Characterizing the Relevance of IRP for Medical Devices: A Cross-Country Comparison

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Objectives

Despite multiple studies confirming International Reference Pricing (IRP) – or external reference pricing – as a central strategic policy tool for pharmaceutical cost controls worldwide, a cross-country analysis of its potential relevance within the medical device space remains an under-researched area. The aim of our research is to understand if and for which markets IRP could feature as one of the influential factors informing pricing and/or reimbursement of medical devices.

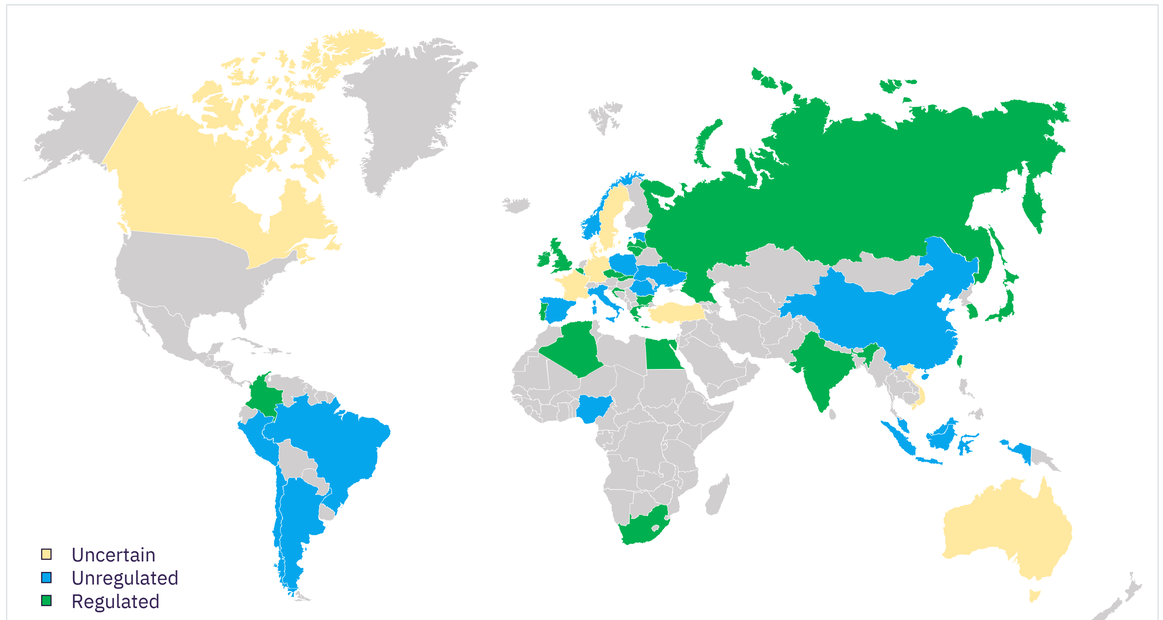
Methods

Desk research based on academic and gray literature was conducted to sense check the regulated or unregulated nature of pricing and reimbursement (P&R) settings for medical devices across 47 markets globally. For the markets showing potential for IRP application, a more comprehensive analysis of regulatory details in legal documents and other relevant ruling was performed.

Results

In total, 20 markets displayed some level of centralized P&R regulation, mainly targeting the maximum reimbursement amount rather than the actual market price. 17 markets showed unregulated pricing frameworks, while it was inconclusive for the remaining 10. Among regulated markets, internal reference, cost-plus pricing, external reference, and cost-effectiveness represent the main influential factors.

Among the nine countries that were subject to regulatory deep dive, relevance of external reference was confirmed for Croatia, Greece, Japan, Latvia, and Slovakia. Affected medical device categories and specific rules differ by country.



Country	Level of Regulation	Price Mechanism
Bulgaria	Market and reimbursed price	Internal Reference
Croatia	Market and reimbursed price	Internal/**External Reference**, Cost-effectiveness
Greece	Maximum compensation price	**External Reference**
Japan	Reimbursed price	Internal/**External Reference**, Cost-Plus
Latvia	Pharmacy and reimbursed price	Internal/**External Reference**, Cost-Plus
Slovakia	Market and reimbursed price	Internal/**External Reference**, Cost-Plus
South Korea	Reimbursed price	Internal, Cost-effectiveness
Spain	Reimbursed price	Internal Reference
Taiwan	Reimbursed price	Internal Reference

IRP exerts the most influence in Greece, with the average of the three lowest purchase prices in the EU impacting the maximum "compensation price".

The Greek National Organization for the Provision of Health Services (EOPYY) is interconnected with European invoicing and compensation networks and European social security institutions to exchange know-how in matters of determining compensation. For the compensation of the medical technological products and the consumable sanitary material, it is mandatory to submit to the EOPYY request for inclusion into ITS Register of Compensated Products. The maximum "compensation price" of the product is determined by the average of the three lowest purchase prices in EU countries. The product must be available in at least three countries of the EU. Data are submitted with separate declarations once a year. Products exclusively produced/marketed in Greece, or in less than three European countries, are classified as "domestically produced" or "domestically circulated", and the price is determined based on costs and approved by decision of the Minister of Health, based on EOPYY opinion.

Conclusions

While IRP continues to thrive for pharmaceuticals as a cost-containment policy tool worldwide, its application for medical devices remains less obvious. However, it is confirmed to play a role in P&R evaluations of some medical device categories in several countries, including Croatia, Greece, Japan, Latvia, and Slovakia. Integrating the above considerations within the launch planning phase can help optimize market access strategy in those markets.