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Viewpoint

Negotiating Drug Prices in the US—Lessons From Europe

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In the US, spending on prescription drugs increased from $30 billion in 1980 to $335 billion in 2018, which is mainly associated with the high prices of brand-name drugs.[1] Prices are substantially higher compared with European countries.[2] One explanation for this price differential is that, unlike in the US, national health authorities in Europe negotiate new drug prices with manufacturers.

The US Inflation Reduction Act, which was signed into law in August 2022, empowers the US Secretary of Health and Human Services to negotiate the prices for a limited number of brand-name drugs, with the greatest spending within Medicare's Part B (which covers clinician-administered drugs) and Part D (which covers retail drugs) programs.[3] The bill stipulates that drug pricing negotiations must consider policies, such as whether a drug represents a therapeutic advance or fulfills an unmet medical need.[3,4] Therefore, policy makers in the US will need to address 2 questions as a matter of priority: How should therapeutic advance (which can also be referred to as therapeutic value) be assessed? How should evidence on therapeutic advance be used to negotiate drug prices? Lessons can be learned from European countries (such as England, France, Germany, and Switzerland) that have a long track record in evaluating drug value and using this information to secure lower prices.

Value-Based Pricing: Comparative Clinical Effectiveness and Comparative Cost-Effectiveness

Value-based pricing is an important and effective tool for price negotiation. Assessments aimed at establishing a drug's value form the basis of negotiations between many European national health authorities and manufacturers. European countries define value in different ways. In general, 2 distinct approaches exist. One approach, as applied in France, Germany, and Switzerland, is to use comparative clinical effectiveness, ie, to determine the added therapeutic value of the new drug compared with the standard treatment for the same indication. France and Germany have designated scientific bodies, such as the Commission for Transparency in France and Institute for Quality and Efficiency in Health Care in Germany, that perform value assessments that consider published and unpublished data on a drug's clinical effects as well as its relative performance against existing alternatives. Switzerland has not developed a similar national health technology assessment process. Instead, the Federal Office for Public Health relies on the assessments from other countries (eg, Germany) or medical associations (eg, the European Society for Medical Oncology).

The second approach for value assessment (as applied in England) is to additionally evaluate a drug's comparative cost-effectiveness. In England, a drug's value is determined by considering the additional cost required to generate an additional unit of health from the new drug, as compared with established treatments in the health system. This incremental cost-effectiveness ratio guides decision-making via the National Institute for Health and Care Excellence, which typically recommends new drugs for coverage in the National Health Service if they have incremental cost-effectiveness ratios ranging between £20 000 and £30 000 per additional unit of health (as measured in quality-adjusted life years). Manufacturers whose drugs are not considered cost-effective in England can negotiate with the government and offer confidential discounts to lower their prices within the health system's explicit incremental cost-effectiveness ratio threshold.

The objective of countries that are assessing the comparative clinical effectiveness of new drugs is to establish an association between the magnitude of the therapeutic value and price. Whether this has been achieved is questionable.[5,6] Even if an association between the therapeutic value and price is established, using comparative clinical effectiveness alone does not allow decision-makers to determine the right price in their health systems. This may be partly responsible for relatively high launch prices in countries that primarily rely on comparative clinical effectiveness evidence in negotiating with manufacturers. By contrast, establishing the cost-effectiveness of new drugs can help anchor drug prices according to a health system's willingness to pay or, preferably, its health opportunity cost (ie, how much is spent to generate 1 unit of health with existing treatments in the health system).

Timing of Therapeutic Value Assessment

In England, France, and Switzerland, the drug's therapeutic value is generally assessed after approval and serves as a basis for the drug's launch price. In Germany, the therapeutic value is assessed during the drug's first year on the market.

For example, value reassessment occurs also after launch in Germany, England, and France when important new evidence emerges for drugs that were initially recommended with considerable uncertainty. Switzerland applies a more systematic approach by reassessing the drug's therapeutic value (and thus its price) every 3 years.[5] In these reassessments, the Federal Office for Public Health assesses the added therapeutic value of the drug against existing alternatives for the same indication, including new drugs.[7]

Failed Negotiations

Payers' ability to say no to highly priced drugs that do not offer a therapeutic advance (either from a clinical or economic perspective, or both) is an effective bargaining tool in drug pricing negotiations. In Europe, one potential outcome of negotiations between national health authorities and manufacturers is not reaching an agreement. One recent example is the gene therapy betibeglogene autotemcel, which is indicated for the 1-time treatment of beta thalassemia. The manufacturer demanded a price of more than $2 million, a price that Germany was not willing to pay. Eventually, the manufacturer withdrew its therapy from the German market.

Notably, such outcomes are rare. In an earlier study, most drugs that offered therapeutic advances compared with existing alternatives remained on the market following pricing negotiations, and only those that did not have a demonstrable benefit vs comparators left the market.[8]

Implications for the US

Value assessments have been associated with lowered drug prices in Europe and should be considered as a basis for negotiating drug prices in the US. An important first step will be to decide how therapeutic advance should be defined. One possible approach could be to evaluate the added therapeutic value of a drug against existing alternatives for the same indication, as occurs in France and Germany.

A further crucial step will be to determine whether such a comparative clinical effectiveness is sufficient or whether an additional comparative cost-effectiveness approach should be implemented. Experience from Europe suggests that a solely comparative clinical effectiveness approach provides a broad discretionary power for negotiation, which may result in an overall lack of association between value and price. An additional cost-effectiveness approach may be more

effective in achieving optimal prices, but it raises the challenge of setting an appropriate incremental cost-effectiveness ratio threshold and may restrict the discretionary power for negotiation.[9]

By contrast to the European countries, the Inflation Reduction Act does not allow for the negotiation of launch prices of drugs. Rather, drugs would be eligible for negotiated prices from at least 9 years after drug approval.[4] Price negotiation also after launch has been proven effective in Europe. For example, in Switzerland's regular reassessment, the therapeutic value of the older drug is assessed against existing alternatives for the same indication, including new drugs.[7]

The drug pricing provisions in the Inflation Reduction Act are a milestone for pharmaceutical spending in the US. Value assessments conducted in European countries offer useful lessons for US policy makers.

ARTICLE INFORMATION

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