

**Pricing & Reimbursement**

**2021**

**Fourth Edition**

Contributing Editor: **Grant Castle**

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# Market access to medical innovations and relevance of international pricing

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## Introduction

Various key geographical markets have developed new pathways and policies to facilitate the earlier adoption of new medicines and medical technologies to stimulate research and development (R&D) and to promote regional competitiveness. These include break-through designations and, most recently, the 21<sup>st</sup> Century Cures Act in the US and PRIME designation in the EU. In December 2020, the European Commission published Pharmaceutical Strategy for Europe. It puts forward a patient-centric, EU-based approach to pharmaceutical policy that envisages enhancing quality and safety of medicines to build a stronger EU wide health policy framework. Following its departure from the EU, the UK has also enacted new primary legislation seeking to expedite product approval of, and improve market access to, transformative medicines and medical technologies with a view to stimulating R&D and improving patient outcomes.

But despite these scientific and regulatory endeavours, payers and policymakers are increasingly objecting to rising healthcare costs. Cost-containment measures have resulted in many innovative therapies, including advanced therapies and those intended to treat rare diseases, not being adopted for clinical applications or otherwise not being made available to patients – through their exclusion from coverage and reimbursement based on their perceived impact on affordability and/or based on the uncertainty of the clinical effectiveness in a real-world setting.

The new reality is that global spending on prescription medicines in 2020 was estimated in the region of \$1.3 trillion. The United States alone spent in the region of \$350 billion. It is projected that these spending rates will likely increase at a rate of 3%–6% annually worldwide through 2025, reaching in the region of \$1.6 trillion in total market size in 2025. This excludes spending on COVID-19 vaccines, where total cumulative spending through 2025 is projected to be \$157 billion.<sup>1</sup>

Thanks to more targeted therapies – as a result of the investment in gaining greater understanding the genomics to identify new molecular targets – cancer treatments account for a significant proportion of prescription medicine costs. It has been reported that in 2018, global spending on cancer treatments was approximately \$150 billion, and has since increased by over 10% annually.

Moreover, in recent years, there is greater impetus among global organisations and NGOs such as the World Bank and the World Health Organization to promote universal health coverage. Various stakeholders have embraced universal health coverage, with the goal of ensuring that patients have equitable access to healthcare they need without suffering financial hardship. The push for universal health coverage is particularly strong in low and

middle income countries as part of the global health sustainability agenda. More broadly, to achieve the objective of equitable access, the NGOs and governmental organisations are more closely scrutinising drug pricing. Some are demanding greater transparency in drug pricing and/or are advocating for international price referencing (see below).

Governments in different jurisdictions are contemplating new approaches to government reimbursement of new therapies – whether by reforming government reimbursement structures or setting prices based on an assessment of “value”. Yet, while governments aim to address drug prices, most governments simultaneously acknowledge the importance of preserving incentives for innovation. In this regard, present-day drug pricing debates come at an interesting moment in time as the COVID-19 pandemic has reinforced the significance and the urgency of rapid biopharmaceutical innovation. The pandemic has brought into stark light the need for deliberative drug pricing policy that balances the competing needs of (i) new financing approaches for novel therapies, with (ii) preserved – or even enhanced – incentives for biopharmaceutical innovation. No doubt the COVID-19 pandemic will continue to be an important backdrop to international drug pricing debates. As we reflect on the drug pricing legal and policy debates unfolding in various jurisdictions across the globe, the following converging themes emerge:

#### Strong, and growing, interest in value-based pricing

Value-based pricing has been a prominent feature of policy discussions. Specifically, governments have expressed an increased desire to achieve better value for money in healthcare spending while keeping incentives to innovate. Accordingly, “value-based pricing” has gained increasing momentum. Underlying the principle of “value-based pricing” is the notion that prices of new medicines and technologies reflect their “value” to the society, as assessed against a range of criteria for the purpose of reimbursement. One important aspect of the value-based approach is that pricing strategy involves more than just setting a price. The strategy seeks to capture the value that is generated in the product development to differentiate the new treatment modality from the existing therapy because the former will fulfil an unmet medical need. It necessitates an early understanding in product development of what constitutes value to guide product development decisions so that the relevant evidence is generated. Differential value assessment is influenced by clinical, health economic and societal considerations. The assessment may vary considerably according to disease area, treatment regimes and patient characteristics.

“Value” can be technically defined as “what consumers would be willing to pay or to give up for a good or service”. Under this definition, the value proposition will depend upon the perspective from which the assessment is conducted. What a patient considers valuable may not be the same as what a physician considers valuable. Moreover, the interests and values of different stakeholders, such as payers, healthcare providers or producers of medicines and medical devices, may not be aligned. Moreover, value refers to the specific features attributed to a given drug in a particular context, such as its degree of innovation, availability or accessibility, or its importance in relation to public health. Therapeutic value has been defined as “the effect conveyed on a patient following administration of a pharmaceutical which either restores, corrects or modifies a physiological function(s) for that patient”.

In jurisdictions like the U.S., value-based pricing is a novel concept when it comes to government payment for drugs. In the U.S., not only does the current legal framework for government reimbursement of drugs not expressly anticipate value-based pricing, there are multiple legal barriers to innovative financing and value-based arrangements that impede implementation of such arrangements even in commercial (i.e., non-governmental) markets.

Accordingly, a shift to value-based pricing models would necessitate certain legal reforms to allow for the types of multi-year, patient-tracking-based, value-based payment models that payers (and drug developers) might wish to pursue in the U.S.

At the same time, the implementation of value-based pricing models can lead to complex and contentious issues. While the rhetoric of policy makers and diverse stakeholders generally aligns in advocating for value-based pricing models, when it comes the time to execute value-based pricing, stakeholders must answer the thornier question of *how* to assess the value of a therapy and *who* should be tasked with doing so.

The UK's healthcare delivery is principally provided through the single payer system, the National Health Service. The NHS spends about \$22 billion annually on pharmaceuticals, of which approximately \$14 billion is spent on branded drugs – representing 13% and 10% of the allocated budgets by the Treasury. Growth in NHS funding is expected to slow, meaning that access to innovative technologies will depend on savings found elsewhere. The UK Department of Health and Social Care uses the pharmaceutical price regulation scheme to control expenditure on branded drugs. This is notwithstanding the fact that manufacturers enjoy freedom of pricing in the UK. However, there are several indirect controls which influence the price set by a manufacturer. The National Institute of Health and Care Excellence (NICE), a non-departmental body of the Department of Health and Social Care, is responsible for determining the “value” of branded drugs. Establishing the value of a drug requires an assessment of whether the additional health expected to be gained from its use exceeds the health forgone as other NHS treatments are displaced by its additional cost. This is achieved by comparing the incremental cost effectiveness ratio (ICER, the ratio of the additional health gained to the additional costs) with a threshold for cost effectiveness. NHS bodies are legally obliged to fund the treatments NICE has recommended.<sup>2</sup> In practice, the supplier of a drug with a high list price will often be prepared to negotiate a discount in order to obtain a positive NICE recommendation. Moreover, the UK policy is to control market access to innovative products by placing a limit on the total NHS spending on branded prescription medicines.

Certain key European countries consider “innovation” as a key determinant for assessing value. Innovative technologies or medicines could be considered in the context that they are either more effective, or cause fewer or milder adverse effects, or are easier to use than existing therapies used for the same condition, although not all commercial innovations have the same therapeutic value. Specifically, the degree to which a product improves health outcomes is considered a core criterion in many European countries coupling with the need to take into account cost-effectiveness or budget impact.

In the U.S., third-party entities such as the Institute for Clinical and Economic Review (ICER) are playing an increasingly prominent, and controversial, role in such discussions of value-based pricing. ICER has been active in assessing a “value” of new-to-market therapies, and in analysing drugs that have had substantial price increases that, in the judgment of ICER, are unsupported by adequate evidence.<sup>3</sup> Recently, ICER indicated that it intends to evaluate the coverage policies of drugs across the largest commercial plan formularies (evaluated based on covered lives) to determine whether the plans are offering “fair” access to treatments.<sup>4</sup> As the scope of ICER's work expands, ICER's role has been controversial. ICER has been criticised for having an “arbitrary, nontransparent, non-peer-reviewed” analysis that, nonetheless, can adversely impact patient access to therapies.<sup>5</sup> Furthermore, ICER's use of the QALY framework in connection with analyses has drawn concerns that less effective, but cheaper, treatments will be prioritised over more effective therapies.<sup>6</sup>

We expect that questions of who is qualified to evaluate value, and based on what metrics, will continue to feature prominently in drug pricing discussions globally. Furthermore, we expect that this trend towards “value” and cost-effectiveness will intensify with the increasing emphasis on personalised or precision medicine, including in connection with advanced therapies such as gene-, cell- and tissue-engineered products, as well as those intended for treating debilitating and life-threatening conditions. The methodological approaches used to assess therapeutic benefits and health economics, and in turn to justify market access, will continue to be a key area of focus for drug developers.

#### Governments’ increasingly active role in scrutinising drug pricing

Second, governments are playing a more active role in questioning the drug pricing decisions of drug developers on anti-competitive and other grounds.

The European Commission and national competition authorities have shown a renewed interest in addressing excessive pricing issue in the last few years. Excessive prices refer to prices set significantly above competitive levels, which reflects the strong market power of a company. The Commission in 2017 opened an investigation into concerns that a pharmaceutical company engaged in excessive pricing in relation to life-saving cancer medicines and questions regarding whether the company abused a dominant market position in breach of EU competition law. In addition, a number of European countries have taken action nationally. In June 2018, the UK Competition Appeal Tribunal quashed the Competition and Markets Authority finding that an epilepsy drug was unfairly priced. The Tribunal judgment stresses that excessive pricing cases should remain rare and that the authorities should be wary of stepping in the shoes of price regulators, unless they do so on a sound basis, informed by proper evidence and analysis. The European Commission considers it necessary to review the system of incentives, improve the competition of generic and biosimilar medicines, and review the EU competition rules in the pharmaceutical sector as important factors to improve the access and affordability of medicines. Importantly, the European Commission notes that the lack of competition in the pharmaceutical market can hinder savings when innovative products lose their market exclusivity. The Commission will also continue to carefully review mergers between pharmaceutical companies to avoid distortion of competition.

In the U.S., political interest in addressing drug pricing and reimbursement has been high in the past few years, with bipartisan legislative and regulatory proposals accompanying Congressional inquiries into pricing practices. In 2014, several members of Congress sent letters to more than a dozen drug developers requesting information about the prices charged for generic drugs, with a particular emphasis on generic drugs subject to large price increases.<sup>7</sup> Over the past few years, several drug developers have been investigated by Congressional committees. Certain developers have been subject to subpoenas, requests for document productions, and Congressional hearings related to drug pricing and competitive practices.<sup>8</sup> Companies may confront financial, reputational, and other costs in responding to these government requests. It is worth noting that, historically, these were not costs that the industry had to bear. Beyond this, the U.S. Congress’ increasingly active role in scrutinising drug pricing reflects another emerging trend – that of the government potentially moving away from a “free market” approach to drug pricing and, instead, seeking to more actively regulate drug pricing decisions. This appears to be a converging trend across multiple jurisdictions.

#### Movement towards a global view of drug pricing

Finally, certain jurisdictions that have traditionally approached drug pricing as a domestic-only matter are adopting a more international view of drug pricing. The issue of price

interdependency between different countries represents a particularly acute challenge for the industry. Proposals to have the price in one country influence the prices in other countries are principally implemented through cross-border price referencing. Cross-border, or geographic, price referencing is a price-control mechanism whereby the health authority in one country references prices in a select group of other countries when determining the maximum price that it will pay for a medicine. This price control mechanism has been applied in many European countries. For example, the UK is among those countries that are most widely referenced by other countries in relation to pharmaceutical prices. Therefore, although the UK pharmaceutical market accounts for just over 3% of global sales, pharmaceutical prices in the UK likely impact on prices in various countries that reference their prices to the UK. Moreover, in 2019 at a global forum on fair pricing and access to medicines hosted by the World Health Organization, delegates from governments and civil society organisations called for greater transparency around the cost of research and development as well as the production of medicines to allow buyers to negotiate more affordable prices.

In the U.S., both political parties have now introduced drug pricing legal reforms that would establish drug reimbursement rates in government health programmes by reference to drug prices in select Organisation for Economic Co-operation and Development (OECD) countries. While no such proposal has yet been implemented – and attempts to implement such proposals have been met with fierce legal challenges<sup>9</sup> – it is increasingly common for U.S. policymakers to suggest that the U.S. should benchmark its own drug reimbursement rates off of prices in other countries – and OECD countries in particular. International reference pricing – which was anathema to many U.S. policymakers a matter of years ago – is now ever-present in political discourse and appears to be here-to-stay for the foreseeable future. This development reinforces the fact that approaches to drug pricing are important not only from a comparative and normative perspective, but also from a pragmatic perspective as foreign approaches to drug pricing may directly influence domestic drug reimbursement.

## Conclusion

Healthcare systems are undergoing significant transformation in the recent years. The practice of medicine has transitioned from largely empirical to more patient-specific treatment pathways. Recent scientific breakthroughs and technological advancements have improved our understanding of disease pathogenesis to enable differential diagnosis, leading to more precise, predictable and bespoke healthcare that is customised for the individual patient. Genetic, genomic, and epigenetic alterations appear to be contributing to different diseases. Thanks to these research efforts and increasing public-private collaborations, we now can enjoy more targeted and effective treatment and prevention of a wide range of conditions and diseases. These advances are important in modern healthcare, and equitable access to them has been considered by global coalition of NGOs and patient advocacy groups to be a fundamental human right. Fulfilling that right creates tremendous social value but demands a significant paradigm shift in health policy because of the inevitably high costs associated with providing more universal access to such healthcare innovations. This has become the new reality in managing limited resources in an increasingly cost-conscious healthcare ecosystem. As described above, global expenditure on pharmaceuticals has increased and will continue to do so.

Across the globe, legislators and regulators are signalling unprecedented interest in addressing pricing of medicines and medical technologies. Many have focused their attention on newly-launched products that are novel not only in terms of their clinical potential in challenging



therapeutic areas where there exists an unmet medical need, but also because of their price. There is a need to align the expectations of all those involved in R&D, public procurement, pricing and reimbursement, and health technology assessment to manage timely market access to innovations in a patient-centric manner. Ultimately, various stakeholders must seek to achieve a balanced approach that ensures that innovations are appropriately rewarded and also recognises that pricing needs to be calibrated according to local legal frameworks and healthcare environments – all in furtherance of the goal of offering equitable access to innovations.

\* \* \*

## Endnotes

1. <https://www.statista.com/statistics/280572/medicine-spending-worldwide/>.
2. The National Institute for Health and Care Excellence (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013.
3. See ICER, *Fair Pricing, Fair Access, Future Innovation, Ongoing Assessments and Unsupported Price Increases*, <https://icer.org>.
4. See ICER, *ICER Publishes Protocol for First Annual Assessment of Drug Coverage Policies That Present Barriers to Fair Access*, <https://icer.org/news-insights/press-releases/icer-publishes-protocol-for-first-annual-assessment-of-drug-coverage-policies-that-present-barriers-to-fair-access/>.
5. See Denise Rolland, *Obscure Model Puts a Price on Good Health – and Drives Down Drug Costs*, Wall Street Journal (Nov. 4, 2019), <https://www.wsj.com/articles/obscure-model-puts-a-price-on-good-health-and-drives-down-drug-costs-11572885123>.
6. R. Kirkdale *et al.*, *The Cost of a QALY*, QJM: An International Journal of Medicine (2010), <https://academic.oup.com/qjmed/article/103/9/715/1581299>.
7. Press Release, House Committee on Oversight and Reform, *Cummings and Sanders Investigate Staggering Price Increases for Generic Drugs* (Oct. 2, 2014), <https://oversight.house.gov/news/press-releases/cummings-and-sanders-investigate-staggering-price-increases-for-generic-drugs>.
8. See, e.g., Press Release, House Committee on Oversight and Reform, *Cummings Condemns Jordan's Effort to Obstruct Drug Pricing Investigation* (Apr. 17, 2019), <https://oversight.house.gov/news/press-releases/cummings-condemns-jordan-s-effort-to-obstruct-drug-pricing-investigation>; House Committee on Oversight and Reform, *Memorandum Re: Notice of Intent to Issue a Subpoena to AbbVie Inc.* (Sept. 1, 2020), <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/documents/2020-09-01%20AbbVie%20Subpoena%20Memo.pdf>.
9. See Joshua Cohen, *Court Injunction Temporarily Upends Most Favored Nation Policy To Lower Prices Of Medicare Part B Drugs*, Forbes (Jan. 2, 2021), <https://www.forbes.com/sites/joshuacohen/2021/01/02/court-injunction-temporarily-upends-most-favored-nation-policy-to-lower-prices-of-medicare-part-b-drugs/?sh=6f0e1f58505b>.





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