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Increasingly global approaches to pharmaceutical pricing and healthcare cost containment

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Background

Despite global disparities in healthcare delivery, each country aims to achieve the same common healthcare objective – to improve the health of their respective population and health outcomes while controlling healthcare costs. Identifying a sustainable equilibrium between incentivising therapeutic innovation and public health needs for innovation and affordability has been a recurrent challenge to the long-term sustainability of healthcare systems globally.

Breakthrough drugs continue to transform patients' lives and well-being. For example, there are nearly 230 distinct rare cancers. Despite the inherent challenges in addressing the diagnosis and treatment of rare cancers due to their low occurrence rates, significant progress has been made in addressing their differential diagnosis and treatment. New therapeutic options aimed at improving patient outcomes will significantly contribute to remission and overall survival benefit of cancer patients. However, development of such transformational treatment strategies comes with a cost.

The economic picture continues to feature increased use of life-saving medicines as well as a growing emphasis on costs. Across the globe, the use of medicines increased by nearly 14 per cent over the past five years, according to a recent global IQVIA study. Pharmaceuticals remain a key contributor to overall healthcare costs. A further 12 per cent increase in the global use of medicines is expected from 2024 through 2028. From 2024 to 2028, aggregate usage of medicines and related spending is poised to increase to approximately USD 2.3 trillion by 2028. Among the various therapeutic areas, oncology drugs are expected to comprise the largest component of aggregate expenditures, reaching nearly USD 440 billion in projected spending by 2028. Regarding geographic dispersion of spending, from 2024 to 2028, drug utilisation in Latin America and Asia is expected to grow faster than in other regions.

Following a similar trend, the size of the global medical device market was valued at USD 542.21 billion in 2024 and is projected to grow from USD 572.31 billion in 2025 to USD 886.68 billion by 2032, exhibiting a compound annual growth rate of 6.5 per cent during the forecast period. North America dominated the global market, with a share of 38.17 per cent in 2024. In 2024, among the various markets, *in vitro* diagnostics represent the largest segment, although the diabetes-care device, general and minimally invasive surgery, dental, ophthalmic and nephrology segments are expected to grow considerably between 2025 and 2032.

In the face of increasing lifespans and the rise of chronic diseases in later life, there is also a general shift from treatment to preventive care in the respective national healthcare systems. In the United States ("US"), President Donald J. Trump's "Make America Healthy Again" initiative focuses on preventive health and addressing chronic disease. The United Kingdom's ("UK") National Institute for Health and Care Excellence ("NICE") predicts that by 2035, two-thirds of adults over the age of 65 will have at least two health conditions, up from 54 per cent in 2015. Across jurisdictions, the burden of chronic diseases is escalating, and there is increased emphasis on addressing the underlying causes, instead of focusing exclusively on managing late-stage diseases.

Against a backdrop of an increasing range of novel medicines and medical technologies, policymakers and payors continue to focus on long-term financial sustainability – a challenge for low- and middle-income countries, as well as countries with developed healthcare systems. In the US, the second administration of President Trump places more emphasis on the global picture of pharmaceutical pricing, with US policy changes and ongoing, as-of-yet-unsettled tariff decisions having potential spill-over effects in global markets.

Europe, including the UK, also persistently face market access challenges to innovation in terms of breadth, speed, and cost, principally guided by an assessment of cost-effectiveness and affordability. Such an assessment may deny access or limit new medical technologies or interventions to smaller populations than that of the approved label claims, and the speed and uptake rate of new therapies could be slower because of the concerns of potential impact on the healthcare budget.

Across jurisdictions, countries continue to confront pressure on health system budgets, as well as a challenging macroeconomic environment, with ongoing, heated tariff discussions, high levels of inflation, and the increasing demands of an aging population. Payors also continue to consider means to limit costs and/or reimburse drugs and healthcare products. This has become a new feature in US government programmes through the advent of the Medicare drug price negotiation programme. Further, there is an enhanced focus on the global pricing differentials for medicines, as well as ongoing discussions of creating more parity across pricing in different jurisdictions. Lastly, governments have reinforced the focus on patients as the ultimate beneficiaries of pharmaceuticals and healthcare items and services, with a particular focus on the costs that consumers bear for pharmaceuticals. This development is giving way to new types of innovation – such as direct-to-patient commercialisation models – that attempt to influence patient out-of-pocket expenditures more directly – but such a policy may not be compatible with a single-payor social healthcare system commonly applied outside the US.

At an international level, the Organisation for Economic Co-operation and Development ("OECD") has considered four policy levers for financing more resilient health systems: increasing government health spending; increasing the allocation to health within the national budgets; reassessing the boundaries between public and private spending; and maximising efficiency gains in healthcare delivery. The Oslo Medicines Initiative similarly considered the urgent need to define more clearly the respective social and ethical responsibilities of the public and private sectors with respect to research on, development of, and affordable access to effective, novel, high-cost medicines. The World Health Organization ("WHO") is actively promoting a fairer pricing system for affordable medicines and health products to be accessed, especially in low- and middle-income countries.

We address these global themes below.

Within the US, an increasingly global lens on drug pricing, with renewed emphasis on patient cost experience

In the US, the federal government continues to take unprecedented steps to address the affordability of prescription drugs.

Under the Inflation Reduction Act ("IRA"), the Medicare programme directly "negotiates" with manufacturers to establish a so-called "maximum fair price" for certain top-spend Medicare drugs – a price that manufacturers will need to accept at risk of significant financial penalties or denial of reimbursement for their drugs under government payor programmes that are the bedrock of the drug coverage landscape in the US. The Medicare drug price negotiation programme targets single-source drugs and biologics that rank among the products with the highest overall Medicare spend, lack generic or biosimilar competition, and have had a minimum of seven or 11 years, respectively, since US Food and Drug Administration approval or licensure. The maximum fair price is capped at a statutory ceiling benchmarked, in part, with reference to US Department of Veterans Affairs prices; the maximum fair price is set through a process that takes into account, among other items, government-perceived cost-effectiveness, considerations of product value *vis-à-vis* therapeutic comparators, and various other subjective data from a wide range of sources. The IRA statute makes no reference to international prices as a benchmark for negotiated maximum fair prices.

In 2026, maximum fair prices will go into effect for the first round of 10 drugs. These 10 drugs include products indicated for diabetes, cancers and immunological conditions, the prevention and treatment of blood clots, and other conditions. The government-published negotiated prices for these drugs will represent a discount of 38 to 79 per cent as compared to the 2023 list price of each drug (recognising that the list price for these drugs does not take into account discounts or other price concessions in the market).

In January 2025, the Centers for Medicare & Medicaid Services ("CMS") announced a second set of 15 drugs that will be subject to maximum fair prices effective in 2027. Selected drugs in this second cohort span multiple therapeutic areas, including diabetes, weight loss, chronic obstructive pulmonary disease, oncology, and psychiatric conditions. The third cycle of drug negotiation will begin in 2026, with negotiated maximum fair prices taking effect in 2028. In this third cycle, Medicare Part B drugs will be included in the Medicare drug price negotiation programme for the first time, whereas in the first two cycles, only Medicare Part D drugs were included. Medicare Part B drugs are outpatient prescription drugs and biologicals typically administered in the outpatient setting by physicians or other healthcare providers, often representing some of the highest spend Medicare drugs.

While government price controls are not new to other jurisdictions across the world, many drug developers and other stakeholders in the US view the Medicare drug price negotiation programme as a significant encroachment on the principles of free market and "limited government" within the US pharmaceutical market. Several companies have abandoned research pursuits in response to the perceived encroachment and related economic harms, threatening the development of future therapies.

Further, numerous lawsuits have been filed, challenging the Medicare drug price negotiation programme on constitutional grounds and under the Administrative Procedure Act. Legal theories in ongoing litigation include unconstitutional taking of property, deprivation of property interests without providing due process of law, excess fines in violation of the Constitution and deprivation of protected speech interests under the First Amendment. While early rulings have been unfavourable for pharmaceutical manufacturers, these rulings have been based mostly on procedural or jurisdictional grounds, and appeals are ongoing. Substantive consideration of the merits of the underlying claims may be on the horizon. In September 2024, the US Court of Appeals for the Fifth Circuit ruled in *National Infusion Center Association v. Becerra* that the industry group plaintiffs had demonstrated sufficient injuries to bring their claims, clearing a major procedural hurdle. That case ultimately was remanded to the district court, and, as of summer 2025, briefing was ongoing to determine the merits of many of the original claims. Other litigation matters related to the lawfulness of the IRA continue to proceed through courts. While litigation is underway, and likely will continue – and be appealed – for years to come, the executive branch of the government continues to proceed with implementation of the Medicare drug price negotiation programme.

As CMS pushes forward with the drug price negotiation process, there simultaneously are signs that Congress may seek to amend the IRA, including to address concerns that the IRA stifles small-molecule

drug development by establishing a different, earlier selection window for small-molecule drugs as compared to biologics.

Holding aside the IRA, other significant recent developments in the US relate to the prospect of new, globally oriented drug-pricing approaches. In May 2025, President Trump issued an executive order calling for executive agencies and pharmaceutical manufacturers to take steps towards setting and delivering most-favoured-nation drug pricing to American patients. The stated purpose of the executive order was to stop American patients from paying higher prices for pharmaceutical products than patients in other countries. Specifically, the executive order directs the Secretary of the US Department of Health and Human Services ("HHS"), in coordination with the Assistant to the President for Domestic Policy, to develop "targets" for most-favoured-nation pricing and communicate such prices to pharmaceutical manufacturers. Subsequent to communication of these targets, pharmaceutical manufacturers are called on to demonstrate "significant progress" towards the most-favoured-nation pricing for American patients, or else, if they fail to make such significant process, face additional regulatory action, including potential rulemaking to impose most-favoured-nation pricing and actions related to drug importation and exportation. HHS later indicated in a press release that most-favoured-nation target prices will be the lowest price in an OECD country with a gross domestic product ("GDP") *per capita* of at least 60 per cent of the US GDP *per capita*. There is uncertain legal authority for HHS to pursue most-favoured-nation pricing under existing US laws. Additional developments in this space – and the prospect of litigation – seem likely as of the time of writing.

At the same time, states continue to look at drug affordability and impose barriers to patient access, including prior authorisation and step therapy. Some states also have mobilised prescription drug affordability boards that seek to impose limits on reimbursement of pharmaceuticals among defined payor segments. These boards have triggered litigation challenging the lawfulness of such state action, demonstrating that in the US, courts increasingly serve as an arbiter of how far the government can go in regulating drug pricing. Early results have yielded a procedural victory for at least one state board. In *Amgen Inc., et al. v. Mizner et al.*, the US District Court for the District of Colorado dismissed a complaint brought by Amgen, ruling that the manufacturer lacked standing because it was not directly regulated by Colorado law establishing Colorado's Prescription Drug Affordability Review Board ("PDAB") and because the manufacturer had not established a sufficiently concrete or imminent injury tied to a determination by the Colorado PDAB. The decision was appealed in April 2025, and future litigation is foreseeable.

State Medicaid programmes, which provide health coverage to individuals with low incomes and disabilities, among others, have used preferred drug lists and prior authorisation to narrow access, and, in some instances, have established reimbursement rates that functionally under-reimburse pharmacies and other providers that purchase drugs. These types of state activities raise concerns that low reimbursement rates can become tantamount to deprived access to drugs, as providers may refrain from purchasing or stocking key drugs.

Commercial payors also have responded to affordability challenges, pushing their own approaches to cost-effectiveness in pharmaceuticals. Within this market segment, supply chain stakeholders have adopted their own approaches to contain drug costs, including rigorous use of pharmacy and therapeutics committees and restricting access to specialty, often higher-cost, drugs.

Finally, the US has seen a general trend towards – and an emphasis on – delivering low costs to *patients*. For example, the May 2025 Trump executive order focuses on establishing most-favoured-nation pricing "to bring prices for American patients in line with [pricing in] comparably developed nations" and on facilitating direct-to-patient purchasing programmes, such that patients can purchase drug products at lower prices directly from pharmaceutical manufacturers. Before the executive order, several drug manufacturers had already started to embrace direct-to-consumer ("DTC") models, bypassing certain intermediary entities in the drug supply chain. While some market trends, such as the increased use of

DTC models, may align with government efforts to lower drug prices for patients, any US government policies and regulatory actions that seek to cause dramatic decreases in drug prices, and/or that destabilise the inherently global market for most pharmaceutical markets (*e.g.*, dramatically increased tariffs), may risk disrupting the delicate, longstanding efforts to incentivise pharmaceutical innovation and ensure patient access to drugs.

Continued challenges to pharmaceutical pricing and market access in Europe

In light of recent legislative and policy developments in the US on pharmaceutical pricing, industry leaders have called on the European Commission and Member States to ensure fast and broad patient access to innovative medicines. This is against a backdrop of the expressed concerns over waning European competitiveness in the sector, and the uncertainty of tariffs that may further reduce incentives to invest in the European Union ("EU"). Specifically, concerns have been expressed over European price controls and austerity measures. It was said that Europe's largest issue was failing to properly value and reward innovation.

Jurisprudence of pharmaceutical pricing

While in a different context, the economics of pharmaceutical pricing is aptly described by Advocate-General Jacob of the EU Court of Justice ("CJEU") in his Opinion in the *GlaxoSmithKline* case. The Opinion states that innovation is an important parameter of competition in the pharmaceutical sector. Substantial investment is typically required in the high-cost research and development of a new pharmaceutical product. Therefore, the decision of whether to invest in developing a new product will obviously depend in part upon whether the manufacturer expects to be able to make sufficient profits to recoup the cost of investment.

The European jurisprudence – derived from CJEU and national courts' decisions – on pharmaceutical pricing establishes that payors have broad discretionary power to control prices and market access, including such measures as price freezing and price reduction, as well as direct product substitution for a cheaper equivalent product to protect financial stability of public healthcare insurance schemes, provided such measures are based on proper reasoning. Moreover, payors are entitled to set both external and internal reference prices to control healthcare expenditures. Excessive drug pricing is also facing increased scrutiny from regulators due to concerns about affordability and access to essential medication based on a two-pronged approach: the difference between the costs incurred and the price charge is excessive; and that the price charged is either unfair in itself or in comparison with competing products.

The English Court of Appeal succinctly summarises the pricing challenges faced by the National Health Service, the single-payor healthcare system in the UK, in *R v Cambridge Health Authority ex parte B:* "*… in a perfect world any treatment which a patient, or a patient's family, sought would be provided if doctors were willing to give it, no matter how much it cost, particularly when a life was potentially at stake. It would however … be shutting one's eyes to the real world if the court were to proceed on the basis that we do live in such a world…*"

Policy framework on market and pricing

According to the WHO, countries in the WHO European Region have voiced concern over the escalating prices and budgetary impact of novel medicines, which have restricted patient access, increased inequities, and in some cases, resulted in financial hardship. Moreover, the demand for these specialised treatments is expected to grow as is the pressure being placed on health systems that are already struggling due to the continued economic strains and socioeconomic recovery from the COVID-19 pandemic.

Europe's position on pharmaceutical pricing is increasingly influenced by the ongoing discussions held at an international level within the WHO, particularly in relation to the need for a fairer pricing system. The concept of fair pricing seeks to strike a balance between the public health needs for innovation and affordability. However, there is no agreement on what constitutes fair pricing.

Traditionally, economic evaluations – which are relied upon during pricing negotiations – constitute an important component of health technology assessment ("HTA") processes. Such evaluations involve a comparison of incremental cost-effectiveness ratio with cost-effectiveness threshold relevant to a health system. The threshold for determining market access should reflect the willingness to pay and the health opportunity cost of reimbursing a health technology within a budget-constrained healthcare system. If the threshold is too low, it would not be commercially viable for manufacturers to supply at a profit – and that will disincentivise investment in developing new therapeutic approaches. For example, in late 2024, NICE clarified that the quality-adjusted life years threshold for determining whether a new health technology represents good value for money was misunderstood as meaning that the National Health Service could not spend more than £20,000–£30,000 per patient per year. It considered that a medicine's yearly treatment costs can be much higher than £30,000 per person and still be considered cost-effective. It emphasised the focus on making regulatory decisions that balance innovation with financial sustainability to deliver the best patient outcomes.

The WHO postulates that the health economic model for fair pricing encapsulates six key parameters: minimum sustainable profit margin; distribution costs; research and development costs; average cost of production; marginal cost of production; and the pricing ceiling (meaning the maximum affordable price) that could be tolerated by a particular health system. The model also requires transparency as a key determinant for what is fair. Governments who are signatories to the World Health Assembly agreed in 2019 to move towards improving the transparency of markets for health products. The resolution aims to enhance public sharing of information on actual prices paid by governments and other buyers for health products, and greater transparency on pharmaceutical patents, clinical trial results, and other factors that are determinative of pharmaceutical pricing. This policy was strongly advocated by such European countries as Italy and the Netherlands, as well as Singapore and Japan in the Asia-Pacific region.

The notion of fair pricing to ensure timely patient access to innovation has also been the subject of extensive discussions within the European Council (the "Council") – consisting of the relevant heads of the EU Member States – over the last decade.

Under the Italian Presidency in 2014, the Council adopted its conclusions on innovation for the benefit of patients. This policy document has laid the foundation for the concerted efforts to be taken at a European level to consolidate early dialogue and scientific advice, new pricing, and reimbursement models through implementation of a "joined up" approach to the HTA process to determine the therapeutic value of a new technology based on cost-effectiveness assessment. Greater emphasis was placed on supporting a framework to facilitate information exchange among Member States on prices, pricing policies, and economic factors that have a bearing on availability of innovative technologies. The agreed policy also emphasised the need to support collaboration among the national authorities, HTA bodies, and the European Medicines Agency throughout the entire product life-cycle to improve availability and accessibility of innovative products to patients.

The Dutch Presidency in 2016 attempted to reconcile the reward for innovation and assurance of affordability. The agreed position was adopted by the Council in July 2016, recognising that the pharmaceutical systems in the EU involving an authorisation process to promote innovation on one hand, and the national approaches on pricing and reimbursement as well as HTA procedures on the other, may be imbalanced and may not always promote the best possible outcome for patients and society. The accord reached by the Council sought to strengthen the balance in the pharmaceutical systems in the EU and its Member States by setting out a number of aspirational goals through enhanced cooperation among Member States through the existing EU technical working bodies such as the Network of Competent Authorities on Pricing and Reimbursement, the Pharmaceutical Committee and the Expert Group on Safe and Timely Access to Medicines to Patients, and the European Medicines Agency. It also acknowledged the benefit of joint HTA and voluntary cooperation on information exchanges of price to facilitate joint price

negotiation. The new EU rules on HTA meet the policy objective of harmonising the clinical evidentiary standard through a collaborative framework of "Joint Clinical Assessment" ("JCA"). The JCA involves an assessment of relative clinical effectiveness and safety against one or more other health technologies or existing health procedures, representative of the standard of care. It remains to be seen as to whether the JCA process will improve accessibility.

In parallel, the European Parliament has also adopted a number of resolutions that actively address the procurement and pricing of medicines and healthcare products. Key areas of focus include security of supply, affordability based on justifiable or fair pricing, and fostering innovation, particularly for disease areas where there exist unmet medical needs. Consistent with the Council's position, the European Parliament has consistently considered the need to encourage the use of JCAs to inform a view of therapeutic value, joint price negotiations as a vehicle to manage pricing such as those already carried out under the BeNeLuxA initiative and the Valleta Declaration.

The BeNeLuxA initiative involves Belgium, the Netherlands, Luxembourg, Austria, and Ireland. This collaboration initiative was established to address the imbalances in the pharmaceutical market, to some extent, by the limitations of national policies on pricing, reimbursement, and on the use of pharmaceuticals. It aims at making a long-term contribution towards sustainable access to, and appropriate use of, medicines in these participating EU Member States through, among others, a shared approach to horizon scanning of new products, mutual recognition of HTA, and increased transparency on pricing among the collaborating countries.

The Valleta Declaration sets out good practice in medicines procurement and negotiation to improve access to effective treatment and support sustainability of healthcare systems. Moreover, increased transparency has been advocated, especially regarding pricing components, reimbursement criteria, and the actual or net prices agreed in different Member States.

Additionally, the European Parliament considered in 2023 the benefit of advance purchase agreements ("APAs") as market access mechanisms to facilitate adoption of innovative medicines and technologies. APAs essentially pledge to purchase a predetermined quantity of a product at a predetermined price, and they represent a form of "pull incentives" where a company receives payment only upon successful product development meeting the pre-defined criteria in an APA. The European Parliament explained that APAs seek to reduce uncertainty for industry due to demand variability.

The EU's proposed legislative proposal to revise its pharmaceutical legislation – which has received the first reading by the European Parliament and consideration by the Council – also aims to achieve the overarching objective of improving patient access to affordable medicines, boosting Europe's competitiveness to support innovation. On 2 July 2025, the European Commission published its European strategy for life sciences (COM (2025) 525 final), hailing it as the blueprint to position the EU as the world's most attractive place for life sciences by 2030. And yet, improvement of accessibility to innovation is apparently absent in this key EU policy document.

Evolving landscape of pricing transparency

Pricing is determined by regulation, market transactions, or a combination of both. Both pricing mechanisms and regulation determine the government's ability to obtain (and consequently share) information on net prices or actual transaction prices.

Regulation may entail establishing list prices that are often publicly available and can serve as reference for future pricing decisions. However, the actual transaction or "net" prices that manufacturers receive for their medicines may differ. The "net" prices may only be known by parties directly involved in the transactions (when pricing is market-driven) or by parties engaged in contractual agreements since rebates and discounts offered by manufacturers are confidential, except the rebates that are imposed on a statutory basis. The common goal of disclosing net prices is to inform price negotiations, and

hence reliability and effectiveness of external reference pricing – the common goal of many pricing and reimbursement authorities.

In certain European countries, the maximum prices may be made public, but transaction prices are kept confidential. Transaction prices may be collected and known by competent authorities. Medicine prices resulting from market transactions through procurement agreements or tendering are most often not known outside the contractual parties to the transaction. Prices of medicines directly sold to hospitals may not be regulated but subject to tendering where prices are negotiated. In Germany and the Netherlands, health sick funds or health insurance funds can negotiate prices below the official list prices, especially for generics.

In many European countries, there is noticeable use of "managed entry agreements" with confidential prices for some new products (*e.g.*, France, Italy, the UK). The net prices are generally known by parties involved in the agreement and cannot be disclosed without the manufacturer's consent. The number of products with this type of agreements may vary widely. In certain countries, legal provisions are in place mandating the public disclosure of medicine prices – but the net prices may remain confidential. For example, the Icelandic Medicine Pricing and Reimbursement Committee publicly discloses online the discounted price reflecting the net price. Products that are subject to contractual confidentiality clauses are on-patent or single-source medicines, high unit-cost medicines, medicines for rare diseases, and high-cost advanced therapies.

At present, few countries are currently sharing net prices with other countries. There are, however, initiatives to promote greater transparency in drug pricing such as the European Integrated Price Information Database containing official prices of publicly reimbursed medicines and the Fair and Affordable Pricing Initiative focusing on developing methods and mechanisms for joint price negotiations and information exchange to enhance the efficiency of public reimbursement systems.

Pharmaceutical pricing programme challenges in China and Japan

In China and Japan, government drug price negotiation programmes have sought to keep drug prices low while simultaneously supporting innovation and access to high-quality medicines. For instance, China's National Healthcare Security Administration ("NHSA") recently proposed working with commercial insurers to increase patient access to innovative and beneficial medicines. The NHSA engages in several months of price negotiation with manufacturers before new drugs are added to the National Reimbursement Drug List ("NRDL") at a significant discount to patients. The NRDL currently contains two categories of reimbursable drugs: Category A, which includes lower-cost medicines that are fully covered by the state-backed Basic Medical Insurance ("BMI"); and Category B, which includes higher-cost medicines that are partially covered by BMI, with patients paying some portion out-of-pocket. The NHSA is planning to expand the list of covered medicines to add a Category C, which will include highly innovative medicines with considerable clinical value and significant benefits for patients. The government will also take measures to incentivise coverage of Category C medicines by commercial health insurers, with the goal of increasing patient access to affordable, innovative medicines.

However, regulatory reforms related to pharmaceutical pricing and market access have placed significant pressure on the Chinese medical insurance system. China's volume-based procurement system, in which the government bulk purchases medicines at low cost from suppliers, has saved the government billions but has also raised concerns that reduced prices may lead manufacturers to compromise on quality and ultimately result in shortages of essential and effective medicines.

In Japan, the Ministry of Health, Labour and Welfare sets the initial drug price that is reimbursed by the National Health Insurance following government negotiation. Periodic revisions to drug prices typically occur every two years based on a survey of market prices and almost always lower the reimbursable drug prices even further, though new innovative drugs are protected from regular price cuts for a period of time

through the Price Maintenance Premium programme. In order to address government spending, in fiscal year 2025 the government implemented an off-year price revision to align the market and reimbursement prices for certain drugs and discontinue some price premiums earlier than expected. The move has drawn criticism, as the off-year price cuts may create a more unstable environment for investment and ultimately exacerbate ongoing issues faced by Japan such as drug lag and drug loss.

Overall, the drug pricing systems in China and Japan shed light on the challenges faced by countries seeking to deliver lower drug prices to patients while maintaining access to innovative, quality medicines.

Conclusions

In an increasingly cost-conscious healthcare environment, payors – including those in developed economies – are actively managing costs by focusing on value-based care, optimising drug utilisation, and negotiating favourable pricing and reimbursement terms. They are deploying various health economic tools to help contain healthcare costs in response to growing expenditures due to new, high-cost, innovative medicines, and medical technologies, while also seeking to maintain or improve patient outcomes. The goal of balancing drug affordability, innovation, and accessibility is an aspirational one, requiring careful navigation of complex trade-offs. Payors and policymakers have recognised that the current path of growth in expenditures cannot be continued indefinitely, and that there is a need to identify new financially sustainable ways to fund innovative products and stay within the allocated health budgets. External reference pricing, also known as international reference pricing (or a mechanism where a country uses drug prices in other nations to inform or determine its own drug prices) has long been used by smaller countries to ensure they are not paying more for medications than other countries. Yet, as other, higher-income countries, including the US, more closely examine the potential use of international reference pricing to potentially control costs, their steps in this space carry risks – including the prospect of discouraging investment in innovation, leading to launch delays or differential market access across jurisdictions, and other forms of pricing or other disruptions that may have broader ramifications for public health and patient care.

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