Iselin Dahlen Syversen

A comparative analysis of international drug price negotiation frameworks

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The Inflation Reduction Act marked a significant policy shift in the United States, granting Medicare the authority to negotiate prices for high-cost brand-name prescription drugs. While many other industrialized nations have long utilized negotiation frameworks, this study aimed to compare these processes across various health systems, focusing on key aspects such as drug selection criteria, negotiation procedures, price-influencing factors, and implementation (1).

My study analyzed the negotiation frameworks of four G7 countries – Canada, France, Germany, and the United Kingdom (England) – two Benelux countries (Belgium and the Netherlands), and one Scandinavian country (Norway), all of which have well-established drug price negotiation models. The U.S. Veterans Affairs Health System was also included for comparison.

The study concludes that the negotiation framework established under the Inflation Reduction Act is far more limited than other frameworks explored in this study. Adding elements from frameworks in other countries could lead to more effective price negotiation in the United States.

Prices for brand-name prescription drugs in the United States are approximately two to four times higher than prices in other comparable countries (2). A key reason for the price differential is that high-income countries apart from the United States negotiate drug prices with manufacturers shortly after market launch, whereas the United States allows pharmaceutical manufacturers to set prices without restriction when entering the market. The Inflation Reduction Act (IRA) of 2022 authorizes the Centers for Medicare and Medicaid Services (CMS) for the first time to negotiate prices for a limited selection of high-revenue brand-name prescription drugs on behalf of Medicare (3). In 2023, CMS released comprehensive guidance on

negotiation plans, which covered the selection of drugs, negotiation procedures, and timelines for implementation (4). For example, qualifying drugs must be single-source brand-name drugs or biological products lacking marketed generic or biosimilar competition and will be eligible for negotiation beginning seven years after Food and Drug Administration approval for small molecule drugs (11 years for biologics), with the negotiated price taking effect two years later (5).

Many health care systems around the world negotiate drug prices using a range of methods to ensure the affordability of prescription drugs. The objective of the study was to compare various negotiation frameworks to identify their strengths and weaknesses. Four main areas were covered:

1. Criteria for selecting drugs for price negotiations (what factors)
2. Procedures for negotiations (structure, timelines, consequences of not reaching an agreement)
3. Factors that influence negotiated prices (how defined and what sources)
4. Implementation of the negotiated prices (how distributed in the supply chain, discrepancies between transaction price vs. negotiation price, price changes over time).

Semi-structured interviews were conducted with in-country experts in each system who have knowledge and first-hand experience in pharmaceutical price negotiations. For each system, relevant legislation, government publications, and guidelines were also gathered to understand the context of the negotiation frameworks.

Findings

All eight systems negotiate the prices of brand-name prescription drugs soon after approval and rely on formal clinical assessments that compare newly approved drugs with existing therapies. Systems differed on characteristics such as whether the body performing clinical assessments is separate from the negotiating authority, how added health benefit is assessed, whether explicit willingness-to-pay thresholds are employed, and how specific approaches for priority disease areas are taken.

High-income countries around the world adopt different approaches to conducting price negotiations on brand-name drugs but coalesce around a set of practices that are largely absent from the current Medicare negotiation framework. U.S. policymakers might consider adding some of these characteristics in the future to improve negotiation outcomes.

Impact nationally and internationally

Countries around the world have developed sophisticated systems to negotiate drug prices effectively, and the findings in the study suggest that there is much the U.S. can learn from these established frameworks. Unlike other high-income countries, the U.S. lacks formal health technology assessments (HTAs), which have been key in strengthening drug price negotiations elsewhere. When price negotiations take place at market entry, it ensures quicker and longer-lasting savings by setting affordable prices. Many health systems negotiate prices as drugs are approved, enabling immediate, cost-effective access. In contrast, Medicare can only begin negotiations seven to 11 years after FDA approval, allowing manufacturers to set high prices for years. While this delay supports industry profits and incentivizes innovation, it results in higher drug costs and slower access to affordable treatments for patients. Implementing strategies from other countries could significantly improve negotiation outcomes for Medicare and ultimately benefit American patients.

Beginning in January 2025, the European Union (EU) will adopt a standardized framework for clinical assessment of newly approved drugs (6). The framework for joint clinical assessment will be implemented across member states in stages, beginning first with oncology drugs and advanced therapies, such as gene therapies. The process will run in parallel with the regulatory review process; when manufacturers submit market authorization applications to the European Medicines Agency, they will provide information at the same time to a European Commission secretariat to inform the HTA process. Member states are obliged to include the joint clinical assessment in their national HTA review (along with additional clinical analyses they may choose to undertake) and will each complete their own cost-effectiveness analyses, price negotiations, and reimbursement decisions. This centralized joint clinical assessment process may help standardize evaluations of new therapies. A more uniform drug assessment process may be especially important given the challenges countries face in addressing uncertainty in clinical evidence and the increasing number of drugs approved based on nonrandomized trials, single-arm studies, surrogate measures as study endpoints, and short follow-up times.

Impact on my career

Equity in health has been one of my main motivations for pursuing further education and has continued as a guiding star throughout my career. The fellowship has been a unique opportunity to join a community of people

from across the world. They have inspired me to see new opportunities to advance health policy on equitable access to medicines and health care.

The need for international knowledge sharing and exchange of experiences is becoming more critical in the coming years to ensure access to medicines and health care. Given the current geopolitical landscape, enhancing cross-border public health policies is more important than ever. The initiative of the European Health Union highlights the importance of a more unified and prepared approach to ensure access to medicines and medical technology, collaboration on health preparedness and crisis response, and reinforcing healthcare infrastructure. The Harkness experience has given me a deeper understanding of the changes needed today to address the challenges of health care in the future. International collaborations as a strategic platform and mechanism to advance policy changes are something I will continue to build upon in my career.

Future Research

The study did not include comprehensive data on access to medications or drug spending in each system, which restricted the ability to assess the overall performance of different negotiation frameworks. The study focused on the processes and procedures that shape drug price negotiation. However, there are numerous exogenous factors, including how societies value health and how much countries can afford to pay, that may affect final agreed-on prices. Additionally, although interviewees underscored the primary importance of added therapeutic benefit and the certainty of evidence in drug price negotiations, they were not asked to formally rank different factors. Future research should quantify how officials (and the frameworks in which they operate) trade off different values when negotiating prices.

Literature

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Iselin Dahlen Syversen
Iselin.syversen@gmail.com
Norwegian Hospital Procurement Trust
N-0151 Oslo, Norway

Iselin Dahlen Syversen is Head of Negotiation Department novel drugs and new technologies, Norwegian Hospital Procurement Trust