THE EMERGING POTENTIAL OF INTERNATIONAL REFERENCE PRICING (IRP) IN THE US: AN ANALYSIS OF TRENDS, CHALLENGES, OPPORTUNITIES AND LEARNINGS FROM EUROPE

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INTRODUCTION

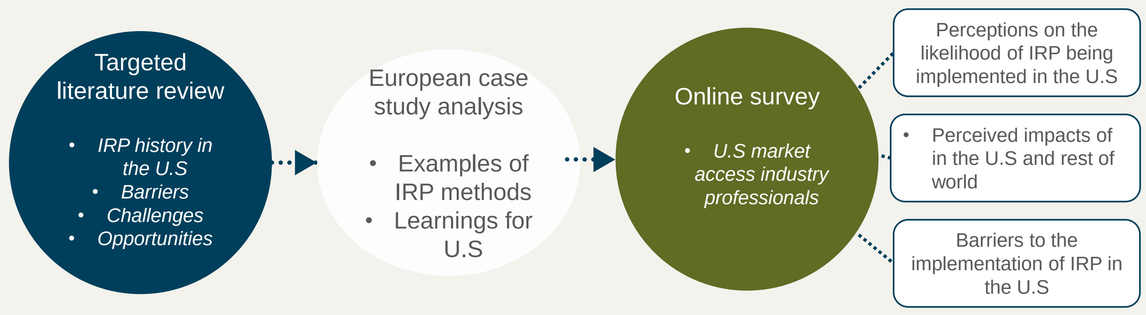
- The United States (U.S) is a major market for innovative drugs and, in contrast to many other markets, allows manufacturers to freely set drug prices.
- A recent report found U.S drug prices were 2.78 times higher than in 33 other nations with healthcare spending reaching 17.3% of U.S gross domestic product (GDP) in 2022. [1,2]
- Some argue high drug prices in the U.S drive global pharmaceutical innovation whilst other countries "freeload" and enjoy benefits of lower expenditure burden.[3]
- International Reference Pricing (IRP) was proposed under the first Trump administration and several IRP policies have been proposed to date (Table 1). Perhaps the most notable policy, the 'Most Favoured Nation' (MFN) model aimed to cut U.S drug spending by referencing the lowest prices in select high-income countries including Canada, Japan and across Europe.[4]
- Whilst, no IRP policies have been enacted to date, there continues to be high-level government support for this cost containment approach, with President Trump's administration's second attempt to pilot IRP within Centers for Medicare & Medicaid Services (CMS) recently proposed. [5]

OBJECTIVE

- To assess the potential impacts and challenges of implementing IRP in the U.S and extract relevant lessons from Europe's experience.

METHODS

- A targeted literature review was undertaken to understand the history of IRP policy recommendations in the U.S as well as the potential barriers, challenges and opportunities to its adoption.
- Various European countries were identified to act as case studies, with the aim to identify learnings from Europe's experience in IRP.
- A survey of U.S market access industry experts (n=10) was conducted to gauge insights into the likelihood of IRP being introduced in the U.S in the near future as well as the perceived barriers and impacts on the U.S and global healthcare system.



RESULTS

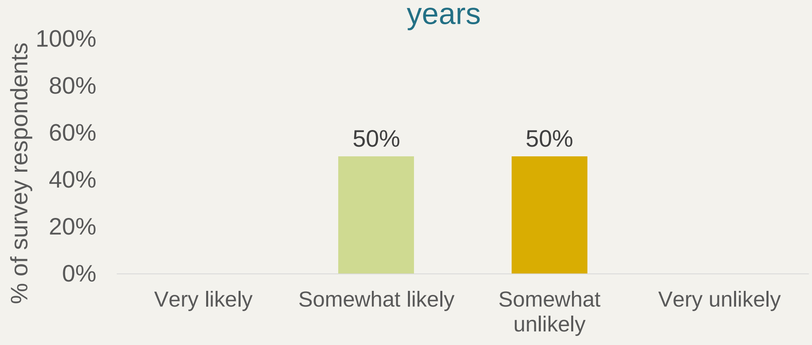
- A targeted literature review revealed a consensus that IRP could yield significant savings in U.S drug spending, with one analysis estimating a 52% discount on national U.S net prices for certain branded drugs.[6]
- Three IRP policies have been proposed to date, although none have passed into legislation (**Table 1**). The HR 3 bill aligned most closely with European IRP strategies, using IRP as a complement to other pricing methods with a smaller reference basket. In contrast, the MFN approach proposed by CMS and the executive order relied solely on the lowest price within the basket and lacked supplementary negotiation mechanisms.
- Of the European country case studies presented in **Table 1**, all used IRP alongside other methods such as HTA and domestic reference pricing mechanisms

Table 1. Characteristics of IRP policies across the U.S and select European countries

Country	# countries in basket	Drug applicable to the IRP	Method for basket referencing	Other methods used
HR 3 policy	6	250 most expensive, brand-name, single source drugs for Medicare	Average	Cost-based pricing
Executive order	~19	All drugs in Medicare Parts B and D	Lowest	N/A
CMS interim final rule	~19	50 Medicare Part B drugs	Lowest	N/A
	4	Brand name and reimbursed	Range between highest and lowest	HTA, DTRP, spending caps, other
	4	Brand name	Average	HTA, DTRP
	~16	Brand name	Lowest	HTA

Table adapted from Rand et al.,2021.[7] CMS = Centers for Medicare & Medicaid Services; DTRP = domestic therapeutic reference pricing; HR 3 = the Elijah Cummings Lower Drug Costs Now Act (HR 3); HTA = health technology assessment; IRP = international reference pricing; N/A = not available. Cost-based pricing considers the costs to the manufacturers to produce the drug

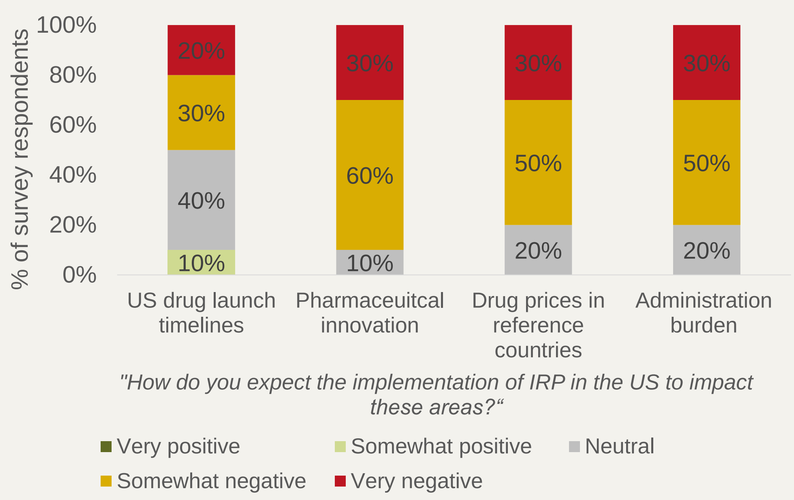
Figure 1. Perceived likelihood of IRP policy implementation in the United States in the next 5 years



"In your opinion, how likely is it that the US will implement some form of IRP in the next 5 years?"

- Survey participants were at odds with whether IRP policies would be implemented in the next 5-years in the U.S, with 50% respondents believing it was "somewhat likely" and the remaining 50% believing it was "somewhat unlikely" (**Fig.1**).

Figure 2. Perceived impacts of IRP in the United States



- **Fig 2**. shows the majority of participants expect the impacts of IRP implementation in the U.S to be "somewhat negative" or "very negative" across four domains; drug launch prices, innovation, impact on reference country prices and administration burden.

Learnings from Europe's use of IRP: Select European countries acted as case studies to compare and contrast IRP methods to identify learnings

1 Use transparent and predictable methods.

Transparency in the IRP process and predictability in the basket selection and revaluation frequency can reduce uncertainty for manufacturers.

2 Utilise complementary strategies

Integrating HTA methods and value-based agreements (VBAs) with IRP can help to build a more robust approach to pricing rather than just relying on one method like IRP.

3 Select an appropriate reference basket

European countries tailor reference countries to market size and economic status. If the U.S. were to implement IRP, it should adopt a similarly strategic approach.

DISCUSSION

- The interest in IRP policies in the U.S has arisen from the need to reduce drug prices and healthcare spending.
- Whilst some studies suggest IRP could yield significant savings for U.S healthcare spending, the implementation of IRP in the U.S would be complex with many implications for industry and patients.
- U.S industry experts had overall negative opinions on the impact of IRP in the U.S across important areas such as drug launch timelines, innovation and administration burden.
- Furthermore, given the size of the U.S market and its impact on global pharmaceutical sales, IRP might lead to increased drug prices in other countries, as manufacturers attempt to compensate for potential revenue losses.
- Europe is experienced with IRP and employs transparent and strategic IRP policies as part of a tool-box in conjunction with HTA and other methods to reduce drug prices where possible.

CONCLUSIONS

- Whilst the future of IRP policies in the U.S remains uncertain, the need to reduce U.S healthcare spending is clear. Thus, the use of IRP remains one option to achieve this alongside other cost-cutting mechanisms.
- The adoption of IRP in the U.S would be complex and U.S policymakers should consider the global unintended consequences of any IRP policies.
- Lessons from the EU emphasize the importance of transparency and predictability in IRP methods, the integration of IRP with other pricing tools like HTA or value-based pricing, and the strategic selection of reference countries.
- Overall, introducing IRP in the U.S would have a significant impact on portfolios and decision making and should be modelled and considered from multiple perspectives to understand the implications and consequences.

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