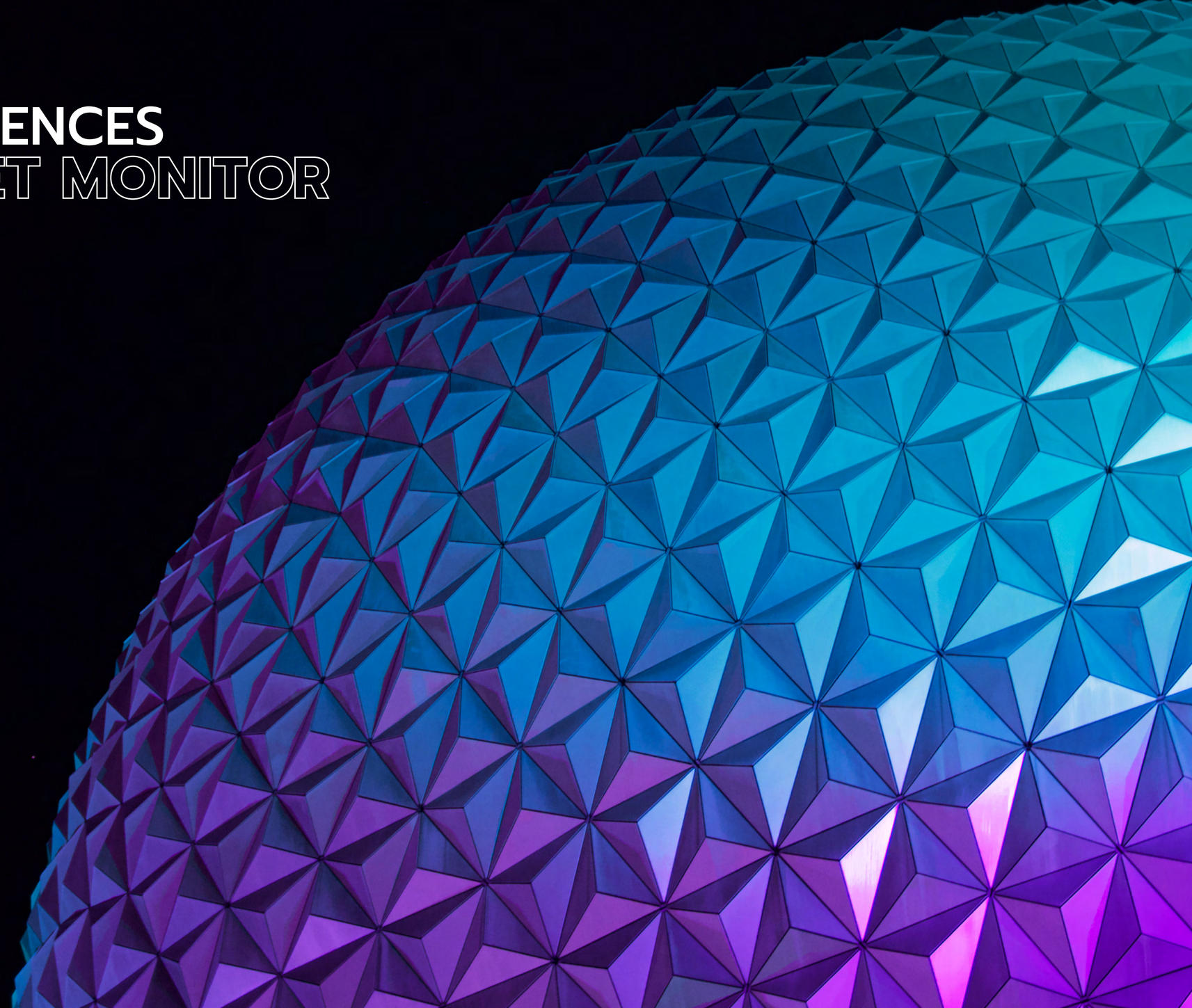
LIFE SCIENCES MARKET MONITOR

2023 EDITION



H/ADVISORS

INTRODUCTION

LIFE SCIENCES
MARKET MONITOR

Aideen Ginnell
European Director

Economies are built on the need for progress and it is the rise of economies beyond the US and Europe which have proved most influential in changing the global life sciences sector. In the last decade countries like China and Japan have worked to liberalize their markets and grant more access to foreign investors. For pharmaceutical companies this opening has proved particularly attractive, with many choosing to head East for new partnerships which support R&D and manufacturing.

Whilst the US market has remained strong by supporting competitive prices for pharmaceuticals, European countries have found themselves fighting over a shrinking slice of the pie. Company leaders in Western European countries are working increasingly hard to convince their global counterparts that their market is worth a bigger punt, whilst turning up the heat on national governments to do their bit.

With companies citing European policy and the financial landscape as key factors influencing decreasing investment, it is unsurprising that sector leaders have reacted badly to the European Commission's new legislative proposals. Constructed to support patient access and the affordability and availability of medicines, the Commission's proposals tinker with Europe's intellectual property framework to the detriment of companies that manufacture innovative drugs. Whilst there is no way to predict with certain whether proposed EU legislation will prompt life sciences businesses to conclusively turn away from investing in European countries, there is ample evidence to suggest that it's a possibility.

The Life Sciences Market monitor draws a line in the sand for 2023, analyzing which markets are most attractive to pharmaceutical companies keen to invest, do business and collaborate with national health systems. As policy and regulatory changes influence business decisions in years to come, H/Advisors will continue to report on the state of the global landscape and shine a spotlight on national indicators that will influence where investment is prioritized.

EXECUTIVE SUMMARY

LIFE SCIENCES
MARKET MONITOR

Power dynamics are shifting across the global life sciences landscape, with less mature but rapidly growing markets coming to the fore and attracting investment.

Fluctuating inflationary rates across the globe have forced governments to review policy measures to tackle the cost of doing business, the cost of living, and the overall competitiveness of their market. Current trends show China and Japan tracking with the lowest inflationary rate at just over 2% and the UAE at the highest at 12%.

Mature markets are becoming ever more regulated and policy saturated. Much of their previous appeal – an attractive talent base, preferable tax incentives, and regulatory alignment – is now being adopted elsewhere globally.

Global variation in interest rates and the cost of investment are also affecting the outlook for life sciences firms, considering the capital-intensive nature of the sector, with recent hikes in rates across Europe, Australia, and South Africa.

EXECUTIVE SUMMARY

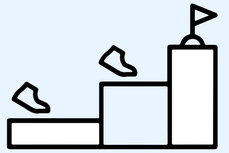
In the last decade, countries in the East have worked to liberalize their markets and grant more access to foreign investors. Asian countries have been gaining ground in the life sciences, attracting investment by promoting their sheer market size (China) and or business-friendly tax arrangements (UAE).

European markets currently remain attractive for industry, due to their advanced policy environment, robust drug reimbursement structures, and strong record of public-private partnerships. However, the EU Pharmaceutical Review proposals may impact the future of investment in the region.

With Brexit, the UK lost regulatory alignment with other EU Member States and long-term access to R&D support through Horizon Europe. However, with its high rate of universal healthcare coverage, excellent academic and research institutions, and strong trade association activity, the UK market still offers potential.

Japan has indicators which make it a particularly attractive target for investment from life sciences firms: a reputation for innovation, political stability, a large and aging population, and high drug prices.

The US retains a strong life sciences sector, with policies to support R&D and quick uptake of innovative medicines. However, the cost of medicines has become increasingly politicized since the passing of the Affordable Care Act. Trade associations are under increasing pressure to loudly champion the sector's interests.



Developing markets are taking steps to enhance their attractiveness to life sciences firms. Through expanding domestic manufacturing capacity (Brazil) or pushing through system-wide reform to national healthcare systems and funding mechanisms (South Africa). However, these remain challenging markets, owing to infrastructure limitations, corruption, and low levels of patient access.

METHODOLOGY

The 10 countries assessed in the 2023 edition of the Life Sciences Market Monitor were selected to reflect the different levels of maturity across life sciences markets and the diversity of healthcare systems globally. The geographic scope includes countries in Europe, North and South America, Africa, and the Asia Pacific region.

The countries were assessed according to a framework incorporating a set of key factors that determine how attractive each market is from a life sciences company's perspective. *(See Appendix for the full framework)*. The framework was used to assign a component score to each country, focusing on three main angles of attractiveness:

To do business

state of reimbursement and pricing, drug approvals and cost containment

To invest

intellectual property framework, infrastructure to support R&D and clinical trials and availability of talent

To collaborate

state of public-private partnerships, health equity and self-care in national policy

We used a RAG scale to visualise the component scores, where the colours can be interpreted as follows:

Highly attractive | Attractive | Neutral | Unattractive | Highly unattractive

The analysis is purely focused on this policy and regulatory environment – rather than considerations of current levels of investment within markets or population sizes.

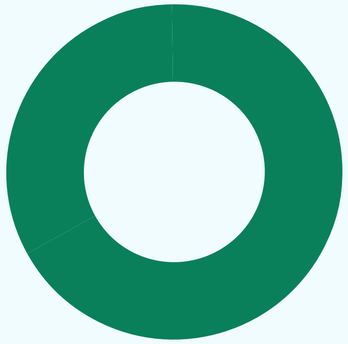
GLOSSARY

FDI	foreign direct investment
PPP	public-private partnership
UHC	universal healthcare coverage
NHS	National Health Service
EMA	European Medicines Agency
GLP	good laboratory practice
GCP	good clinical practice
GMP	good manufacturing practice

JAPAN

To do business

To invest



To collaborate

To do business

Japan has a highly efficient and stable health system. The country offers its citizen's UHC through the provision of social health insurance and a mix of private provider options. UHC reaches 98% of the population in Japan, with social health insurance giving the population access to acute, primary, speciality and mental healthcare in addition to prescription drugs. The life sciences market is also harmonised with international standards, including GLP, GCP, and GMP.

Citizens in Japan pay premiums to the Statutory Health Insurance System (SHIS) to access public health provision. This includes an additional 30% coinsurance and some additional co-payments for a variety of services. The system is composed of a tight and balanced set of institutions that extend linearly from a national to a local level. Provision is delegated to prefectures, which is then delegated further to municipalities which are further decentralised into specific bodies that provide differing areas of public health provision.

To invest

Regulations are formed based upon the systems more centralised elements and the national government direct policy at a national level. Regulatory bodies such as the Japan Council for Quality Healthcare and the Pharmaceuticals & Medical Devices Agency operate between the national government and the prefectures through the establishment of regulations which must then be implemented by the prefectures.

JAPAN

The stability of the healthcare system in Japan makes the country an attractive target for foreign investment. The country has a well-established and strong life sciences sector. A substantial amount of research & development (R&D) activity takes place domestically. The growth of the sector is mostly driven by domestic factors, such as large market size, as well as a growing elderly population.

Gaining market authorisation for a healthcare product is also accessible for firms, as the system remains flexible to the interests of industry. For example, the Ministry of Health may grant a marketing licence in special circumstances such as to prevent urgent spread of a disease or if the product has already been granted by an equivalent foreign approval system. Additionally, the development of orphan medicines, or for those of high unmet need, are met with less stringent regulations to encourage development.

The costs of medicines are split between the patient and payment agencies which allows population access to medicines in healthcare settings, including community pharmacy. The cost paid by the payment agency is then reimbursed by health insurance providers, which includes the SHIS.

Since 2023, the government has been actively promoting generic pharmaceutical products, with the aim of increasing volume shares of generic medicines by 80% in all prefectures. However, the government also promotes the development of branded medicines by increasing the price that the state is willing to pay for new products that are not yet replicated by generics.

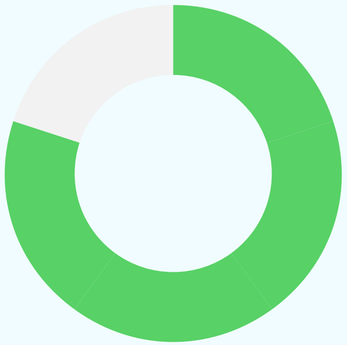
The drug price is determined by efficacy seen through clinical trials, which allows increases in drug price for paediatric, orphan, precursor, or specialised drugs. The drug price can be adjusted up to four times a year, however, only in exceptional circumstances. The system for drug pricing and reimbursement is generally transparent, however, new legislation allows the Ministry of Health to adjust prices flexibly and at its own discretion. This may be concerning for some firms when developing products in areas that may be anticipating future regulatory developments.

To collaborate

The stability of the Japanese health system has allowed the government to take a broad and global approach to health policy. Since 2003, the government has had an active strategy in place to tackle non-communicable diseases (NCDs) through the Health Promotion Act and the Healthy Japan 21 strategy. In 2013, the government founded a global network of public private partnerships alongside major industry players in the Japanese life sciences sector and the Bill and Melinda Gates Foundation. This network is the Global Health Innovative Technology Fund (GHIT) which focuses on the promotion of R&D for medications to treat tuberculous, malaria, and neglected tropical diseases (NTDs). GHIT is a fund to fight these diseases in lower to middling developed countries.

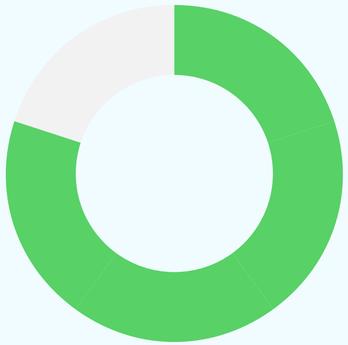
There are a multitude of factors not mentioned that also contribute to Japan's robust health system. These include an extensively planned infrastructure network and sufficient funding into health services (accounting for 11.9% of Japan's GDP in 2018). The stability and transparency of the system, in addition to the promotion of generic and branded medicines through R&D, makes Japan a viable and attractive option for foreign investment. The large market size means the pharmaceutical, biotech, and medtech industries can make substantial domestic returns without the need to rely on exports. This has led to Japan being a favourable market for domestically owned Japanese firms and international life sciences firms.

GERMANY



To do business

To invest



To collaborate

To do business

Sitting in the heart of the European Union, Germany presents a wealth of opportunities for life sciences firms that are looking to invest. The country offers its citizens UHC, with public health insurance reaching approximately 88% of the population. The remaining 12% are supplemented by private health providers. Germany's medicines regulatory authority, the Federal Institute for Drugs and Medical Devices (BfArM) is the largest in Europe and boasts close ties with the European Medical Agency (EMA) with both organisations collaborating to share expertise.

The life sciences market continues to thrive in Germany. Over 13,000 medtech firms operate within the country, alongside over 500 life sciences firms and 710 biotech firms. The federal government places a strong emphasis on fostering industry, and as early as 1996, has undertaken initiatives for the advancement of healthcare entrepreneurialism. The Ministry of Education established BioRegions in several areas across the country as a means to foster ties between research firms and universities in addition to providing grant funds to attract development.

To invest

First time entrants into the German market may become confused by the legal framework surrounding drug pricing, reimbursement, and rebates. The 2011 launching of the AMNOG system through the Market Reorganisation Act is unique to Germany. The system presents firms with no formal pricing or reimbursement framework

GERMANY

and instead introduces several legal mechanisms that allow for the regulation of drug prices.

The AMNOG system consists of two processes, which includes a health technology assessment to establish the cost-effectiveness of a drug, and then an additional assessment to determine where the drug fits into the price reference system. The system of reference pricing was introduced in 1989 and covers the majority of medicines. If a firm produces an innovative medicine, the AMNOG system takes a different course – the second process is determined by an additional benefit assessment. Due to this, the authority responsible for conducting the additional benefit assessment (which is established based upon clinical trials and head-to-head studies) takes a 'bottom-up' approach to the reimbursement negotiations that follow.

This system has received criticism from industry based upon the imbalanced nature of the assessment which impacts resulting negotiations. A primary issue is that nearly half of all additional benefit assessments result in a negative result, which affect the price of an innovative medicine. Between 2011-2020, 42% of all assessments led to negative results. In addition, firms are subjected to rebates that amount to 7% of the cost of the medicine paid by the Social Health Insurance System. The rebate is then extended to 10% on all generic products which can be problematic for firms following a negative additional benefit assessment.

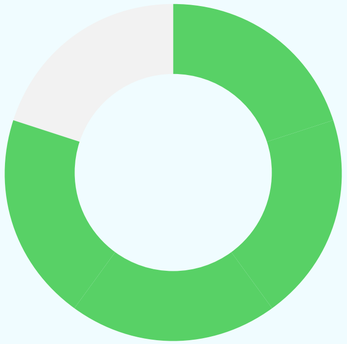
To collaborate

While a shortage of talent and healthcare professionals has been an increasing cause of concern, the federal government has attempted to address this by loosening restrictions on immigration. In 2023, an average of 60% of roles in health, social care, and nursing lacked suitably qualified candidates which prompted the government to look abroad to attract talent.

The Immigration Law of 2023 plans to allow dual nationality for non-EU citizens in an unprecedented move for the federal government. This will likely be welcome news for both German citizens and healthcare firms and will help relieve some strain on healthcare services and facilitate a wider talent pool.

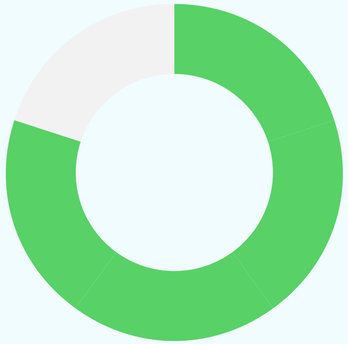
Generally, the German health system looks to the future and has a strong infrastructure for supporting public health. The Robert Koch Institute (RKI) is the German government's central scientific institution. It exists to prevent and control diseases and is highly acclaimed by the WHO and EMA. Firms may look to Germany as a prime hub of investment due to the substantial market size, the incentives towards R&D, and the advanced and forward-thinking healthcare system.

IRELAND



To do business

To invest



To collaborate

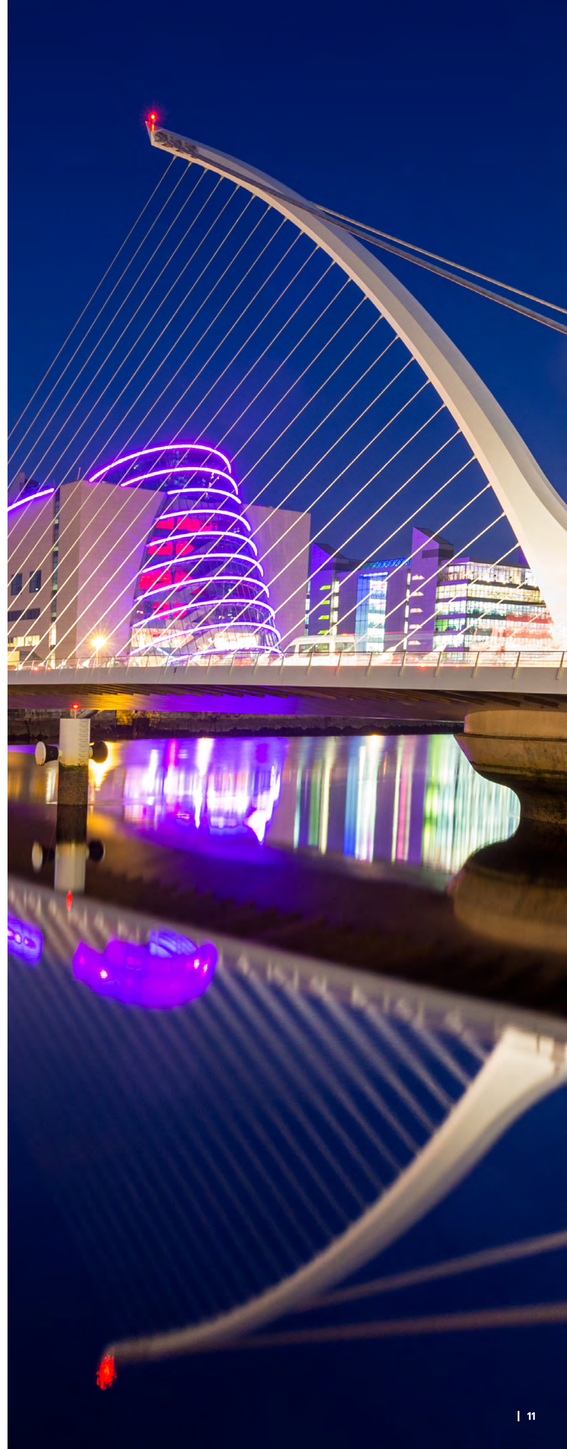
To do business

The Republic of Ireland is a country on the fringes of Europe boasting headquarters for many of the world's global life sciences corporations.

As a member of the EU, Ireland has an open economy and access to the EU single market. Ireland's medicines regulatory body, the Health Products Regulatory Authority (HPRA), is harmonised with the EMA. Since 2018, the HPRA has been a member of the EU-US Mutual Recognition Agreement which harmonises international compliance standards for pharmaceutical goods manufacturing.

The Health Service Executive (HSE) is the Irish public health provider. It offers primary care services and public hospital services. The country does not offer universal health coverage instead opting for a dual healthcare system which consists of public and private healthcare options. The HSE assigns patients with access to care through two categories. The first category includes medical card holders, who have free access to public health services amounting to 32.4% of the population. The second category includes patients who receive services from public hospitals and prescription medicines at subsidised rates. Those within category 2 must pay full price for primary care through General Practitioner services.

The HSE procures medicines through negotiations with the country's pharmaceutical representative body, the Irish Pharmaceutical Healthcare Association (IPHA). Beginning in 2013 through the Framework Agreement on the Supply and



IRELAND

Pricing of Medicines, these negotiations take place every 4 years and function as a cost-containment measure as the state reimburses 80% of medicines expenses.

However, the reimbursement process is susceptible to mild delays. While policy requires the medicines procurement approval arm of the HSE, the National Centre for Pharma-economics (NCPE), to process applications for reimbursement within 180 days, this process often takes longer for innovative medicines. The NCPE advises the HSE based on an ICER of >€45,000 per QALY. There is no standardised process for price renegotiation if the HSE decides to reject a firm's reimbursement application based on a medicines cost-effectiveness. This leads to significant barriers to market access for the R&D of innovative or orphan medicines.

To invest

Ireland provides significant incentives to multi-national life sciences firms and the country has become a global and EU hub for medicine manufacturing facilities. While its modest 12.5% corporation tax rate will be adjusted upwards to 15% in 2024, the country has a strong strategy in place for attracting and developing life sciences talent. Talent from abroad may be attracted by the SARP initiative which provides income tax relief for individuals earning over €100,000 per annum. The initiative was introduced in 2012 and was set to expire in 2022, however, it was extended through the Finance Act 2022 for a further three years until 2025.

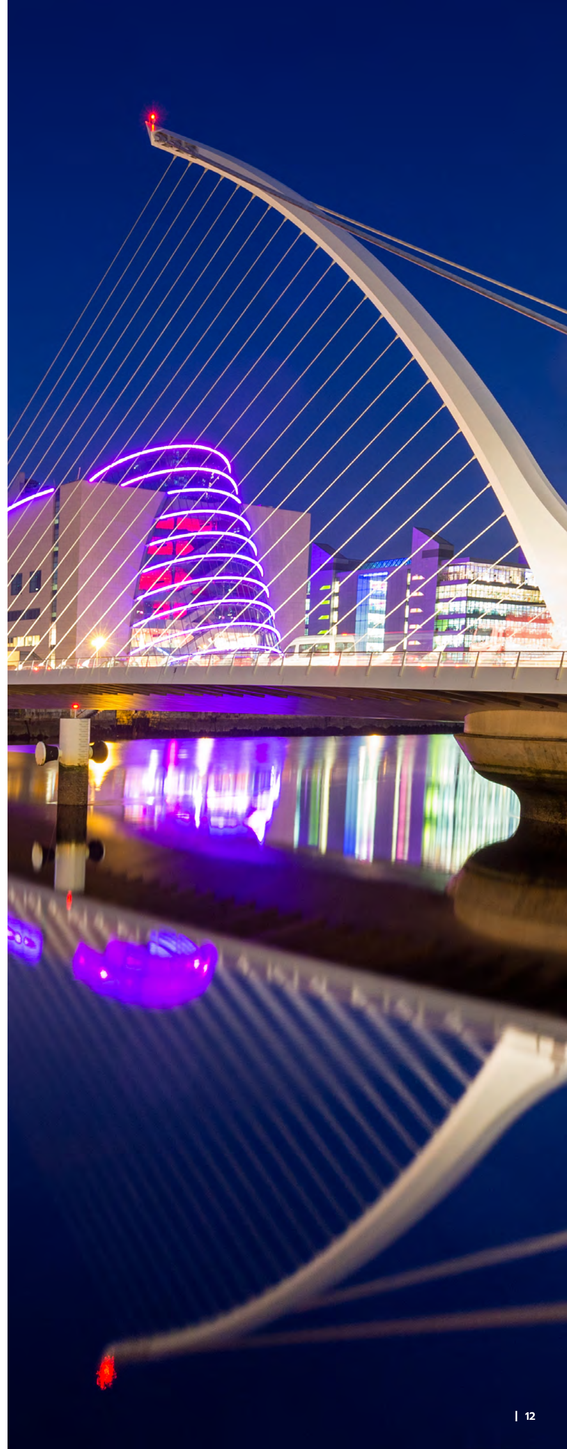
The state also focuses heavily on developing home-grown talent. The Student Support Act 2011 offers young students a range of grants and improves access to university education, while the STEM Education Plan 2017-26 aims to develop learning in the sciences. Over 50% of 25–34-year-olds have a third-level qualification which is above the EU average of 40%.

To collaborate

Energy infrastructure presents a challenge for the further investment of life sciences firms in Ireland. During 2022, the IPHA lobbied the Irish government to attain energy security following issues with the procurement of energy which disrupted the pharmaceutical manufacturing supply chain. 53 firms have established manufacturing activities in the country, with 64% being global or EU manufacturing centres.

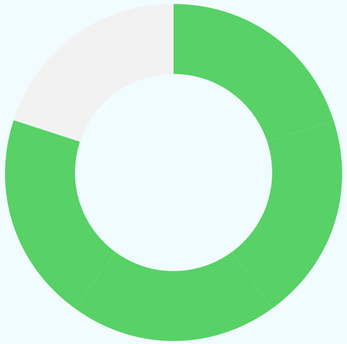
The energy grid is also under additional stress due to the widespread construction of data centres which currently consume 14% of the Ireland's electricity supply, a process which became formalised through the government's Statement on the Role of Data Centres in Ireland's Enterprise Strategy. Ireland will have to significantly scale up its generation capabilities and stabilise EirGrid to balance the interests of pharmacy and ICT. If it fails to do so, it is likely to create market access barriers to prospecting new entrants.

Ireland's health system is currently subjected to a series of reforms following the staggered implementation of Slaintecare. These reforms aim to achieve UHC and include strategies to tackle health inequalities and workforce shortages. This includes a regional overhaul of the state's primary care system, which has traditionally provided the basis for Ireland's collaboration with the private sector in providing healthcare services. Since 2009, 10% of Ireland's primary care centres (PCCs) have been privately owned, while 55% are privately leased. It is unclear how collaboration between the public and private sector will evolve. However, the country plans to fully remove private-sector care from public hospitals following the planned implementation of the Slaintecare Consultant Contract.

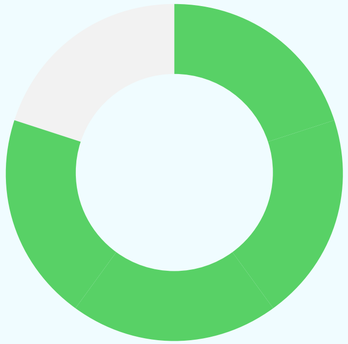


UNITED KINGDOM

To do business



To invest



To collaborate

To do business

The UK market has historically been highly attractive for life sciences firms due to its well-established legal system, research and development infrastructure and strong record of public-private partnerships in healthcare. The high coverage of universal healthcare provided through the NHS paired with the country's robust drug reimbursement frameworks means that firms have access to a large patient population.

However, with the UK's departure from the EU – and thus from its standardised regulatory framework – the country has seen growing concern from industry about whether the country can grow as a global leader in life sciences and attract investment. These concerns have been exacerbated by the UK's failure to deliver on key pledges in the 2021 Life Sciences Vision.

To invest

A key concern for industry is around the limited incentives for the development of medicines with high production costs. The UK's Voluntary Scheme on Branded Medicine (VPAS) mandates a 2% NHS budget cap for the total spend on branded medicines over a period of 5 years. In addition, the mandatory discounts negotiated between the NHS and life sciences firms can be as high as 90% of the list price.

With firms' decisions about whether to invest in R&D being largely driven by expected return on investment, there is a risk that the current pricing rules and the wider regulatory environment make the UK a less attractive market. Recent months have seen

UNITED KINGDOM

large life sciences pulling out of the VPAS mechanism and scrapping clinical trial plans. The UK's key pharma trade association, the Association of the British Pharmaceutical Industry, has been calling for reform to maintain the competitiveness of the UK life sciences sector and the UK government is gradually starting to respond.

To collaborate

The country's healthcare policy landscape is highly saturated, with a number of strategies in place for improving different aspects of provision. The NHS Long-Term Plan (published in 2019) sought to create a pathway for the modernisation of the health service. However, with the COVID-19 pandemic and the subsequent treatment and diagnosis backlogs across the country, the focus on system inefficiencies and staff shortages have only sharpened in recent years. In 2020, NHS England published the People Plan 2020/21, which emphasised the need for better deployment of resources and skills in the workforce and providing more training and upskilling opportunities. Workforce shortages have continued to fuel widespread strike action among healthcare workers.

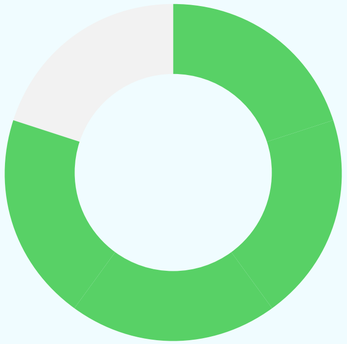
The most significant shift in UK healthcare policy in recent years has been the introduction of integrated care systems, with the passage of the Health and Care Act (2022). The ICS framework aims to coordinate and harmonise provision in localised areas and leverage these place-based partnerships to improve the efficiency of healthcare delivery. While the framework has generally been received positively due to its focus on addressing health inequalities and improving access, senior stakeholders in the healthcare sector have voiced concerns about the challenges of reconciling nationally defined targets with the needs of the local community.

In 2022, the Department for Health and Social Care published its Plan for Digital Health and Social Care, which focuses on accelerating the adoption of digital and technology solutions across the health service, with the aim of providing more opportunities for personalised at-home care and digital self-care. Another key objective of the UK's healthcare reform is to better integrate healthcare and social care.

Despite initiatives to understand healthcare in a more holistic way that is centred around population wellbeing, healthcare policy in the UK is still largely focused on acute care.

The performance of integrated care systems is measured against criteria related to hospital-based treatments and service provision. As the allocation of resources also favours acute care, this prevents a shift towards a more prevention-based model that prioritises health creation and reducing the risk of developing chronic conditions.

UNITED STATES



To do business

To invest

To collaborate

To do business

The United States leads all countries in per-capita pharmaceutical spending by a significant margin – its history of minimal price controls (changing based on current law, subject to legal challenge) and efficient regulatory processes, quick access to the market post-regulatory approval, and robust PPPs to support the rapid development of therapies have made the US an extremely lucrative market for the life sciences industry. That said, navigating the US market is becoming increasingly complex under both shifting political attitudes that have brought "big pharma" under the scrutiny of both major political parties and an inconsistent patchwork of state policies post-Affordable Care Act (ACA) that feature varying reimbursement schemes, especially between those states that have and have not opted into Medicaid expansion.

Pre-COVID-19, regulators at the Food and Drug Administration (FDA) across Republican and Democrat administrations supported and adopted policies intended to adapt the approval process to the explosion of data in medicine, keep the US on par with the rapid pace of scientific innovation, and encourage more broad competition in the industry. These moves – like the FDA's 2018 new strategic framework to advance the use of real-world evidence to support the development of drugs and biologics – enjoyed wide support from the life sciences industry.

The pandemic then saw agencies like the FDA and the National Institutes of Health (NIH) engage in robust public-private partnerships to accelerate the development

UNITED STATES

of the COVID vaccine. Emergency Use Authorizations – which have since become full FDA approvals – for mRNA COVID vaccines has helped accelerate the development of new therapies. Further, Congress continues to support R&D with key policies – like the recent Prescription Drug User Fee Act (PDUFA) and Biosimilar User Fee Act (BsUFA III) reauthorizations – that strengthen the FDA's ability to rapidly bring new innovations to market.

To invest

Both industry and government's top healthcare priority is cost. Payers, providers, and life sciences all jockey to maximize the revenue they can extract from the US system while lawmakers and regulators target each industry with reforms meant to maximize efficiencies and reduce costs in Medicare, Medicaid, and the national ACA exchange. Payers, providers, and industry all employ robust lobbying and public relations efforts – both individually and through association memberships – to influence government action on cost.

Payers and industry, for example, have lobbied against each other heavily after the passage of the ACA, both trying to avoid scrutiny and blame for high prescription costs. PhRMA – the pharmaceutical industry's main advocacy group in the United States – launched a campaign following the passage of the ACA urging as many states as possible to opt-in to Medicaid expansion in an effort to broaden the base of patients who fall under the program's out-of-pocket cost caps. More recently PhRMA has launched an ad campaign villainizing payers' relationships with pharmacy benefit managers (PBMs), blaming them for high prices.

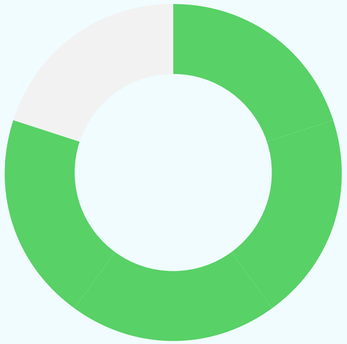
Examples of legislation and executive orders targeting cost savings post-ACA include action on surprise medical bills (providers), capping out-of-pocket costs and determining coverage of pre-existing conditions (payers), and drug price caps (pharma). Most recently, the life sciences industry has been disrupted by former President Trump's executive order to cap insulin prices and additional price caps put in place under the Biden Administration's Inflation Reduction Act (IRA). While these caps will be challenged in court, they represent a broader problem for the life sciences industry: shifting political attitudes have put a target on "big pharma's" back for both Republicans and Democrats. Even if IRA price caps are defeated in court, they have set a precedent for action that is likely to be mirrored in subsequent bills, federal regulation, and various legislative efforts across the states.

This is especially true ahead of the 2024 presidential election considering that Republicans can no longer run on "repeal and replace Obamacare" as their top health care policy/message.

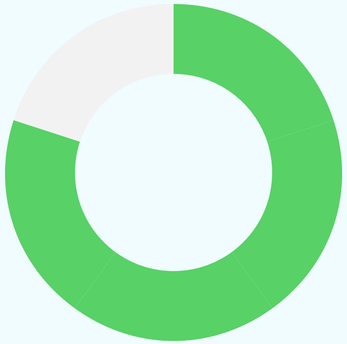
To collaborate

Congressional gridlock prevents government from leading from the front on healthcare issues beyond cost. Federal government agencies will often offer guidance or create high-level action plans to tackle health care's biggest issues, but they often have no teeth. The most robust action on equity, access, mental health, and self-care are all driven by the private sector, and progress is usually associated with strong market tailwinds that encourage action. For example, the recent, rapid proliferation of telehealth for primary care and mental health care - and associated deal activity to acquire companies in the space by both payers and providers – was driven almost entirely by the pandemic.

CHINA



To do business



To invest

To collaborate

To do business

The Chinese life sciences industry has experienced rapid growth over the past decade, making it an attractive prospect for firms seeking expansion opportunities. With a population of over 1.4 billion, the potential patient pool is enormous. The rising middle class, increased healthcare spending, and the expanding elderly population further contribute to the expansion of the market. Trade associations – both domestic and foreign – are active in China. The interests of life sciences firms operating in the country are represented by local organisations like PhRDA, as well as international chambers of commerce such as the European Chamber of Commerce and the AmCham.

To invest

The country's drug reimbursement system has undergone reforms in recent years, increasing accessibility to affordable medications through the introduction of the National Reimbursement Drug List (NRDL).

For the life sciences sector, this means improved access to the country's patient population.

To ensure a continued supply of workforce in the rapidly evolving healthcare industry, China has launched talent programs aimed at attracting both domestic and overseas professionals in the life sciences field. These programs include the Thousand Talents Program, the National High-level Personnel of Special Support Program, and the Recruitment Program of Global Experts (also known as the "Thousand Foreign Experts Program"). These programs offer

CHINA

financial incentives, research funding, and other supports to attract and retain top-tier talent.

Although the sheer size of the Chinese market presents a significant revenue opportunity for pharmaceuticals, China has implemented measures to control drug prices, including centralized procurement and negotiation mechanisms. This can impact profitability for pharmaceutical companies operating in the country.

Other challenges that must be noted include the fact that China is still only considered a partially open economy. While the country has been working to align its regulatory standards with international practices and has engaged in mutual recognition agreements (MRAs) with other countries to facilitate the registration and importation of medicines, its regulatory framework operates primarily at the national level, and its regulations and policies are set and enforced by domestic regulatory authorities.

China's regulatory processes are not always transparent, meaning that foreign life sciences firms need strong local expertise to be able to successfully access and do business in the country.

To collaborate

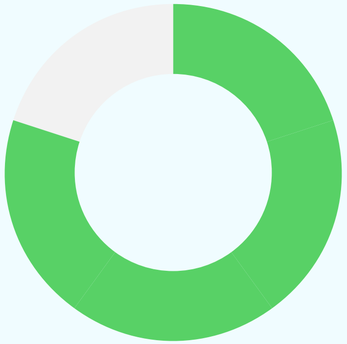
While public-private partnerships are gaining traction in China, they are still in the early stages of development. Life sciences firms seeking to collaborate with the public sector may face challenges in finding suitable partners and establishing mutually beneficial relationships.

Since the COVID-19 pandemic, China's leadership has been particularly focused on health policy. The government has invested heavily in healthcare infrastructure, including hospitals, research centres, and manufacturing facilities, providing a solid foundation for life sciences firms. Over the past decades, China has emerged as a major player in the global clinical research landscape, with the government working to align its regulations with international standards and improve the transparency and integrity of clinical trials conducted in the country.

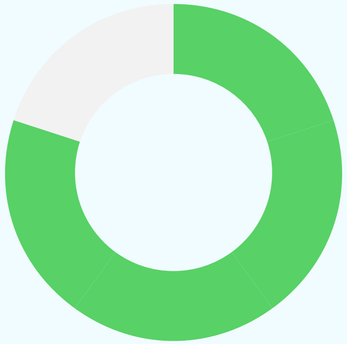
The main piece of legislation governing the healthcare system is the Law on the Promotion of Basic Medical and Health Care and the Promotion of Health, adopted in December 2019. Among the legislation's stated objectives are a greater focus on prevention, the creation of a health education system that addresses health literacy, and the implementation of a people-centred healthcare model with all major policies incorporating a health element. The provisions of the law are key to supporting the Healthy China 2030 initiative, a national strategy that aims to improve Chinese citizens' major health indicators, promote health technology innovation and the integration of digital solutions into healthcare delivery. In addition, China's "Internet Plus Healthcare" strategy seeks to leverage internet technologies, big data, and artificial intelligence (AI) to transform and enhance healthcare services. This strategy encourages the integration of online platforms, mobile health applications, and telemedicine to improve healthcare accessibility and efficiency.

The Chinese leadership have recently published their 2023 Legislative Work Plan. The Plan includes commitments to improving people's quality of life through the adoption of new pieces of legislation such as the Pharmacist Law and the Medical Security Law, as well as the revision of the Law on the Prevention and Control of Infectious Diseases.

UNITED ARAB EMIRATES



To do business



To invest

To collaborate

To do business

Within the global life sciences industry, the UAE has become known for its business-friendly economic policies, which have attracted significant foreign investment and contributed to the country's rapid economic growth.

With a stated objective to be a hub for life sciences in the region, the government has prioritised investment in healthcare over the past few years and adopted policies that set out an ambitious vision for the industry, centred around innovation and health technology (e.g., the Innovation Health Strategy).

The country has been proactive in promoting international trade through numerous free trade zones, such as Dubai International Financial Centre (DIFC), Dubai Airport Free Zone (DAFZA), and Jebel Ali Free Zone (JAFZA). These zones provide incentives like tax exemptions to attract foreign companies. As a member of the World Trade Organization (WTO), the UAE has been committed to reducing trade barriers and has signed trade agreements with regional and international partners, aiming to enhance market access, stimulate economic growth, and diversify its trade relationships. In addition, public-private partnerships are promoted by initiatives like the Dubai Healthcare City (DHCC) or the Abu Dhabi Public Private Partnership Model.

The UAE government has established regulatory bodies, such as the Ministry of Health and Prevention (MOHAP) and the Department of Health (DOH), which oversee the pricing and registration of pharmaceutical

UNITED ARAB EMIRATES

products. The key responsibility of these bodies is to monitor the prices of medications to ensure affordability and prevent excessive pricing. The country has implemented a reference pricing system, which sets maximum prices for certain medications based on the average prices of equivalent products in a reference group of countries. This approach seeks to promote price competition among pharmaceutical manufacturers. Cost-containment in healthcare is promoted through frameworks such as the Essential Medicines List, which includes a range of essential drugs considered vital for the healthcare system. The list is regularly updated and serves as a reference for healthcare providers, insurers, and patients.

The interests of the sector are represented via trade associations, the most active of which is the Pharmaceutical Research and Manufacturers Association-Gulf (PHRMAG). The PHRMAG membership consists of multinational research-based life sciences firms operating in the Gulf region.

To invest

From an incentive's perspective, the UAE has introduced measures over the past few years to stimulate R&D in the domestic life sciences market. One notable initiative is the Dubai Science Park (DSP), a free zone dedicated to the life sciences and healthcare sector. DSP provides a supportive environment for life sciences firms and offers incentives to attract research and development activities, such as subsidized office spaces, access to specialized facilities, and collaboration opportunities.

The UAE is known for its medical tourism industry, attracting patients from around the world who seek high-quality healthcare services. The country hosts numerous medical conferences, symposiums, and exhibitions throughout the year, further promoting clinical activity and knowledge exchange among healthcare professionals in the Gulf area and globally.

To collaborate

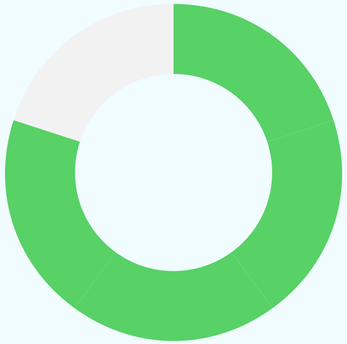
Despite these advantages, the UAE healthcare sector – while fast-growing – is relatively immature and as such, there are a number of challenges that impact on its attractiveness as a market. The UAE does not have UHC. While the government operates public healthcare facilities, such as hospitals and clinics, where certain medications may be available at subsidized rates, non-nationals and expatriates generally have to bear the costs of their medications. Relying on private health insurance is very common in the UAE.

There remain significant inequalities across the population in terms of access to quality healthcare services. Major cities like Dubai and Abu Dhabi tend to have a higher concentration of medical infrastructure and clinical activity compared to rural areas.

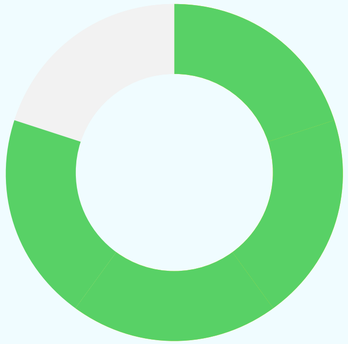
Although the country has become a hub for healthcare talent, the majority of the workforce are not Emirati nationals. The UAE has a relatively open immigration policy, attracting a large expatriate workforce. The UAE has emphasized the development and training of its own citizens to join the healthcare workforce. Through initiatives such as Emiratization, the government aims to increase the number of Emirati healthcare professionals and improve the representation of nationals in the healthcare sector and contribute to reducing disparities in healthcare access and quality.

AUSTRALIA

To do business



To invest



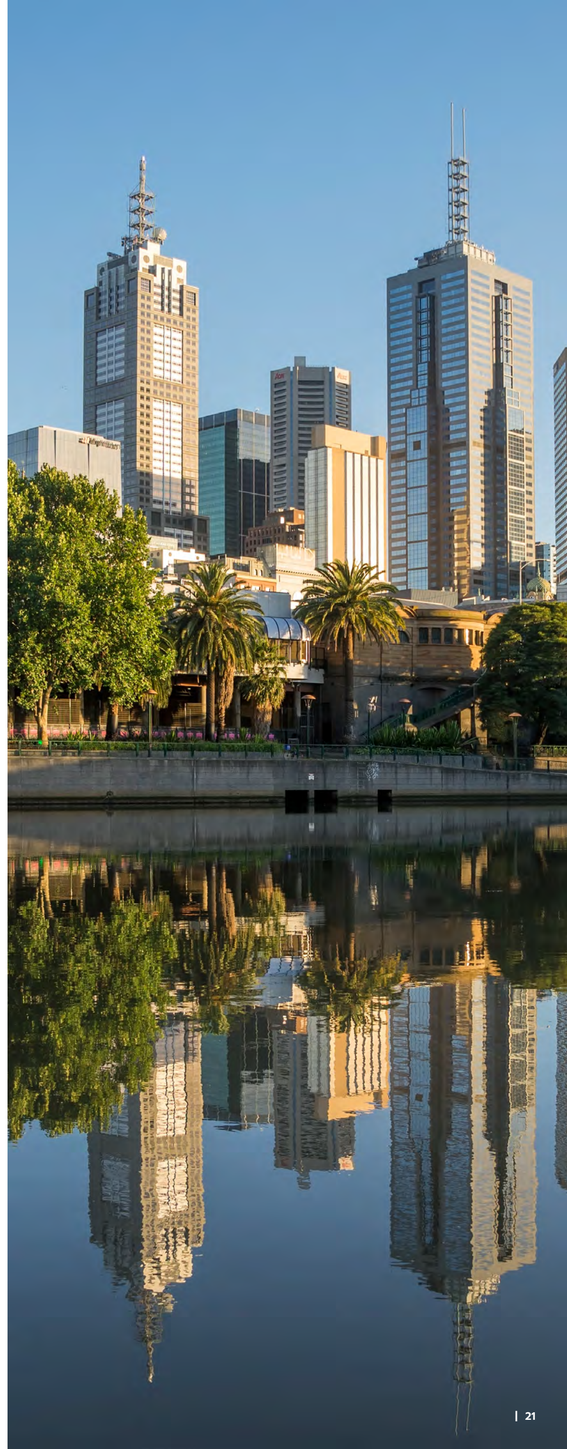
To collaborate

To do business

Australia's attractiveness as a market for the life sciences industry is in a current state of flux. The tentpole pieces of legislation – Medicare and the Pharmaceutical Benefits Scheme – showed clear signs of age during the pandemic. As such, the Federal Government has made significant commitments to new health measures and reforms in 2023-2024.

This includes significant investment into Medicare, Australia's universal healthcare system, to the tune of $6.1 billion to improve access to primary care for patients across Australia – broadly welcomed by industry. However, many other long over awaited policy initiatives remain still in the consultation phase. For example, the government is currently consulting on the Health Technology Assessment review, for the first time in 30 years. This review will look at how innovative health technologies may pose a challenge to Australia's current funding structures, how Australia's funding pathways and timelines compare to international systems. The outcome of this consultation is expected at the end of 2023 and will likely have a significant impact on the attractiveness of Australia as a country for global life sciences investment.

Where industry is calling for further reform is in relation to the Pharmaceutical Benefits Scheme, the government-subsidy model used to fund prescriptions, with the current approach seen as underfunded. Furthermore, the Medicines Supply Security Guarantee has also been introduced following the pandemic, where Australia saw significant supply chain issues in obtaining over



AUSTRALIA

500 PBS listed medicines. The Guarantee has called on Australian-based medicine manufacturers to commit to holding 4-6 months of stock in Australia, in case of future global supply chain shocks, but Australia remains particularly exposed in this respect due to the low levels of national medicine manufacturing.

To invest

Australia has also introduced strong financial incentives to attract R&D activity from global players – with those firms earning less than $20 million a year eligible for a tax rebate of 43.5% for clinical expenditure, while those earning over $20 million eligible for a 38.5% tax rebate. Furthermore, Australia's harmonisation of regulatory approach with the US, allows for automatic acceptance by the FDA, enabling immediate commercialisation within the US post-approval. Nonetheless, long-standing bureaucracy challenges, such as jurisdictional and state-level duplication and navigation had been a further barrier to Australia's attractiveness for new clinical trials. As such, last year the Australian Government Department of Health, in partnership with the Clinical Trials Project Reference Group, launched a consultation for a "National One Stop Shop and National Clinical Trials Front Door", with the goal "to make it easier for patients, researchers, industry representatives and sponsors to find, conduct, participate and invest in high quality and ethical research in Australia."

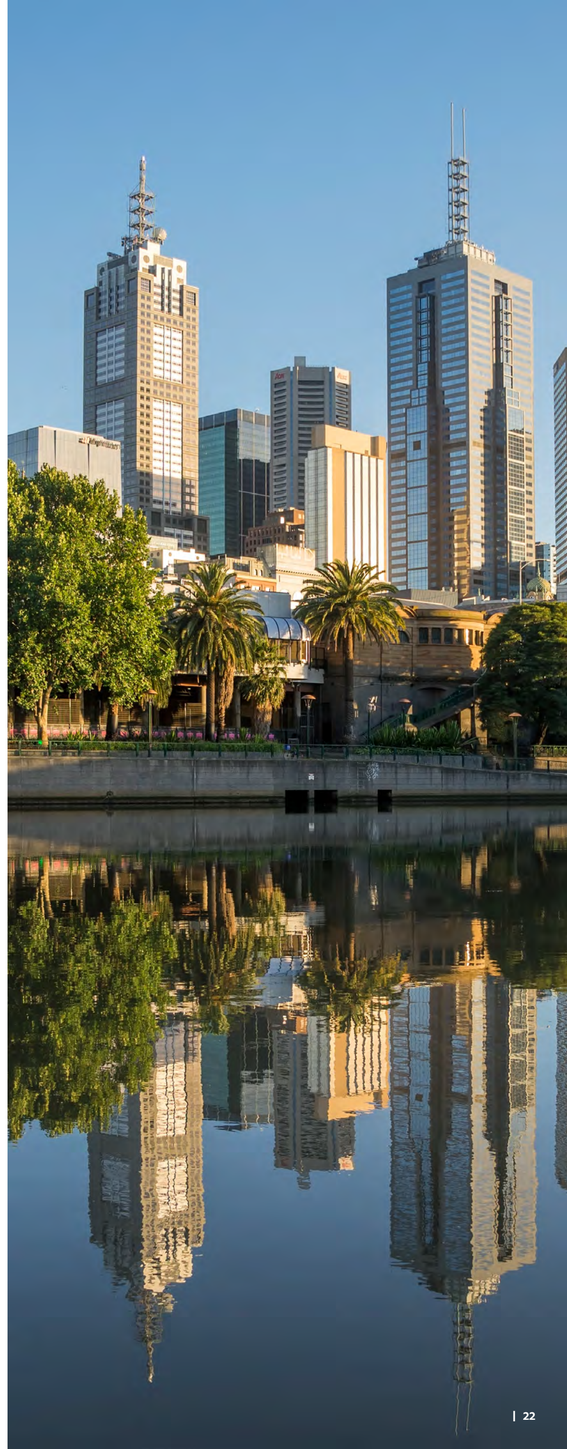
To collaborate

On developing its digital health strategy, the pandemic was a clear policy trigger in Australia to accelerate policy. Australia's National Digital Health Strategy set out clear priorities that were essential to developing digital health by 2022. Specifically, this included the national roll-out of "My Health Record", a standardised electronic patient records, facilitating digital prescriptions and enabling increased telehealth services. For a country with the geography of Australia, enabling digital-first approaches has even greater benefits in meeting the population health needs across the country.

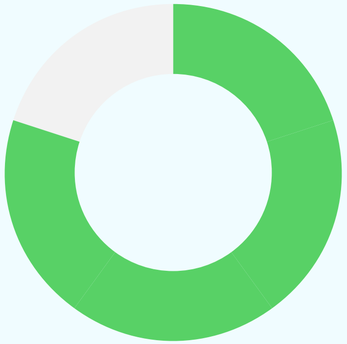
However, where Australia is currently falling behind other markets is in its approach to preventative health approaches, particularly in reducing levels of health inequality across the country. While National Health Reform Agreement from 2020 re-affirmed that all state governments need to commit to eliminating differences in health outcomes across Australia, few practical steps are yet to be taken to meet this objective. A standalone health inequalities policy hasn't been released in the last decade. Further reforms included in the National Health Reform Agreement cover improvements to health literacy, enhanced health data, and enabling flexible government-funded payment models for health services.

As such, this year the Treasury in Australia issued its first "Measuring What Matters" statement. This initiated a consultation this year looking to develop a national framework on wellbeing that will evolve over time, focusing on adopting broader view to understand the social and environmental indicators of community wellbeing.

The consultation received submissions from the main, and activity, pharmaceutical trade associations in Australia supporting the initiative to link economic prosperity with leading healthier lifestyles. Adopting a population-level approach to holistically understand people's health and wellbeing will only strengthen the policy environment from a collaboration perspective for life sciences firms to do business within Australia.

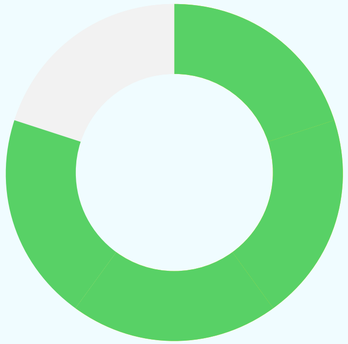


BRAZIL



To do business

To invest



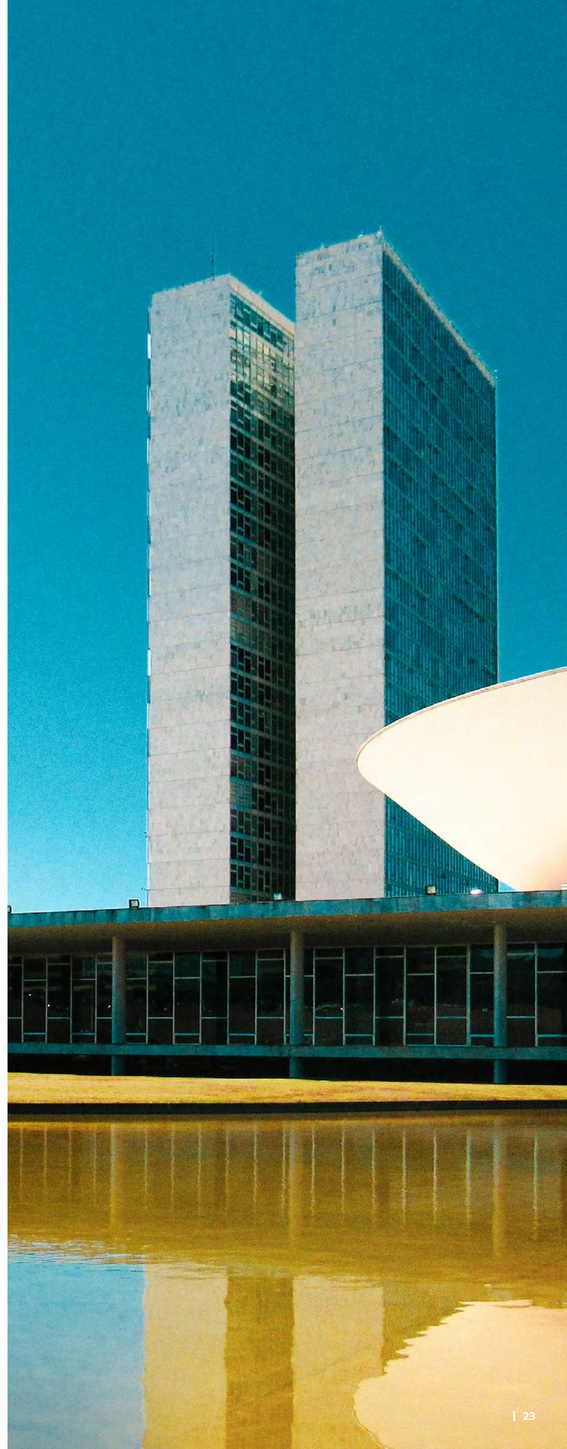
To collaborate

To do business

The Brazilian population receive healthcare from the highly decentralised SUS. Established in 1988, the cornerstone of SUS strategy has been primary care through policies such as the 1994 Family Health Strategy (FHS). The FHS has been accredited as a cost-effective method for reducing infant mortality, unnecessary hospitalisations, and overall health inequalities through the provision of intimate community care. However, the Brazilian Government moved away from this policy framework in 2017 with the National Primary Care Policy (PNAB). The much-criticised PNAB moved funding from the core components of the FHS, resulting in the drastically reduced effectiveness of Brazilian primary care. In 2017, 62.5% of Brazilians relied on the FHS to receive primary care, compared to 40.5% in 2020.

The Brazilian Government focuses on maintaining and promoting the domestic manufacturing of medicines as state policy. This is done through the prioritization of domestic manufacturing of generic medicines. Generic equivalents have been continually promoted since the 1999 Generic Medicines Act and have led to 28% of the sector being composed of generic equivalent products. This act was later amended in the 2000s to require firms to register generic products through equivalence tests provided by ANVISA, Brazil's drug regulatory authority.

Domestic firms have since been offered a fast-track approval process for the registration of generic products. Additionally, firms looking to acquire a patent for branded medicines initially had to seek approval from ANVISA, however, the need for ANVISA



BRAZIL

consent has since been abolished and ANVISA continues to expense firms for their application process in a figure that is calculated by the firm's overall revenue. In 2021, the Federal Supreme Court established minimum patent protection for a term of 10 years for innovative medicines, however, this is the maximum amount of IPP that a firm can receive.

To invest

Life sciences firms that choose to operate in Brazil will face a strict regulatory environment. Brazil's drug regulatory body, ANVISA, is not a member of a supra-national regulatory agreement, meaning that a product's approval from the FDA or EMA does not guarantee market access in Brazil.

Medicines approvals are split into three categories and firm's must perform their own clinical trials to prove a drug's efficacy. If approval is granted, a firm will meet the Brazilian Chamber which further categorises the product. The Chamber is responsible for providing a price cap on pharmaceutical products and requires the firm to collect a dozen 'basket of prices' from jurisdictions that have already granted the product market authorization. The Chamber sets the price cap at the lowest price listed in the 'basket of prices.'

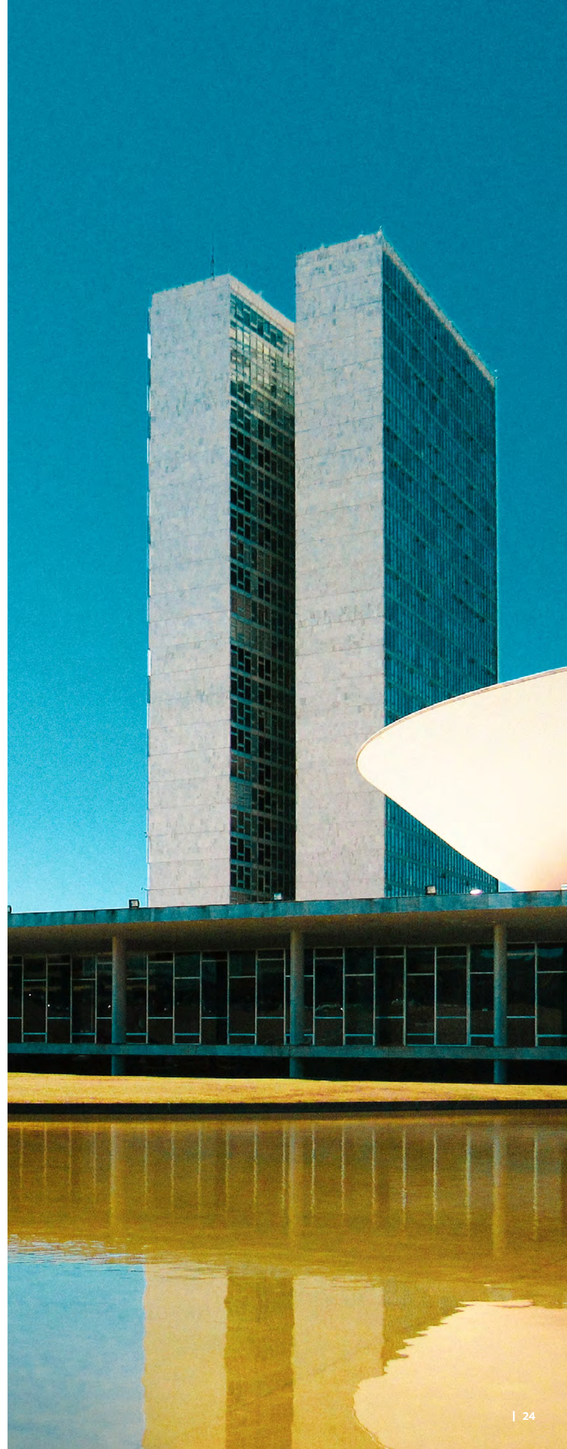
This reference pricing method is problematic for firms because a product's price ceiling in Brazil may be affected by another country's policy or other external market implications. However, the Chamber was partially reformed in 2020 to provide for greater transparency in setting price ceilings and add further flexibility to the Chamber's requirements from life sciences firms.

Similarly, the Competition Law of 2012 strictly regulated M&A in Brazil through the competition regulator CADE, which also serves to promote domestic production and provide barriers to entry for global life sciences firms. These measures have led to the market being strictly protected as 66% of Brazilian life sciences manufacturing sites are domestically owned.

A total of 43 sites operate in Brazil, however, only 13 of these have FDA or EMA approval. The barriers that Brazil provide to firms is likely to change. Between 2015-19, the amount of drug's purchased by the SUS increased by 31.4%, and as demand for medicines continues to grow post-COVID, Brazil will likely have to reduce stringent regulation in order to allow future investments to meet this demand.

To collaborate

Sizeable shifts in overall health policy occurred in the 2010s, with the SUS becoming increasingly dependent on PPPs. While the state offers UHC, the health system has been described as a duplicate and supplementary model with significant opportunity for PPPs. Many SUS hospitals have since been contracted to private health providers, in addition to notable state subsidies being offered to private health insurance firms. In 2016, the Government amended a law in its constitution that applied a minimum requirement of funding from the Brazil's states to the SUS. The amendment removed this requirement as the utilisation of PPPs has increasingly been seen as a cost-containment measure in providing public healthcare since the 2013 Brazilian economic crisis. This suggests that the growth of PPPs in providing public healthcare is likely to continue.



SOUTH AFRICA

To do business

To invest

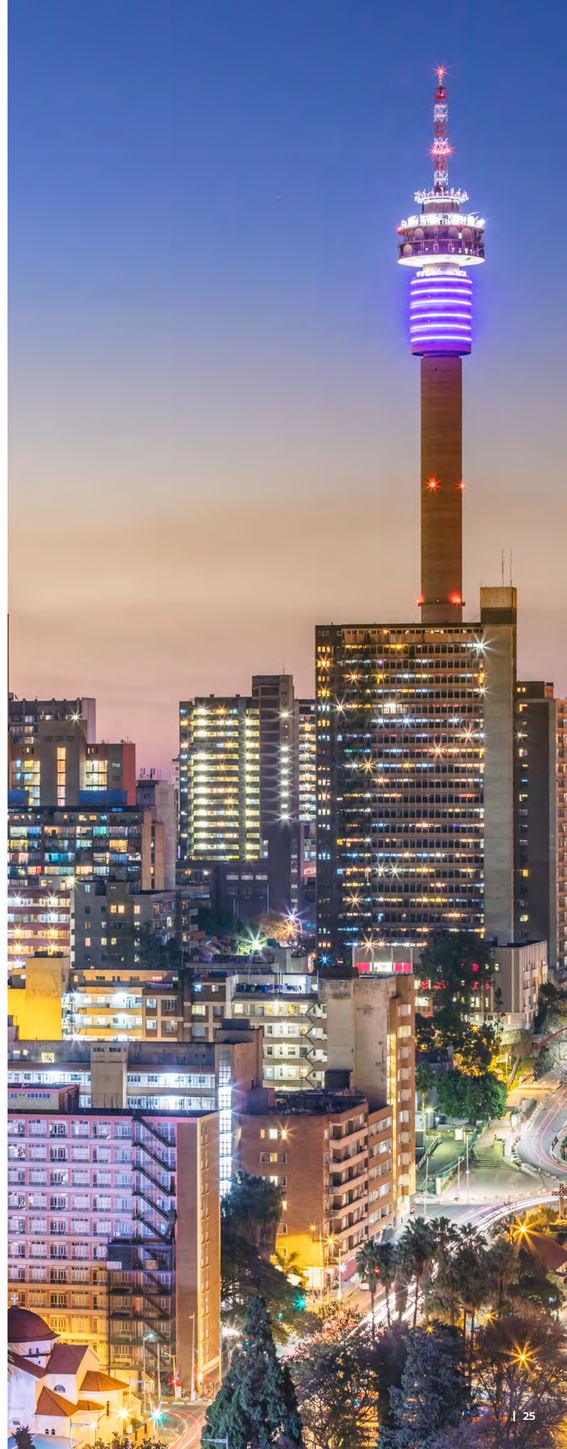
To collaborate

To do business

South Africa presents a paradox to prospecting healthcare industries seeking an attractive market. It is often considered a regional hub in Sub-Saharan Africa and shows investment potential due to its open economy and large market size. Despite this, South Africa's healthcare policy fronts numerous barriers that act as a roadblock to investment.

The National Health Insurance (NHI) reforms are set to implement a system of UHC by 2026 and shake up a healthcare landscape dominated by private healthcare providers. After building a public fund, the government intends to purchase private sector health services at a lower price. Several cost-containment measures are also set to be introduced for the socialising of primary health services and hospital services. While the NHI is likely to substantially transform the relationship between industry and the state, concerns have been voiced over the lack of transparency in the process and doubts have been cast over the feasibility of the plans.

Anxieties surrounding the implementation of NHI in South Africa will continue to affect private sector providers. Meanwhile, the drug approval and reimbursement framework will need significant reform to support national uptake and use of innovative medicines for the benefit of patients enjoying universal health coverage from 2026.



SOUTH AFRICA

To invest

The drug reimbursement process is similarly outdated. The 1996 National Drug Policy implemented a drug pricing framework that continues to prompt concerns from industry over its lack of transparency. Imported generic medicines form the bulk of the South African life sciences market.

The intellectual property framework continues to be a sore issue for industry as it continues to result in high drug costs for innovative medicines. Since joining the TRIPS agreement in the late 1990s, South Africa has failed to take advantage of the agreements flexibility, resulting in a prolonged conflict between Government and Industry due to the state's ad hoc approach to IPP.

To collaborate

South Africa's healthcare policy is largely outdated. Its precedence was set in 1965 with the Medicines Act which continues to dictate the relationship between the state, healthcare providers, and industry. UHC is not offered in the country and its current health system has consistently been criticised as a relic of the apartheid – and with good reason.

The scale of health inequalities is unlike anything seen elsewhere and certainly takes a racial element, with 73% of white individuals eligible for public care through a medical scheme, compared to only 10% of black individuals. The healthcare system is also harried by additional pressures, including the ongoing AIDS epidemic and a large shortage of medical professionals.

These issues are compounded by state policy which frames the relationship between the healthcare system and industry. The process for gaining approvals for medicines essentially collapsed in 2017 due to a backlog of over 16,000 applications, some dating back to 1992. This led to the formation of SAHPRA which has vastly increased the staffing size of the regulatory authority with the main aim of reducing the average amount of days for approval which is currently at 1,422 days.

Finally, a major roadblock to investment in South Africa is the poor state of the electricity grid. The state-owned energy company, Eksom, is currently operating above capacity and the country experiences frequent and sporadic events called 'load-shedding.'

This means that hospitals and private firms have their electricity cut throughout the day in order to ease demand on the energy grid. Many commentators have argued that the poor state of the energy grid is due to high level state corruption. These factors provide a major deterrent to prospecting firms looking to invest in South Africa.

CONCLUSION

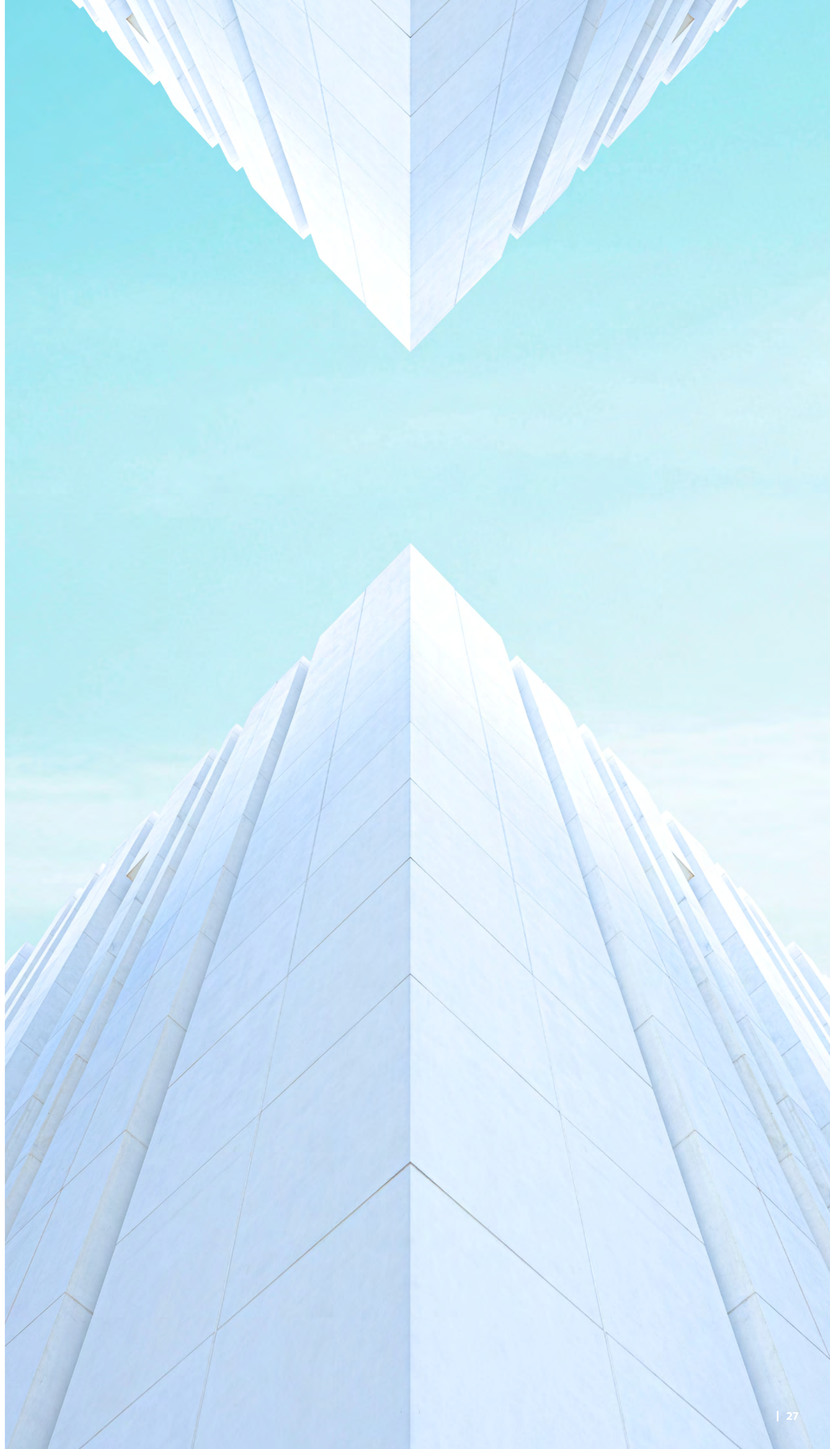
Although globally life sciences firms invest more heavily in the US and China than other countries, Japan has indicators that make it an attractive target for investment. The highly stable and organised healthcare system is complemented by universal healthcare coverage, a flexible reimbursement and approval system and prioritisation of R&D in the market.

Whilst still attractive targets for life sciences firms, Germany, Ireland, and the UK have been consistently criticized for their drug pricing, rebate ,and reimbursement processes for various reasons. However, these countries have a long history with the global life sciences sector and have been well-known and respected partners of business. There is scope for the UK and Germany in particular, to make changes that will refresh their attractiveness in the eyes of industry.

The countries analyzed in South America and the Middle East – Brazil and the United Arab Emirates – have the potential in the long term to attract significant investment from life sciences firms. Both markets are currently building the infrastructure necessary to support this objective. The UAE's heavy emphasis on foreign direct investment through the creation of free trade zones stands out in a traditionally conservative region. Meanwhile, Brazil is in a similarly positive position, with transparent cost containment measures and a drug approval process described as timely and efficient. Long term, it is predictable that both countries may successfully challenge for life sciences investment. Whilst there is little sign of China reducing role on the world stage as a leader in the life sciences, the US is arguably in shaky territory.

Having for many years enjoyed refuge with the Republican party, the costs of drugs are a significant issue at the forefront of US politics today and trade associations are under increasing pressure from members to preserve the most positive elements of the current regulatory setup.

Of the countries analyzed South Africa was found to be the outlier. Although the countries' planned reform of national healthcare policy represents a tremendous opportunity, there is still a long way to go before the market realises its true potential as Sub-Saharan Africa's regional hub for life sciences investment.



ABOUT US

LIFE SCIENCES MARKET MONITOR

H/Advisors Public Affairs combines the talents of Havas Group agencies H/Advisors Cicero and H/Advisors Abernathy. It brings together experts in healthcare public affairs, communications, and policy from across the EU, UK and USA to deliver campaigns for some of the world's largest listed businesses.

The team includes a number of Senior Advisors such as the former Deputy Prime Minister of Britain, a former EU Head of Public Affairs for a leading life sciences company, a former advisor to a Minister of Health, and senior public affairs practitioners from healthcare companies and trade associations.

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Account Director

Lili Katona
Senior Account Executive

Josh Perry
Account Executive

Mark Detlor
Senior Account Executive

H/ADVISORS

APPENDIX

JAPAN

ATTRACTIVENESS		
to do business	**to invest**	**to collaborate**
Are there robust drug reimbursement agreements in place between the state and industry?	Does the country have an open economy?	Does the country have a strong record of successful public-private partnerships in healthcare?
Does the country offer universal healthcare coverage?	Is the country a member of a supranational regulatory agreement with standardised regulatory practices?	Is there a dedicated plan in place for the digitalisation of healthcare services (& the use of health tech innovation)?
Are the interests of the pharmaceutical sector represented by strong trade association activity?	Does the state provide strong financial incentives to promote R&D (e.g., intellectual property protection)?	Does the country have a strategy for addressing health inequalities and improving patient access?
Are cost-containment measures transparent?	Is there a consistently high level of clinical trial activity in the country?	Does the country have a self-care strategy that promotes health literacy?
Are drug approval processes timely and efficient with minimised backlog?	Does the country provide an effective framework for developing and attracting life sciences talent?	Does the country have a clear plan for pharmacies & community wellbeing?
Are the country's regulations on drug pricing conducive to the development of medicines with high production costs?	Are pharmaceutical manufacturers supported by robust infrastructure and planning processes?	Is the health service in the country well-staffed with a dedicated workforce strategy?

GERMANY

ATTRACTIVENESS		
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APPENDIX

IRELAND

ATTRACTIVENESS						
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UNITED KINGDOM

ATTRACTIVENESS						
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APPENDIX

UNITED STATES

ATTRACTIVENESS		
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CHINA

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UNITED ARAB EMIRATES

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to do business	**to invest**	**to collaborate**
Are there robust drug reimbursement agreements in place between the state and industry?	Does the country have an open economy?	Does the country have a strong record of successful public-private partnerships in healthcare?
Does the country offer universal healthcare coverage?	Is the country a member of a supranational regulatory agreement with standardised regulatory practices?	Is there a dedicated plan in place for the digitalisation of healthcare services (& the use of health tech innovation)?
Are the interests of the pharmaceutical sector represented by strong trade association activity?	Does the state provide strong financial incentives to promote R&D (e.g., intellectual property protection)?	Does the country have a strategy for addressing health inequalities and improving patient access?
Are cost-containment measures transparent?	Is there a consistently high level of clinical trial activity in the country?	Does the country have a self-care strategy that promotes health literacy?
Are drug approval processes timely and efficient with minimised backlog?	Does the country provide an effective framework for developing and attracting life sciences talent?	Does the country have a clear plan for pharmacies & community wellbeing?
Are the country's regulations on drug pricing conducive to the development of medicines with high production costs?	Are pharmaceutical manufacturers supported by robust infrastructure and planning processes?	Is the health service in the country well-staffed with a dedicated workforce strategy?

AUSTRALIA

ATTRACTIVENESS		
to do business	**to invest**	**to collaborate**
Are there robust drug reimbursement agreements in place between the state and industry?	Does the country have an open economy?	Does the country have a strong record of successful public-private partnerships in healthcare?
Does the country offer universal healthcare coverage?	Is the country a member of a supranational regulatory agreement with standardised regulatory practices?	Is there a dedicated plan in place for the digitalisation of healthcare services (& the use of health tech innovation)?
Are the interests of the pharmaceutical sector represented by strong trade association activity?	Does the state provide strong financial incentives to promote R&D (e.g., intellectual property protection)?	Does the country have a strategy for addressing health inequalities and improving patient access?
Are cost-containment measures transparent?	Is there a consistently high level of clinical trial activity in the country?	Does the country have a self-care strategy that promotes health literacy?
Are drug approval processes timely and efficient with minimised backlog?	Does the country provide an effective framework for developing and attracting life sciences talent?	Does the country have a clear plan for pharmacies & community wellbeing?
Are the country's regulations on drug pricing conducive to the development of medicines with high production costs?	Are pharmaceutical manufacturers supported by robust infrastructure and planning processes?	Is the health service in the country well-staffed with a dedicated workforce strategy?

APPENDIX

BRAZIL

ATTRACTIVENESS		
to do business	**to invest**	**to collaborate**
Are there robust drug reimbursement agreements in place between the state and industry?	Does the country have an open economy?	Does the country have a strong record of successful public-private partnerships in healthcare?
Does the country offer universal healthcare coverage?	Is the country a member of a supranational regulatory agreement with standardised regulatory practices?	Is there a dedicated plan in place for the digitalisation of healthcare services (& the use of health tech innovation)?
Are the interests of the pharmaceutical sector represented by strong trade association activity?	Does the state provide strong financial incentives to promote R&D (e.g., intellectual property protection)?	Does the country have a strategy for addressing health inequalities and improving patient access?
Are cost-containment measures transparent?	Is there a consistently high level of clinical trial activity in the country?	Does the country have a self-care strategy that promotes health literacy?
Are drug approval processes timely and efficient with minimised backlog?	Does the country provide an effective framework for developing and attracting life sciences talent?	Does the country have a clear plan for pharmacies & community wellbeing?
Are the country's regulations on drug pricing conducive to the development of medicines with high production costs?	Are pharmaceutical manufacturers supported by robust infrastructure and planning processes?	Is the health service in the country well-staffed with a dedicated workforce strategy?

SOUTH AFRICA

ATTRACTIVENESS		
to do business	**to invest**	**to collaborate**
Are there robust drug reimbursement agreements in place between the state and industry?	Does the country have an open economy?	Does the country have a strong record of successful public-private partnerships in healthcare?
Does the country offer universal healthcare coverage?	Is the country a member of a supranational regulatory agreement with standardised regulatory practices?	Is there a dedicated plan in place for the digitalisation of healthcare services (& the use of health tech innovation)?
Are the interests of the pharmaceutical sector represented by strong trade association activity?	Does the state provide strong financial incentives to promote R&D (e.g., intellectual property protection)?	Does the country have a strategy for addressing health inequalities and improving patient access?
Are cost-containment measures transparent?	Is there a consistently high level of clinical trial activity in the country?	Does the country have a self-care strategy that promotes health literacy?
Are drug approval processes timely and efficient with minimised backlog?	Does the country provide an effective framework for developing and attracting life sciences talent?	Does the country have a clear plan for pharmacies & community wellbeing?
Are the country's regulations on drug pricing conducive to the development of medicines with high production costs?	Are pharmaceutical manufacturers supported by robust infrastructure and planning processes?	Is the health service in the country well-staffed with a dedicated workforce strategy?

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