SHIFTING PARADIGM OF INTERNATIONAL REFERENCE PRICING. IS IT BENEFICIAL TO PAYERS, MANUFACTURERS OR PATIENTS?

Kumar P, Yelchuri M, Dobariya N, Pushkarna D

kinapse
a SYNEOS HEALTH company

Introduction

- International reference pricing (IRP) is defined as “the practice of using the published prices in one or several countries in order to derive a benchmark or reference price for the purpose of setting or negotiation the price of the product in a given country”
- IRP aims to reduce the costs of the products by selecting the lowest or an average price rule within the specified basket countries. Countries of similar economic situations that are geographically close are chosen as a reference
- Most European countries use ex-factory prices for comparison as it eliminates price difference that occurs due to the difference in distribution mark-ups
- This policy leads to interdependency of prices affecting markets differentially. Thus, it is highly important to understand changing dynamics of IRP system and how it influences the pharmaceutical market and its differential impact on payers, manufacturers and patients

Objective

- The objective of this study was to understand the changing landscape of IRP and its impact on the key stakeholders (payers, manufacturers, and patients)

Methods

- An international reference pricing map was created and reviewed to see if the basket of countries referred by nations to price their pharmaceuticals had changed
- Goal-oriented research was conducted using OECD and various pricing bodies in order to assess the pricing policies and launching a sequence of drugs
- Real-world evidence was gathered using the latest reports and published news to support the data of shifting paradigm in the US

Results

- Twenty nine European countries use IRP to set or influence the pricing of prescription drugs either formally (Denmark, Norway and Hungary) or informally (Belgium, France, Italy)
- Recently, countries like Greece, Croatia, Lithuania, and Moldova have updated their IRP rules
- IRP guarantees savings to health insurance funds as some of the countries (example Belgium), the reference price is set at 69% of the price of the originator medicine on the day that the patent expires
- Further, US is also adopting (high ex-factory price) the IRP for part B drugs which would eventually save $17 billion for Medicare in 5 years, which reflects huge cost savings for payers
- Both manufacturers and healthcare payers benefitted from the IRP by reducing the price transparency in different ways to minimize the spillover effect by payback mechanisms as shown in Table 1
- Due to IRP, manufacturers come up with a range of strategies to maximize the profit including the strategic launch of drugs in high priced markets (Netherlands and Denmark) firsts followed by the low priced markets as shown in the Figure A
- On the contrary, in countries that use IRP, patients face significant restrictions in accessing new medicines and treatment options compared to the US in general and lifesaving cancer drugs as shown in Figure B
- The differential impact of IRP on the three key stakeholders is presented in Table 2

Limitations

- This research is goal oriented and it’s not a systematic approach to fully establish the strong evidence
- There is a data gap in identifying the effect of IRP on co-payments and our search is limited to English articles only

Conclusion

- IPR is a widely used pricing policy in Europe and is still actively used as well as adjusted by national authorities. However, there is still some room for improvement in price transparency in negotiation and the kind of price published
- Due to the delays and the non-availability of new medicines in low-price countries, IRP may be likely to have negative impact
- Based on the evidence presented, healthcare payers are mostly benefitted from the IRP policies whereas similar impact was not observed on patients and manufacturers

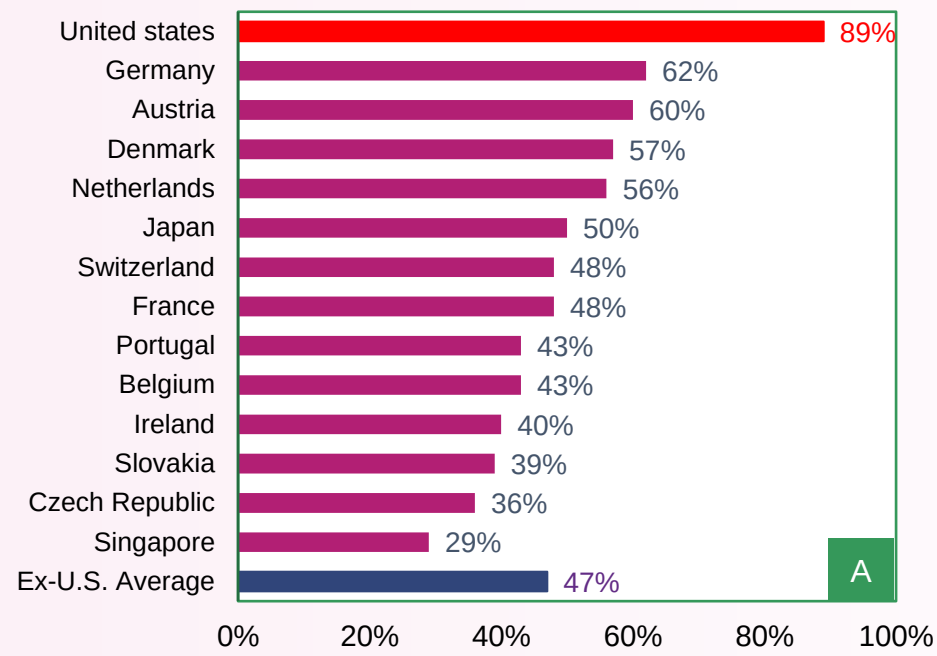

Figure A: Number of new medicines available by country (of 290 drugs launched worldwide 2011-2018)
Figure B: Average delay in availability of cancer medicines in months

Table 1: Cost-containment policies by Healthcare

Strategy	Method
Pay-back mechanism	In this method, payers negotiate a set reimbursement budget with companies based on sales forecasts. Companies pay a rebate of any sales beyond the predetermined level in the form of annual lump-sums
General discounts	In General discount system, manufacturer returns the predefined (1, 2, and 3%) of their annual sales to Ministry of Health
Profit control system	Companies freely set the prices of branded medicines but if it exceeds the national Health Services' predefined profit margins, they have to pay back the exceeded profit or need to reduce the price in the following year
Risk-sharing agreements	It varies from country to country. In UK and Italy, outcome-based agreements are usual practice for certain therapeutic areas such as oncology where payer is not required to pay for drug if it is not effective, but listed price applies when it works for 100% patients

Country flags represents the countries using the respective strategies

Table 2: Overview of IRP impact on Healthcare payers, Manufacturers and Patients

Criteria	Healthcare Payers	Manufacturers	Patients
Cost containment and savings	●	●	●
Lower Pharmaceutical Prices	●	●	●
Launch delays, launch sequencing or no launch in low priced markets	○	●	●
Incremental innovation and investment in (incremental) R&D	○	●	●
Generics’ entry and penetration	●	●	●
Availability of New medicines	○	●	●

● Positive Impact ○ Neutral Impact ● Negative Impact

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