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Continued global pressure on drug pricing and reimbursement for effective market access: A hard pill to swallow?

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Introduction

We are now into the third year of the COVID-19 pandemic, which has brought about a global upheaval with particularly dramatic and enduring changes for the life sciences and healthcare sectors. New Omicron subvariants are creating new concerns in many countries that may call for new bivalent vaccines and antiviral agents to be developed with ambitious timetables for approval and access. COVID-19 will become a critical inflection point for drug pricing and reimbursement. The pandemic has brought about significant changes to the business and legislative environments for drug pricing, and it will continue to do so in ways that will alter the pharmaceutical supply chain and patient access to innovative, cutting-edge preventive and therapeutic drugs and biologicals.

Pricing and patient access to affordable drugs have been the subject of international attention. The World Health Organization ("**WHO**") and World Bank reported in 2017 that: at least half the world's population lacks access to essential health services, including access to drug treatments; some 800 million people spend more than 10% of their household budget on healthcare; and almost 100 million people are pushed into extreme poverty each year because of out-of-pocket health expenses.[1] Since the publication of these data, the world has been struck by not only the COVID-19 pandemic, but also exorbitant fuel prices and now a cost-of-living crisis, all of which bring about additional challenges to treatment access.

A significant portion of healthcare costs is spent on drugs. In 2021, IQVIA published a report that found that total drug spend in 11 major international markets[2] averaged 15% of total healthcare costs, with countries' individual spend rates ranging from 9–20% of those countries' total healthcare costs.[3] As the list price of new drugs continues to increase, it is likely that, in the coming years, the total spend on drugs will account for an even greater percentage of the healthcare costs. Multi-faceted reasons have been reported for the continued increase in drug prices, including, for example, inflation, costs of sourcing high-quality materials, and the high costs to develop and produce targeted drugs. In light of the widely held perception that drug prices are already too high, this trend will become an increasingly hard pill to swallow for cash-strapped public health services with finite resources, especially those countries with a single payer system.

In the years preceding the pandemic, there was protracted and heated debate about drug pricing across the full political spectrum and various jurisdictions. In response, legislators and policymakers in various jurisdictions introduced new frameworks to regulate drug pricing and reimbursement. In the United States ("**U.S.**"), legislators and regulators contemplated direct government negotiation of drug prices for federal healthcare programmes, and the potential use of international reference prices as benchmarks for

government reimbursement rates. States introduced drug affordability review boards and discussed capping state reimbursement of drugs. The pharmaceutical industry and other stakeholders decried such attempts at regulation as contrary to the free market principles that undergird the U.S. pharmaceutical market, and to research and development ("**R&D**") and innovation.

It may have felt to some pharmaceutical industry players that these arguments fell on deaf ears, as political and legislative clamouring for further price controls and austerity measures continued. This was further exacerbated by the public health emergency brought about by the COVID-19 pandemic, which drew further attention to the need for cost-effective preventative agents and drugs for all. That need has endured, as has the need to continue to promote innovation to respond efficiently and effectively to new viral variants as well as other emerging infectious diseases. Globally, more than two years since the start of the pandemic, work continues to develop and disseminate preventive agents and drugs. At the same time, the COVID-19 pandemic has resulted in tremendous government outlays of funds for vaccines and drugs – a trend that has reinforced the importance of ensuring appropriate reimbursement and use of public funds.

The dual needs for incentivising pharmaceutical innovation, and safeguarding the use of government funds, will continue and will remain somewhat in tension. Now that the acute phase of the COVID-19 pandemic appears to be over, there are many other important legislative and policy questions that will continue to challenge the global pricing and reimbursement landscape that will bear on the timely access to innovation: the impact of changing demographics on public spending; the health economics underpinning the decisions on effective market access; and the competitiveness of innovation in certain therapeutic areas where there remains an unmet need.

Against the ever-changing external environment, governments, policymakers and payers across the globe are increasingly committed to containing drug prices. In this ever-evolving landscape, existing cost-containment measures have been given more bite, and new measures have been developed on health economic grounds. This chapter points to several global trends observed to date, and signals what may come in the future. We explore certain legislative, regulatory, and business and innovation trends at the global level, and how they might impact those operating in the industry: from measures aimed at increasing the transparency of drug pricing; to the increasing use of real-world evidence ("**RWE**") in health technology assessment ("**HTA**") procedures; and new approaches to international drug pricing.

Greater government influence in drug development, approval, and procurement

The implementation of state healthcare systems in many countries, such as those in Europe, created a much more stable market, both for the prescription of drugs and, much more importantly, their reimbursement. Market stability produced a major incentive for further commercial investment in R&D and manufacture. This greater role for the state was paralleled on both sides of the Atlantic, with increasing government regulation of medicine production. During the acute phase of the COVID-19 pandemic, we saw unprecedented levels of government involvement in pharmaceutical R&D and procurement. In the U.S., in May 2020, the Department of Health and Human Services initiated "Operation Warp Speed", a collaborative effort involving multiple federal agencies, with funding provided through the Biomedical Advanced Research and Development Authority. The U.S. government provided more than $19 billion in Operation Warp Speed assistance to manufacturers to

develop or produce a vaccine or treatment for COVID-19. Once COVID-19 vaccines were available, the U.S. government funded their procurement, bypassing the traditional pharmaceutical supply chain as part of a broader policy effort to ensure swift access to vaccines. In March 2022, the Biden administration requested an additional $22.5 billion in COVID-19 response funding, largely to support additional investments in the development, manufacturing, and procurement of COVID-19 vaccines and drugs.

This level of direct government investment in R&D, and direct procurement, of drugs and biologicals is unprecedented in the U.S. Some have pointed to the importance of the government playing a formative role in supporting the development of vaccines and drugs, given that the private market may underinvest in such social goods. The government's enhanced role raises interesting policy and legal questions related to drug pricing – including, what are the government's pricing and other legal rights with regard to innovations the government helps pay to develop? And what level of transparency should the government and private citizens have into the pricing of drugs, and the costs of their R&D?

Transparency in drug pricing

In recent years, there has been a concerted global effort by regulators and lawmakers to promote greater transparency in drug pricing as a means to bring down drug prices, prevent drug price differentials between jurisdictions, and promote competition. Legislators in various jurisdictions continue to explore different approaches to mandating the disclosure of drug prices at all levels of the pharmaceutical supply chain.

In the U.S., legislators and regulators have broadly demanded increased transparency around health plan-negotiated rates for items and services, with broad disclosure requirements imposed on plans through regulation. Those transparency requirements have aimed to empower consumers to make choices about where to seek care. Researchers have emphasised the utility of empowering patients to select their provider based on transparent price metrics. Notably, analogous drug price-specific disclosures were imposed on certain health plans through the Transparency in Coverage rulemaking, but ultimately were not implemented or enforced. Stakeholders – the Pharmacy Benefit Manager Trade Association, the Pharmaceutical Care Management Association, and the Chamber of Commerce – challenged the government's authority to impose such drug price disclosure requirements on procedural and substantive grounds. Ultimately, government agencies stated that they would decline to enforce the requirement that health plans disclose negotiated drug pricing information pending further notice-and-comment rulemaking. It is unclear whether or when such rulemaking will take place.

At the same time, legislators and regulators have imposed other transparency and disclosure requirements with regard to drug pricing. For instance, under the Consolidated Appropriations Act of 2021, entities that contract with group health plans in connection with the drug benefit must disclose their direct and indirect compensation to group health plans. The Affordable Care Act and some more recent federal statutes have imposed broader-based disclosure requirements related to drug prices. These statutes typically mandate disclosure at the aggregate level, such as across a plan-year or for aggregate rebates, rather than rebates or discounts that may be available on a drug- or claim-specific basis.

States in the U.S., in turn, have required manufacturers to report pricing information in connection with the launch of new drugs with prices over specified thresholds, or when manufacturers take price increases that exceed specified amounts. Most of those disclosures, too, are at the aggregate level. The upshot is a universe in which pharmaceutical

manufacturers and others in the pharmaceutical supply chain must increasingly disclose pricing-related information to many different regulators but, for the most part, drug-specific net prices remain confidential and proprietary, and sheltered from legally mandated disclosure. There are important differences between drug prices and prices of other healthcare items and services that may merit distinct treatment under U.S. laws and regulations. For instance, a patient prescribed a single-source, patented drug cannot shop for a therapeutic equivalent product, as she could shop for a primary care provider. In general, it remains to be seen whether drug price disclosures will remain at the aggregate level – and, therefore, whether mandated drug price disclosures remain categorically different from disclosures for other items and services.

The political push towards net price transparency does not end at the border of the U.S. Over the years, numerous attempts have been made by regulators to increase the transparency of how drug prices are set. For example, during the late '80s, the European Union ("**EU**") adopted Directive 89/105/EEC on the transparency of measures regulating the prices of medicines for human use and their inclusion in the scope of national health insurance systems, which, in essence, sought to provide transparency of the decision-making processes used by the national competent authorities of the various EU Member States. In 2020, the WHO European Region published the Oslo Medicines Initiative, which outlines an approach between governments and industry to provide equitable access to drugs across the EU. At the same time, according to a survey published by the European Integrated Price Information Database, 22 EU Member States reported the use of confidential discounts. That survey led some EU Member States to request manufacturers to provide price information across EU countries and to report negotiated discounts.

Pharmaceutical companies have long claimed that high drug prices are required in order to cover R&D spend. However, in 2018, a report published by the WHO concluded that "*the costs of R&D and production may bear little or no relationship to how pharmaceutical companies set prices of cancer medicines. Pharmaceutical companies set prices according to their commercial goals, with a focus on extracting the maximum amount that a buyer is willing to pay for a medicine*".[4] Unsurprisingly, policymakers have set their sights on understanding R&D spend and how that translates to the price asked by developers for a drug.

In February 2019, Italy submitted a draft resolution to the World Health Assembly ("**WHA**") of the WHO, which called for WHO member states to legislate for greater transparency into various components of the biomedical innovation system, including R&D cost data. Specifically, Italy urged[5] WHO member states to "*[r]equire as a condition of registration for drugs and vaccines annual reports on (a) Sales revenues, prices and quantities, (b) Outlays on marketing, (c) R&D costs, including enrolment and outlays on each clinical trial separately, and (d) Grants, tax credits or any other public sector subsidies and incentives relating to the development of the product*". Italy also called on the WHO Director-General to "*[c]ollect and analyse data on health technologies of public health importance, including but not limited to: (e) Actual Costs of R&D on specific drugs and vaccines, including the enrollment and costs of individual clinical trials, (f) Actual manufacturing costs of specific drugs, vaccines and health technologies, (g) Manufacturing know-how, and (h) The landscape of patents, including information about disputes about the validity and/or relevant of asserted patents*".

Despite a majority of WHO member states supporting Italy's resolution, it was not approved by the WHO in its original form due to pressure from certain countries including Canada,[6] the United Kingdom,[7] Germany and Hungary. A pared-back version of the resolution, WHA

72.8,[8] was passed by the WHO in May 2019, which simply encouraged, but did not require, WHO member states to "*take the necessary steps, as appropriate, to support dissemination and enhanced availability of, and access to, aggregated results data and, if already publicly available or voluntarily provided, costs from human subject clinical trials regardless of outcomes or whether the results will support an application for marketing approval, while ensuring patient*". A handful of WHO member states have taken concrete steps in this direction. For example, the French parliament adopted an amendment to its applicable law, which requires companies to make available to the Economic Committee for Health Products the amount of public investment in R&D from which they have benefitted for the development of medicinal products.[9]

In light of the trend towards greater transparency in drug pricing, and a multitude of reporting requirements across jurisdictions, the time is ripe for a holistic global assessment of disclosures of drug prices and R&D costs surrounding the development of new, innovative drugs.

Real world evidence: a more holistic industry understanding of innovation and downstream market access

The healthcare delivery system has increasingly emphasised patient-centred care and value-based payment approaches. In recent years, the pharmaceutical industry has been asked to consider innovation and market access through a more holistic lens that spans the lifetime of a product. Manufacturers collect rigorous clinical trial data, through closely controlled studies, in advance and in support of regulatory approval. Pre-launch data collection often stands in stark contrast to post-launch data collection. Indeed, subsequent to regulatory approval, there generally are limited coordinated efforts around data collection and aggregation. This is the case notwithstanding the fact that there will likely be voluminous data to be collected to define the therapeutic position and safety of a new product in a broader population.

In the majority of jurisdictions, before an approved drug can be commercialised, it must undergo an HTA to inform and guide the conditions for market access to a new drug. An HTA is an evidence-based process that allows national competent authorities to determine the relative clinical and cost effectiveness of a new or existing health technology. HTAs focus specifically on the added value of a new health technology in comparison with other new or existing health technologies. Historically, the clinical effectiveness assessment of HTAs has been based solely on evidence generated from clinical trials, with randomised controlled trials ("**RCTs**") being regarded as the most robust and reliable trials.

Indeed, RCTs have long been, and still are, the gold standard of evidence to support regulatory approvals and HTA assessments. RCTs are prospective studies that measure the effectiveness of a new intervention against a control group in a highly selective population and in tightly controlled settings. These types of studies generate robust datasets to establish treatment-related outcomes due to the minimisation of the effect of bias. However, a disadvantage of RCTs is that participants may fail to reflect the actual clinical setting in which the product is to be used in the real world, given the clear set of inclusion or exclusion criteria. This, in turn, can make it challenging to extrapolate the results of an RCT to diversified situations that exist in the real world.

In recent years, there has been significant interest in filling the gaps left by RCTs with data generated from alternative diversified sources. RWE has been favoured as an alternative data source as it describes, in broad terms, data generated in real-time from a whole range of different sources, including electronic health records, patient registries and patient-generated data, all of which have benefitted from the exponential rise in the use of mobile

devices, wearables, and other biosensors. With the advent of AI and machine learning, the datasets that these sources generate can be subject to sophisticated analysis to understand more about the drug utilisation in the real world. The main advantages of RWE include the better representation of routine clinical practice, lower costs and longer time of observation, thus optimising the collection of specifically defined events of interest.

However, the use of RWE as a means to assess clinical effectiveness of an investigational drug does pose certain methodological challenges. Relative to RCT, trialists have generally assigned RWE lower credibility because of the risk of bias, and whilst certain statistical analyses could help minimise the effect of confounders, the generalisability of RWE can be difficult to achieve.

Additionally, by gathering RWE from a whole range of different sources, it can be difficult to organise the information into a dataset from which reliable conclusions can be drawn. That said, the most valuable aspect of RWE is also its biggest drawback: by generating data from uncontrolled environments, the impact of unaccounted-for variables can make the accurate interpretation of these datasets difficult.

Furthermore, while payors may assemble their own datasets that are used to inform coverage and reimbursement decisions, there are no industry-standard templates or structures for the collection and sharing of such data. As a result, data generally ends up being payor- or stakeholder-specific. The failure to collect and meaningfully (as well as lawfully) exchange data may come at the expense of future progress, as such data likely contains relevant information to elucidate further the clinical effectiveness and other information (especially those that are patient-specific outcome measures) based on real-world experience. There is increasing desire, among payors and others, to have a single, compatible dataset that can inform cost-effectiveness assessments and, in turn, coverage and reimbursement decisions. It is also worth noting that there is large variation between jurisdictions in their digital health capabilities and the acceptability of RWE for assessment purposes.

In light of the increasing interest in, and prevalence of, RWE, HTA bodies are grappling with how it can be utilised in the HTA processes. For example, in its "Conclusions on Access to medicines and medical devices for a Stronger and Resilient EU",[10] the EU Council invited Member States and the Commission to explore the possibility of establishing an RWE data collection and evidence-generation action plan, to promote better collaboration between ongoing national and cross-border initiatives. This could contribute to reducing evidence gaps in HTA and payer decisions. The U.S. mostly relies on privately funded HTA and, historically, has had limited use of RWE in drug value assessments. However, there has been growing enthusiasm regarding incorporating RWE into the HTA process, with the U.S. Food and Drug Administration releasing 2018 guidance regarding how pharmaceutical manufacturers may communicate health economic information to payors and formulary committees.

Placing too much reliance on RWE data may lead to issues in jurisdictions where it is not so readily accepted, especially in the context of regional variations in clinical practice to render the data not sufficiently generalisable. However, at a practical level, RWE and RCT should be considered mutually complementary in establishing the therapeutic value of a new product. Manufacturers are likely to be asked to participate in, and respond to the results of, RWE collection. This may require industry participants to accept that the collection and dissemination of RWE will lead, differentially, to winners and losers. Certain drugs may outperform their clinical trial results; others may underperform. On the whole, collecting and sharing such information – with the differential consequences – may need to be viewed as a price of scientific progress.

An international approach to drug pricing

As demonstrated during the acute phase of the COVID-19 pandemic, a drug's price can vary significantly across different jurisdictions. These pricing differentials can have a knock-on effect on the drug's availability in less lucrative geographies in that, for commercial reasons, developers may favour sales to more profitable countries. On the flip side, jurisdictions where drug prices are generally high, such as the U.S., often feel like the high prices they pay for drugs are funding supply to middle-low income countries.

Many jurisdictions across the globe, particularly in Europe, employ a system known as international reference pricing ("**IRP**") as a way to harmonise and contain drug prices. IRP is a mechanism whereby a government considers the price of a medicine in other jurisdictions to inform or establish the price in its own jurisdiction.

IRP is not without issues. For example, prices used in different markets may not be comparable due to geographical differences in the burden of disease, approved indications, uptake, financial resources, and in the components included in pricing formulae, e.g. distributor margins, sales taxes, etc. Foreign prices also may not take into account the different legislative and enabling environments for innovation – with jurisdictions such as the U.S. having broad-based intellectual property and other laws that help promote innovation. Furthermore, IRP has the potential to push prices up in middle-low income jurisdictions, which may undermine efforts being made towards universal health coverage.

Despite these well-documented issues, in recent years we have seen a trend towards certain jurisdictions with historically higher drug prices, such as the U.S., requiring disclosure of the prices for the same drug in different jurisdictions. Regulators hope that such requirements will expose unjustified price differentials. Beyond this, in recent years, legislators and regulators in the U.S. have advanced – but not yet implemented – proposals that would establish reimbursement rates for federal healthcare programmes based on IRP benchmarks. IRP-based reimbusement would be unprecedented in the U.S., where the free market has largely determined drug pricing.

Government intervention in drug prices and market access is not new to many countries outside the U.S. where it is largely based on a single payer to fund the national health systems. Such national interventions include direct regulation of drug prices, control of reimbursement or profits, control of prescribing and dispensing behaviours as well as control of access to new technologies based on a health economic assessment to determine whether a new drug provides value for money relative to an existing comparator or standard of care.

As indicated above, many European jurisdictions already employ IRP as a method for containing drug prices, and related efforts are now being made to collaborate and pool resources for the conduct of HTAs. Following the publication of the European Commission's proposal for a regulation on cooperation on HTAs in 2018,[11] the EU has recently passed Regulation (EU) 2021/2282 on HTAs[12] (the "**HTA Regulation**"). Pursuant to the HTA Regulation, and subject to the expiry of certain transition periods and the satisfaction of certain conditions, the clinical assessment element of the HTA process will be conducted by one of the EU Member States' HTA authorities, the outcome of which all other HTA authorities must give "*due consideration*". The HTA authorities of individual EU Member States will continue to carry out the non-clinical elements of the assessments (for example, the economic, social and ethical considerations) but the duplication of clinical assessment will be dramatically reduced. Although the joint HTA submission will not come into application until 2025, pharmaceutical companies seeking to launch drugs in the next three years should evaluate their evidence-generation strategy to substantiate a pricing position that has broader implications than currently planned.

A trend of international collaboration on HTA and associated regulatory oversight, which pre-dated the COVID-19 pandemic, has been reinforced by it. Whilst the aim of containing costs in traditionally more expensive markets is worthwhile, the secondary impact on middle-low income countries may make the attainment of universal health coverage even more challenging. This will be a difficult balance for regulators to strike, but one for developers to keep an eye on.

Conclusion

As we look to the future and a COVID-endemic world, much is uncertain but a few things seem predictable. The role of governments in the development and procurement of preventive agents and drugs is likely to increase, creating new government pricing pressures even in markets like the U.S. that have traditionally had sizeable private sector payor presence. Those pricing pressures will need to be balanced against the continuing desire to safeguard a conducive ecosystem that seeks to promote and incentivise medical advances and innovation.

Additionally, the knowledge-based economy surrounding drug development will continue to expand to usher in RWE in the time after product launch. Patient centricity will remain a key theme underlying legislative and regulatory proposals relating to drug pricing, with a closer focus on patients' experience accessing drugs, including cost-sharing and drug-utilisation controls. For instance, in the U.S., notwithstanding intense government scrutiny of drug prices, few legislative or regulatory proposals have focused on reducing patients' out-of-pocket costs. Decreases in patient cost-sharing may be a downstream side effect of proposals such as direct negotiation for drug pricing or imposing price caps; however, these proposals primarily focus on reducing payor costs. There are a few notable exceptions – legislative and regulatory proposals that would directly address patient cost-sharing liability, such as proposals around insulin pricing, Medicare Part D benefit redesign, and restructuring pharmacy price concessions in the Medicare Part D programme. However, by and large, legislative and regulatory proposals aimed at drug pricing reform have not focused on patients as consumers of healthcare or patients' out-of-pocket costs. Even value-based market access agreements – which offer payor refunds if a drug does not meet a pre-specified clinical or outcomes-based benchmark or criterion – typically do not refund or reimburse the cost-sharing if the drug fails to meet the benchmark.

Market access, often shaped by cost-effectiveness and affordability, may be the next critical area for innovation in order to ensure sustainability in healthcare provisions. Accordingly, addressing patient access challenges is the next frontier. Drug pricing legislative and regulatory proposals must grapple with patient cost-sharing and utilisation management barriers if they are to meaningfully ensure that patients can access next-generation, targeted or otherwise personalised drugs.

* * *

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