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TABLE OF CONTENTS

Challenging global market access environment for pharmaceuticals and healthcare products – greater emphasis on affordability and cost-effectiveness

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Margaux Hall
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Introduction to contextual issues

The life sciences and healthcare sectors are entering a golden era of innovation that could positively impact the way health conditions are studied, diagnosed, managed and treated. This is the result of a greater understanding of disease pathophysiology at a molecular level and technological advances based on the convergence of physical, biological, material and computational sciences. Many breakthrough interventions for multiple diseases are reshaping patient care and disease management.

The industry sector will continue to respond to the evolving new world of promising scientific and technological breakthroughs, streamlined research and development, continued momentum in genomic revolution in advancing the development of bespoke therapies and increased use of digitalised technology to facilitate targeted communication. These novel therapeutic approaches necessitate greater concerted efforts to facilitate timely patient access to transformative innovations.

While the sector was consumed by the pandemic for more than three years, the World Health Organization ("WHO") declared in 2023 that a disease that is well established and ongoing would no longer fit the definition for a Public Health Emergency of International Concern – a formal declaration by WHO that designates a given disease as an extraordinary event that constitutes a public health risk to other states and potentially requires a coordinated international response. With the end of the global health emergency, government attention has refocused on broader macroeconomic healthcare trends, including the continuing growth in healthcare expenditures across various jurisdictions.

Across the globe, the use of medicines increased by nearly 15 per cent over the past five years, according to a recent global IQVIA study. Pharmaceuticals remain a key contributor to overall healthcare costs. Global spending on medicines grew by 35 per cent during this same time period. A further 12 per cent increase is expected through 2028, bringing annual use of medicines to an estimated 3.8 trillion defined daily doses – an internationally recognised measurement for drug consumption based on the assumed average maintenance

dose per day for a drug used, based on its main indication in adults. Over the next five years, 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 be the largest components of aggregate expenditures, reaching nearly USD 410 billion in projected spending by 2028. With regard to geographic dispersion of spending, there are areas of likely rapid growth, as well. Specifically, drug utilisation in Latin America and Asia is expected to grow faster than other regions in the next five years.

Following an essentially similar trend, the size of the global medical device market was valued at USD 518.46 billion in 2023 and is projected to grow from USD 542.21 billion in 2024 to USD 886.80 billion by 2032, exhibiting a compound annual growth rate ("CAGR") of 6.3 per cent during the forecast period. North America dominated the global market, with a share of 38.16 per cent in 2023. Among the various markets, cardiology devices represent the largest segment, and the market size for interventional cardiology devices is expected to be worth around USD 38 billion by 2032, up from USD 19 billion in 2023, growing at a CAGR of 8 per cent during the forecast period. These devices are designed to address various cardiac conditions, including coronary artery disease, valvular heart disease and structural heart abnormalities.

A number of factors have been identified as contributors to spending growth, including ever-changing demographics with an aging population, increased public demand and expectations and costs associated with delivery of medical interventions. By 2050, there will be 2 billion people around the world who are over 60 years of age. Longer lifespans, together with an increase in unhealthy lifestyles, have contributed to increased disease prevalence, particularly for chronic diseases. Not surprisingly, greater prevalence of chronic conditions increases spending because of the need to treat more cases on an ongoing basis. Many commentators have considered that the principal driver for burgeoning healthcare expenditures is attributable to advances in medical technology and their adoption across health systems. Despite their costs, some medical advances or technologies have been reported to improve the efficiency of care delivery by reducing procedure time, length of stay or number of hospitalisations, also increasing the capacity of hospitals to treat additional patients.

In the face of increasing lifespans and the rise of chronic diseases in later life, there also is a general shift from treatment to preventive care in the respective national healthcare systems. The UK's National Institute for Health and Care Research predicts that by 2035, nearly 69 per cent of those aged 65 will have at least two serious conditions or impairments, up from nearly 55 per cent in 2015. 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.

Novel transformative therapies for common and rare diseases continue to be developed to address diverse disease areas, e.g. neurology, oncology, hepatology, immunology, ophthalmology, musculoskeletal conditions and infectious diseases. For each of these disease areas, unmet medical needs persist in various strata of the population. Certain novel medical interventions have been developed with the aim of stopping or reversing the progression of diseases through genetically altering the affected cells or tissues to overcome genetic failures. In some cases, therapies have been found to have a curative effect after a single use, replacing the need for potentially costly, long-term chronic treatment.

Additionally, governments are dedicating more concerted efforts to anticipating emerging infectious diseases. Over the past 50 years, there has been an alarming increase in the

emergence of new infectious agents into the human populations, e.g. AIDS, Ebola, SARS, avian flu, Zika and COVID-19. Known parasites and bacterial and fungal pathogens are re-emerging due to significant changes to the ecosystem that may lead to the development of synergistic epidemics.

In view of the medical advances, policy-makers and payors are developing health policies that account for the long-term financial sustainability of a healthcare system. Persistent challenges around sustainable financing for health affect not only low- and middle-income countries, but also countries with developed healthcare systems.

The Organisation for Economic Co-operation and Development 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. In addition, health policy is also being developed to create headroom for innovation by freeing up resources through greater use of generic and biosimilar products after losses of exclusivity of the originator products in order to redirect savings to reward innovation.

Nonetheless, across jurisdictions, with growing pressure on health system budgets, there is a challenging economic climate, with competing priorities impacting the public funds available for health. High levels of inflation and the increasing demands of an aging population exacerbate the budgetary pressures. Payors are noticeably struggling to provide access to breakthrough or transformative interventions because they are considered unaffordable or not cost-effective against the allocated or otherwise constrained budget. Affordability concerns arise when a treatment has a high budget impact, and present particular challenges for decision-makers when the treatment offers what would normally be considered good value at the individual patient level. While a new treatment may be of greater value than cheaper treatments that offer smaller incremental health benefits, the health system still may be unable to fund the new treatment in either the short or longer term. In that regard, affordability concerns may outweigh strong value-based cases for individual therapies.

In addition, payors have looked at capping costs, such as by imposing firm limits on the prices they will pay or reimburse for drugs and healthcare products. They also have limited access to therapies that are perceived as lacking cost-effectiveness, either because their efficacy itself is still believed to be unproven, or because the established efficacy is not seen as justifying the price tag.

Promoting sustainable health financing demands reliable, accurate data that can be utilised to measure, compare and support decision-making. Health metrics are an important analytical tool to evaluate the impact of, and return on, investments in health.

New types of responses to these market access challenges, focusing on affordability and cost-effectiveness, are reverberating across jurisdictions. In this chapter, we explore these trends across three key jurisdictions – the European Union ("EU") and the United Kingdom ("UK"), the United States and China. Each jurisdiction has adopted its own set of laws to address affordability challenges, and yet common themes span jurisdictions.

European approaches to address affordability and cost-effectiveness

Market access of medicines and healthcare products is highly regulated in the EU and the UK. Even an innovative product is approved on grounds relating to safety, quality and

efficacy, and access is determined by health economic grounds according to the local law and policy as to whether the new product is affordable and/or cost-effective, based on an assessment of the price point and the relative clinical effectiveness of the new product against the standard of care.

Because each Member State is individually responsible for managing its own healthcare system, market access conditions and local pricing and reimbursement policies may vary considerably. Consequently, medicines and healthcare products may be accessible to patients in some Member States but not others. However, there is a general theme emerging despite the national variations – Member States evaluate new therapeutic methods on their value for money before deciding whether they should be reimbursed for them to be adopted for clinical use. It is noticeable that many innovative and transformative medical interventions are not accessed in certain Member States because their access has been perceived to have an adverse impact on health budgets. Significant rebates, discounts or price freezes have become recurrent health policy applied by national health systems seeking to contain healthcare expenditures. Most recently, the Court of Justice of the EU ruled in the context of the EU Transparency Directive that the requirement for macroeconomic analysis would not be required for a price freeze measure whose purpose was to control the prices of certain medicinal products on an individual basis. This is notwithstanding that a price freeze on all medicinal products or on certain categories of medicinal products statutorily triggers the need for a Member State to carry out such a review at least once a year to ascertain whether the macroeconomic conditions justify that the freeze be continued unchanged.

For the past seven years, the European legislature and the European Commission have been addressing ways to reduce barriers to access to innovation as a matter of priority. The European Parliament previously put forward a resolution offering 58 recommendations for improving access to medicines for the European Commission and the Member States. The resolution calls for such action as promoting competitive and fair pharmaceutical markets, directing innovation to therapeutic areas of unmet medical need, and improving coordination between Member States to align market access policies to provide equitable access to healthcare products across the EU. Particular focus is placed on improving affordable and sustained access to medicines. Moreover, there would be a need to develop a compulsory legislative framework for a health technology assessment to establish the relative effectiveness at an EU level. This policy objective is reflected in the Health Technology Assessment Regulation, which came into force in January 2022, focusing on an evaluation of the relative clinical effectiveness and relative clinical safety of a new health technology. There is also a general policy drive for increasing cooperation among the Member States as regards price-setting procedures.

The European Commission adopted a policy document entitled "Pharmaceutical Strategy for Europe" in November 2020. The published strategy is based on four key policy pillars: ensuring access to affordable medicines for patients and addressing unmet medical needs; competitiveness; innovation; and sustainability of the EU's pharmaceutical industry. In April 2023, the European Commission published a proposal to overhaul EU pharmaceutical legislation to implement the policy objective of ensuring that all patients across the EU have timely and equitable access to safe, effective and affordable medicines through primarily generic or biosimilar competition. This is achieved by reducing the regulatory exclusivity period. The legislative proposal received the first reading in the European Parliament in April 2024. As the draft legislation currently stands, an innovator can earn

an additional exclusivity period through generation of relative clinical effectiveness data through comparative clinical studies.

To ensure timely and affordable access to medicines, the EU legislature has also considered the need for parties responsible for procurement of medicines to base the assessment of tenders on reliable criteria. Intensified collaboration among Member States on price negotiations and procurement for COVID-19 countermeasures could serve as an important reference for stimulating discussion and initiatives that future actions can draw on to strengthen the negotiating power on pricing through joint procurement agreements. What is being postulated is to rely upon the most economically advantageous tender criterion as described in the EU Public Procurement Directive in medicine tenders to enable a sustainable and responsible supply of medicine. A Commission Notice adopted in 2021 considers the economically most advantageous tender as the only award criterion referenced in the directive, and a smart setting of such a criterion rewarding both quality and price represents important potential for innovation procurement. The definition of "most economically advantageous tender" has now been expanded so that the most economically advantageous tender is to be identified on the basis of price/cost using a cost-effectiveness approach, which may (but need not necessarily) include best price–quality ratio. For simple public contracts where price per unit is the only real factor that distinguishes one bid from another, it is still possible to use price alone to establish the most economically advantageous tender.

The cost-effective and rational use of medicines and healthcare products has become an essential component of managing the gaps between limited health resources and expanding health service demands within a national health system. Health economic assessment is routinely deployed in Europe to examine the technical performance, safety, cost-effectiveness, organisational implications, social consequences and legal and ethical considerations of introducing a new health technology or method modality. The main purpose is to inform policy decision-making in the adoption of cost-effective new technologies while preventing those technologies that are of doubtful value for the health system. Reasons why technologies might fail to secure reimbursement could be insufficient comparative effectiveness data and the shift of countries toward value-based models for reimbursement. A demonstration of added benefit or incremental benefit against therapeutic alternatives is a relevant consideration in advancing the therapeutic value of a new technology, which is an evidence-based assessment deduced from the available data. Therefore, one of the most important structural choices of such an assessment is the comparator because an inappropriate comparator may introduce biases on the outcomes and the recommendations of a health economic analysis. Ordinarily, such a comparative assessment would involve a standard of care. However, heterogeneity in the definition of a relevant comparator exists to inform such a cost-effectiveness assessment. Health technology authorities have relied upon authorised methods of treatment, off-label use or unlicensed methods of treatment as comparators. Most recently, the policy of the German Federal Joint Committee responsible for additional benefit assessment to require comparative assessment against off-label use products was challenged in the Federal Social Court, with the Court considering such a requirement for an approved therapy with a "solo status" unlawful. An "added therapeutic benefit" is conceptually similar to significant benefit provided in EU law. The German Court position is consistent with the proposition under EU law for significant benefit which is synonymous with clinical superiority according to recent European Court rulings for comparative treatment-related effects to be established against an authorised method of treatment.

In the UK, good value for money has been the mantra for adopting medicines and healthcare products for use in the National Health Service ("NHS"), the publicly funded healthcare system. To achieve efficient allocation of resources across the NHS, new cost-incurring drugs must provide good value for money relative to the benefits provided by other treatments across the NHS. In funding decisions, the NHS must consider the health lost as a result of the displacement of these existing interventions to fund new treatments, generally known as health opportunity cost. UK health economists engaged by the National Institute for Health and Care Excellence ("NICE") have considered that paying prices for new drugs that exceed the marginal cost-effectiveness of NHS treatments and therefore do not represent value for money results in a net reduction in population health. Due to restrictive health budgets allocated centrally, there is a disconnect between cost-effectiveness and whether the NHS budget can cover treatments that are considered cost-effective. This is exemplified by the 2014 decision that NHS England could not afford to fund a new drug for hepatitis C that was considered cost-effective by NICE. Despite the positive cost-effectiveness assessment, the NHS did not fulfil its statutory obligation to make funding available for treatments within the statutory period. To avoid a recurrence, in 2017, NICE introduced a budget impact test to manage access to high-cost drugs, with some success. As an increasing number of new, cost-effective drugs with high budget impact will continue to become available in the UK in the future, the budget-impact test will become critically important for drug reimbursement in the UK. That said, focusing narrowly on the budget impact of cost-effective new drugs may neglect the importance of their value to the health system. The Voluntary Scheme for Branded Medicines Pricing and Access (VPAS) sets a yearly cap on the total allowed sales value of branded medicines to the NHS each year, with sales above the cap paid back to the government as claw-back. The voluntary scheme is complementary to the statutory scheme, according to the official position, to control the spending on branded medicines. With the change of government in the UK after the general election on 4 July 2024, the new administration appears to recognise the need to implement a plan for procurement, adoption and diffusion of new technologies in the NHS by identifying which goods and services should be procured centrally at volume to secure the best value for the taxpayer.

Affordability and cost-effectiveness developments in the United States

In the United States, the federal government continues to take unprecedented and highly controversial steps to address the affordability of prescription drugs. In August 2022, President Joe Biden signed into law the Inflation Reduction Act ("IRA"), omnibus federal legislation that contains the most noteworthy healthcare provisions in more than a decade. The IRA includes, controversially, a "negotiated" price for drugs in the Medicare programme that provides health coverage to elderly persons, among other patient populations. Under the new drug-pricing regime, which will go into effect starting in 2026, the Medicare programme will directly "negotiate" 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 a bedrock of the coverage landscape in the United States. The Medicare price negotiation programme targets single-source drugs and biologics that rank among the products with the highest overall Medicare spend, that lack generic or biosimilar competition and that have had a minimum of seven or 11 years, respectively, since FDA approval or licensure. While 2026 is a few years away, the relevant government agency has staffed up and is working in earnest to negotiate the "maximum

fair price" of the first set of 10 drugs in the programme. That maximum fair price will be published by fall 2024. The amount is capped at a statutory ceiling that is benchmarked, in part, off the Department of Veterans Affairs prices. Based on guidance made available to date, the government intends to develop its maximum fair price through examination of cost-effectiveness, real-world evidence, considerations of value of a product *vis-à-vis* therapeutic comparators and various other subjective data from a wide range of sources.

While other jurisdictions across the world have long encountered government price controls, the advent of the IRA government drug-price negotiation programme has been unprecedented and highly controversial in the United States, with many drug developers and other stakeholders viewing this as a significant encroachment on the free market and the principle of "limited government" within the pharmaceutical market. Numerous lawsuits have been filed, challenging the IRA's drug price negotiation programme on several constitutional grounds and under the Administrative Procedure Act. Legal theories in the 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. Early rulings in the cases have been unfavourable for pharmaceutical manufacturers (often on procedural, and not substantive, grounds). However, the litigation is still underway, and the cases are likely to continue, and be appealed, for years to come. On a parallel track, the executive branch of government continues to proceed with implementation of the Medicare negotiation programme.

The IRA is not the only US government payor programme adopting a novel approach to drug affordability. State Medicaid programmes, which provide health coverage to individuals with low incomes and disabilities, among others, continue to grapple with the rising costs of drugs and constrained state budgets. States have responded, in part, by adopting different approaches to reimbursing pharmaceuticals, including evolving approaches to value-based arrangements. Such value-based arrangements have had particular appeal and traction in the context of state Medicaid programmes due, in part, to complex government price reporting dynamics in the United States. In other instances, states have used reimbursement tools to respond to affordability challenges. State Medicaid programmes generally are required to cover most outpatient drugs under federal law, but they retain certain flexibility over reimbursement rates. We therefore have seen instances of states establishing reimbursement rates that functionally under-reimburse pharmacies and other providers that acquire pharmaceuticals, leaving these providers underwater on their drug purchases. Such under-reimbursement can lead providers to no longer purchase or stock key pharmaceuticals, creating potentially significant patient access challenges. State activities in this regard have presented a lens into the possibility that very low reimbursement rates can arguably become tantamount to deprived access to pharmaceuticals.

States, too, have started to mobilise prescription drug affordability boards that will impose limits on reimbursement of pharmaceuticals among defined payor segments in the states. These boards, too, will undoubtedly result in litigation that challenges the lawfulness of such state action. In the United States, courts increasingly serve as an arbiter of how far the government can go in regulating drug pricing.

Apart from government payors, commercial payors have also responded to affordability challenges, pushing their own approaches to cost-effectiveness in pharmaceuticals. The commercial market segment remains dominant in the United States, as the majority of

Americans continue to access health coverage through their employer or that of a family member. The employer-sponsored insurance market has far less regulation than other market segments, allowing for "market-based" approaches to evolve to address drug costs. Within this market segment, we have seen supply chain stakeholders adopt their own approaches to contain drug costs, including rigorous use of pharmacy and therapeutics committees and restricting access to specialty, often higher-cost drugs. At the same time, key supply chain intermediaries in the United States themselves financially benefit from higher drug-list prices. As a result, where the "free market" reigns in the United States, we continue to see conflicting incentives around drug prices and cost control.

Drug-pricing developments in China

State-backed Basic Medical Insurance ("BMI") accounts for over 90 per cent of China's healthcare payments. In recent years, price negotiation through the National Reimbursable Drug List ("NRDL") has become one of the most effective methods that the Chinese government uses to contain drug procurement costs and expand BMI coverage. The NRDL is the main pathway for pharmaceutical reimbursement in China. Each year, the National Healthcare Security Administration ("NHSA") implements a negotiation process spanning several months for the inclusion of new and innovative drugs on the NRDL. There are several factors that tend to impact the price-setting of a drug listed on the NRDL, such as the actual market price, international reference prices, cost level of comparative drugs, budget constraints and pharmacoeconomic evaluations. Out of the 143 drugs participating in the 2023 negotiation and competitive bidding round, 121 were included in the final NRDL, representing an average price cut of 61.7 per cent, which was roughly on par with the 60.1 per cent drop in 2022. Once listed, supply prices on the NRDL are up for review every two years, and further price reductions are typically expected.

The NHSA has pushed for support of innovative drugs through several measures in the past year, including further amendments to the renegotiation process and the simple renewal process. The simple renewal process uses a clear algorithm that determines the price of renewal if no major market changes occur. If the proposed renewal price is not satisfactory, the company may opt for the full renegotiation for a potentially less steep price cut. In 2023, roughly 70 per cent of the 100 drugs up for renewal were renewed at their original prices. Thirty-one were given reduced prices because the drugs exceeded expected sales volume, with an average price cut of 6.7 per cent.

The NHSA has also been keen to set budget constraints for spending on healthcare services and pharmaceutical products administered at public hospitals as a method of indirectly containing drug costs. The agency released a three-year plan for the Diagnosis-Related Groups and Drug Intervention Package ("DRG/DIP Systems") payment reform in 2021, with the goal of establishing comprehensive coverage nationwide by the end of 2025. As of December 2023, over 90 per cent of the country's public sites have successfully adopted the new payment structure. The DRG/DIP Systems are designed to provide a standardised method for calculating reimbursement and payment rates based on the actual diagnosis and treatment of patients. The model uses complex algorithms and past fee information and data to predict how much it would cost to provide comprehensive services for a patient seeking treatment for a similar disease (the "DRG System"), or if the treatment requires similar types of drugs and medical intervention (the "DIP System"). The payment rates assigned through the DRG/DIP Systems reflect a variety of factors, including complexity of patients' conditions, length of hospital stay and the types of drugs, procedures and

treatments involved. However, certain innovative drugs and cutting-edge procedures that come with much steeper price tags fall under the "special case" category and do not count toward the standardised cost calculations.

China has pushed policies for rapid medical reform over recent years, causing global ripple effects and shifts in business focus for both domestic and multinational pharmaceutical companies. Profit margins in China have faced challenges under the current NRDL practice. Highly priced, non-domestic CAR-T, ADC and PD-1 products, for example, have had an extremely difficult time trying to obtain inclusion on the NRDL. It will be crucial for pharmaceutical companies to stay well informed and prepared for upcoming policies, and to adjust business strategies as the Chinese medical reimbursement systems mature and stabilise.

Conclusion

Countries across the globe are struggling to strike a right balance of embracing innovation and ensuring affordable access to transformative costly medicines and medical technologies. In a world of growing pressure on healthcare budgets, there is increased scrutiny of new health technologies and their effectiveness, safety and cost. It is in this context that health economic assessment has been recognised as an important tool to guide decision-making. The purpose of such an assessment, principally based on cost-effectiveness or added value, is to provide decision-makers with the necessary evidence to decide whether to adopt a new health technology in a healthcare system. Such a health economic assessment is regarded as bridging the gap between research evidence and health policy. Budget-impact assessment is now recognised as an integral part of evaluating whether a healthcare system can afford to pay for new treatment that is considered to have a high budget impact. Governments and other payors may ultimately conclude that a new technology is absolutely unaffordable (notwithstanding the fact that it is truly transformative) because its cost exceeds all available current and realistic potential future resourcing. Many innovative or otherwise breakthrough treatments have been shown to offer good value by most standard health economic methodological approaches but have led to major challenges for affordability at price points being sought by manufacturers in a number of national healthcare systems. As a result, we expect to see increased focus not only on value on cost-effectiveness grounds, but ultimately and foundationally, also on overall affordability. We anticipate that this dual-pronged analysis will become the new phenomenon for determining market access.

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