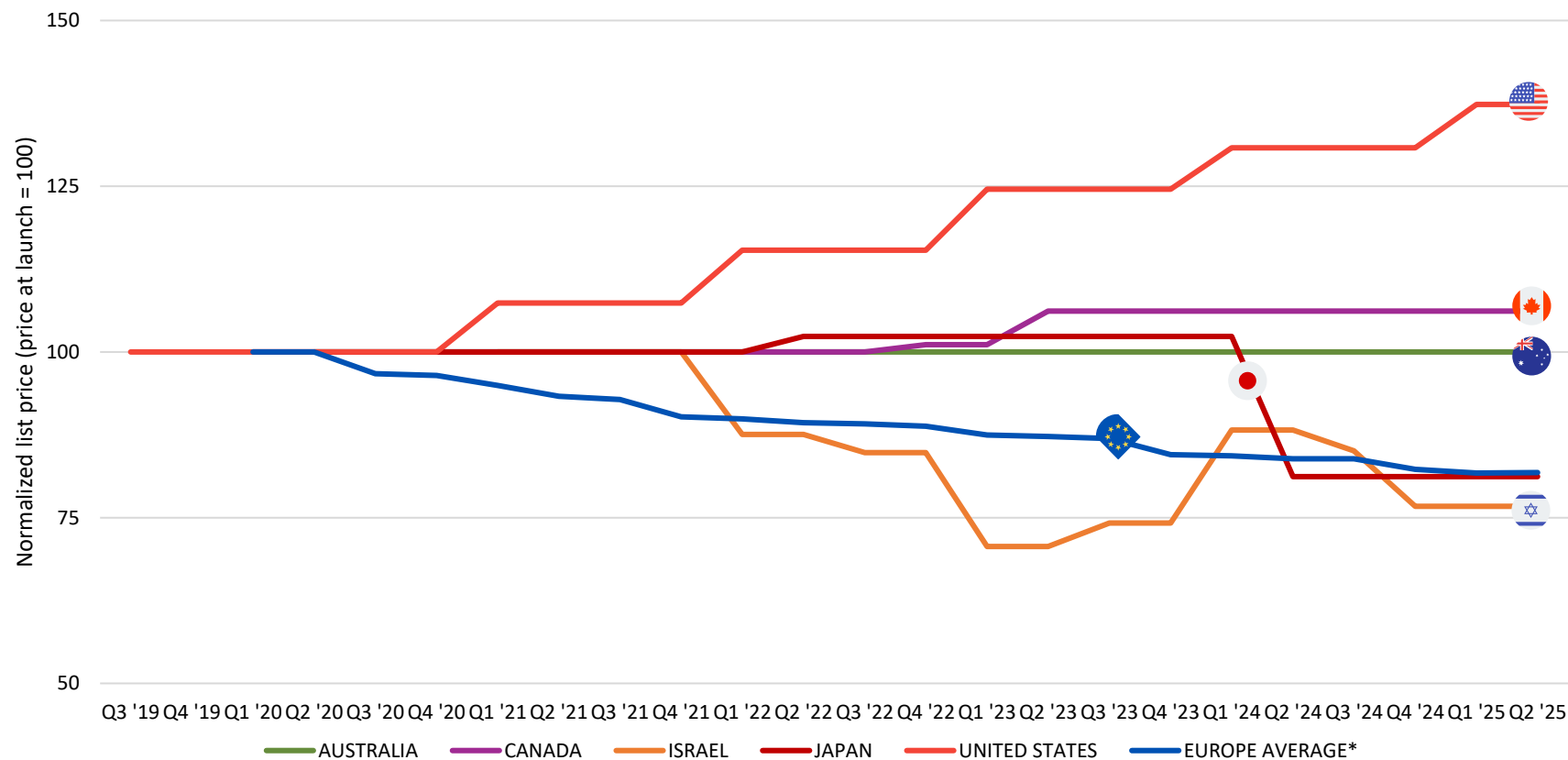


Source: Navlin. Notes: Ex-factory (WAC) list prices are used, converted to USD at the average quarterly rate at launch reported by the IMF. Canadian prices are approximated by Ontario's prices. Germany's prices are at launch post the P&R process, price of Zolgensma in Germany is hospital price as the ex-factory price was not reported.

● Lowest price

The gap between US and ex-US list prices only widens over time – creating dynamic implications if MFN is applied periodically

RINVOQ: Evolution of list prices (list price at launch = 100)



Why do ex-US list prices behave this way?

Canada – agreement reached with pan-Canadian Pharmaceutical Alliance in Q4 2022 affecting the list price

Australia follows a set of statutory repricing rules, e.g., 5, 10, etc. years after launch. Rinvoq is approaching its first repricing

Europe's average list price can move due to indication extensions, HTA re-evaluation due to new data, IRP, routine re-negotiations

Japan conducts routine annual price revisions as well as “special rule” revisions as in Q2'24 where Rinvoq was subject to market size expansion (indication extension) repricing

Israel medicines are subject to annual IRP and mid-year IRP if EUR-ILS exchange rate fluctuations break the 3% corridor

Source: Navlin. Notes: Ex-factory (WAC) list prices are used, converted to USD at the quarterly rate, reported by the IMF, averaged over the period since the first launch of Rinvoq. Canadian prices are approximated by Ontario's prices. Germany's prices are at launch post the P&R process. *Europe average includes the following countries: Austria, Belgium, Denmark, Finland, France, Germany, Ireland, Luxembourg, Netherlands, Norway, Sweden, Switzerland.

Abbreviations: MFN = Most Favored Nation.

Why do prices in ex-US behave this way?

Changes in drug's value proposition and price renegotiations

Following an indication extension



- *Indication extensions may significantly affect the drug's value proposition or eligible patient population, and in turn, the budget*



RINVOQ's case

Following HTA re-evaluation of the same indication



- *Manufacturer may request new HTA re-evaluation if significant new evidence is available, triggering a subsequent price renegotiation*



Potential of price increase, but rare

Changes in external environment

Routine re-negotiations



- *Periodic renegotiations*
- *Expiration of price-volume agreements*
- *Major changes in competitive landscape*
- *Combo therapy with the drug in question*

Periodic IRP



- *Some countries apply IRP periodically, e.g. Israel applies it up to 2 times per year*

We want you to leave with these three insights...



1

Although U.S. list prices are generally higher, exceptions exist

2

The country with the lowest list price varies by product, so does the price gap vs. the US

3

List prices typically decline over time because of changes in drug's value proposition and built-in repricing mechanisms

Today's agenda



**INTRODUCTION TO
THE MFN POLICY**



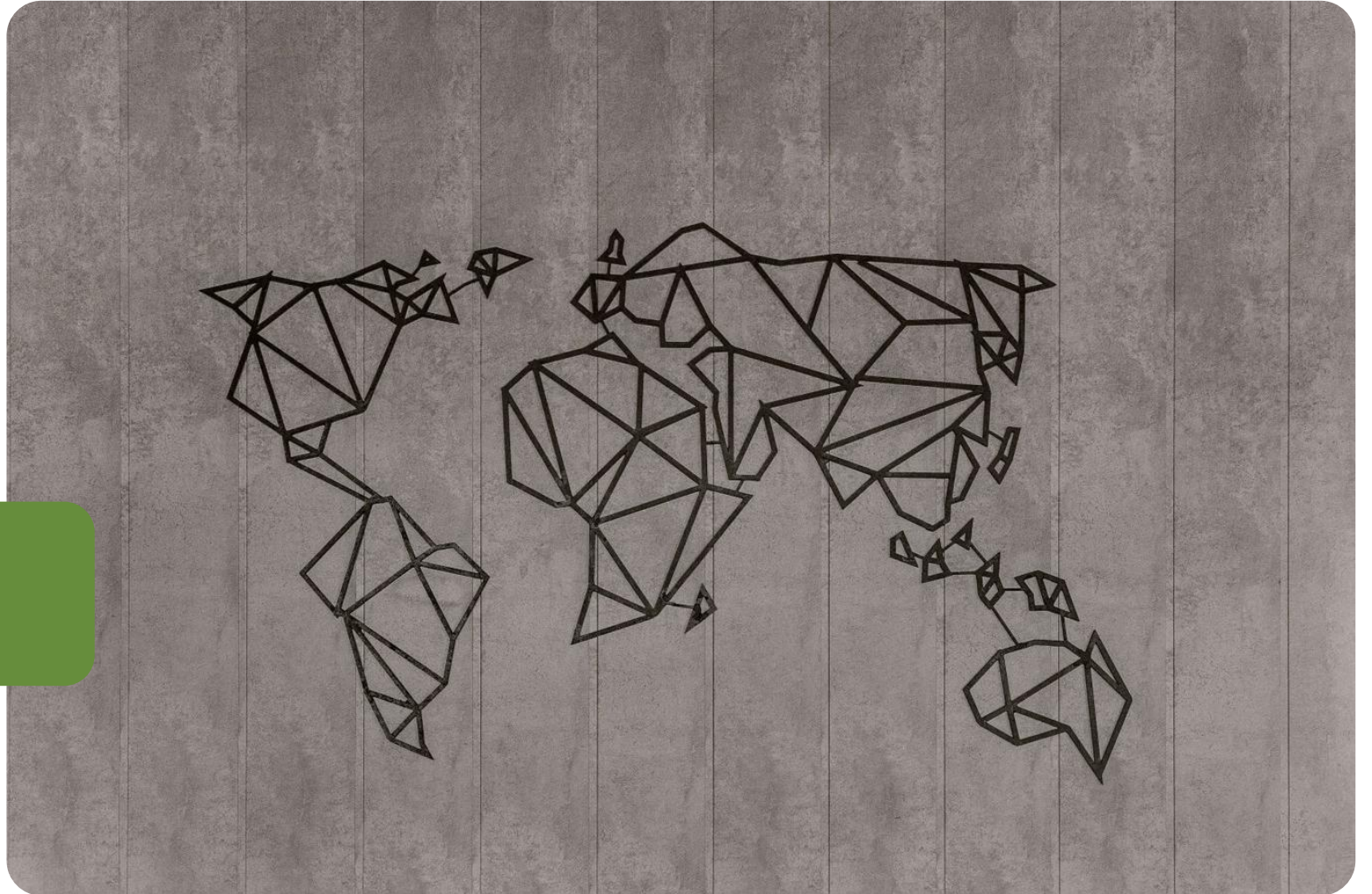
**Ex-US PRICE
SETTING & ITS
CONSEQUENCES**



**POTENTIAL GLOBAL
MFN IMPLICATIONS**

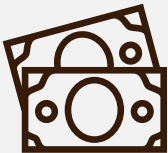


AUDIENCE Q&A



What do we think the effect of the MFN will be on the prices they will be compared to?

**Ex-US markets
are not willing
to pay more**



There is little political or fiscal appetite in Europe to raise drug spending.

Trung Huynh,
Healthcare
Analyst, UBS,
May 2025



Australia will not compromise on our policy setting. The Pharmaceutical Benefits Scheme is not up for negotiation.

Australian
Department of
Foreign Affairs
and Trade,
May 2025



Raising prices in Europe can't just happen without changing national laws. There would be strong public and political pushback.

Prof. Kerstin
Vokinger,
University of
Zurich, May
2025



Drug prices are a national matter in Germany, governed by law. Our regulatory framework remains unchanged.

German
Health
Ministry
spokesperson,
May 2025



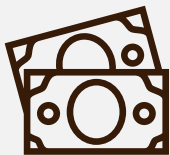
Unless there is an overhaul of UK law or policy, Trump's order will not result in higher UK prices.

Dr. Daniel
Howdon,
Health
Economist,
University of
Leeds, May
2025



What do we think the effect of the MFN will be on the prices they will be compared to?

**Ex-US markets
are not willing
to pay more**



**Companies will be
stricter on their
ex-US list prices**



**Greater emphasis
on ex-US markets
will be essential
for strategic
decision making**



Executive Insight | A trusted partner of global pharma across functional areas



**25-year track
record of success**



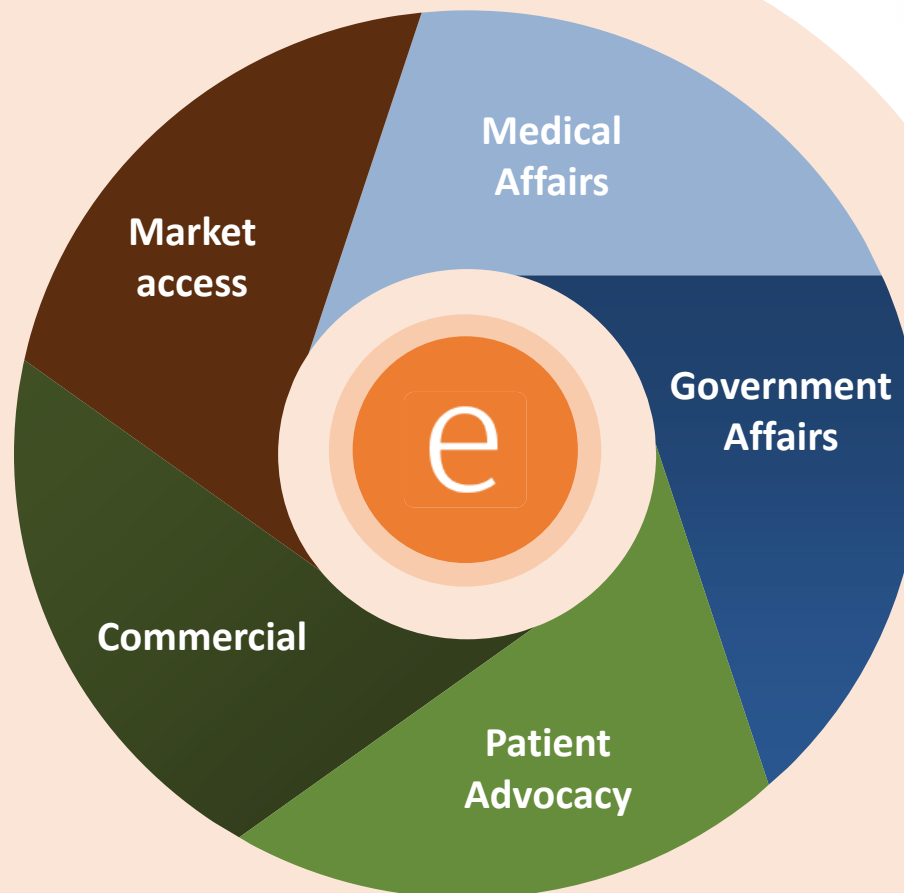
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