



Site Selection for Life Sciences Companies in Asia

India, China, Hong Kong SAR, Singapore and
the emerging markets of Southeast Asia

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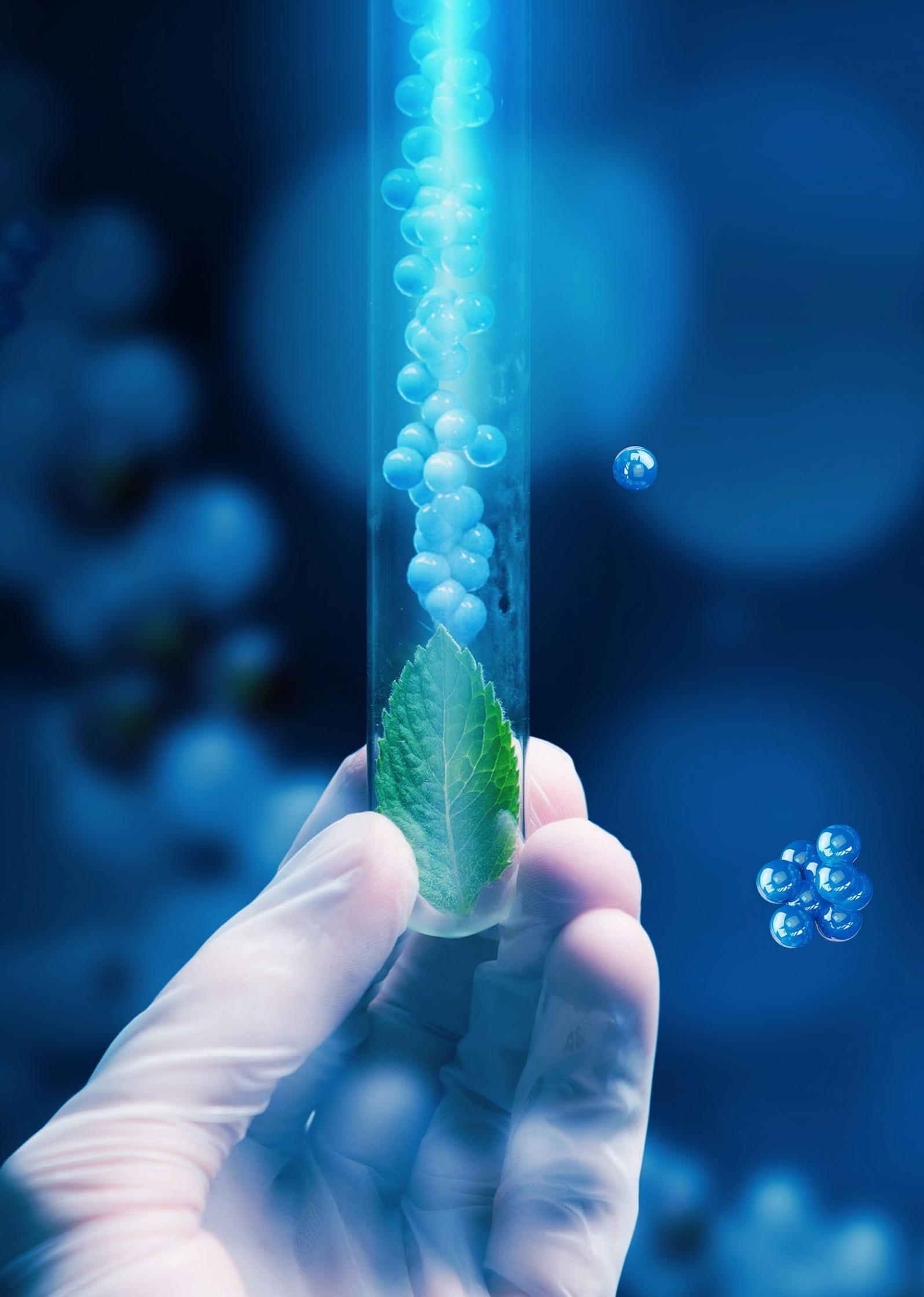


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Foreword

Site Selection for Life Sciences Companies in Asia

Asia is the world's fastest growing market for pharmaceutical products, medical devices and healthcare services. Rising middle class incomes and aging populations are combining with a growing number of public and private healthcare programs across the region to increase demand for quality products and services. While a significant proportion of this demand continues to be satisfied by non-Asian companies, the domestic industry is also growing quickly – and many domestic players have global growth ambitions.

Due to the evolving dynamics of the industry in Asia, and following the success of our Site Selection for Life Sciences Companies in Europe series, we are pleased to launch our first edition of "Site Selection for Life Sciences Companies in Asia". It addresses the needs of companies that may be considering setting up regional headquarters, manufacturing or R&D facilities close to key Asian end-markets. This is particularly timely as the COVID-19 crisis emphasizes the importance of localizing parts of the value chain and ensuring multiple sourcing close to consumers.

André Guedel

Head of International Headquarters
KPMG Switzerland

The huge differences between Asian countries in terms of population size and the stage of development of the local Life Sciences industry, plus the varying degrees of market and regulatory maturity, means we have focused the detail of our report on the most relevant, fastest growing markets: India, China, Hong Kong SAR and Singapore. We also provide overviews of Indonesia, Malaysia, the Philippines, Thailand and Vietnam.

The publication introduces the business and regulatory frameworks in these countries, with particular reference to locating elements of businesses' value chains there. We have included articles from subject matter experts on key topics of interest such as the IPO landscape, healthcare digitalization, and comparing the clinical trial application environments in China and the EU.

We hope you find the publication thought-provoking, and we would be delighted to discuss how it may assist you in your plans to enter, expand or consolidate your Life Sciences operations across this high-potential region.

Chris Hardesty

Director Life Sciences, Asia
KPMG Singapore



India

Why India - in a nutshell

A huge market in which structural reforms are gaining traction, India's has a liberal foreign direct investment regime and a rapidly improving business environment. These factors have helped it rise up the rankings in recent years to 63rd in the World Bank's Doing Business report 2020, from 142nd in 2014. A wide range of fiscal measures and incentives is promoting R&D, and the country is producing a large pool of qualified Life Sciences personnel from universities and technical institutes.

India is a key component of the global Life Sciences industry. Its manufacturers are one of the largest sources of generic drugs, supplying 50 percent of global demand for a range of vaccines, 40 percent of generic demand in the US – where Indian firms are expanding – and 25 percent of UK medicines.

Long known as a low-cost manufacturing location, confidence in product quality has been a challenge. New safeguards on manufacturing and product standards are providing much-needed reassurance to customers at home and abroad.

Supporting a move to the next phase in the industry's evolution, many states are actively building incubator hubs to attract start-ups. At a national level, the Department of Biotechnology is seeking to establish Biotech parks and incubators across the country. Coming together under the National Biotechnology Parks Scheme, this is also creating an ecosystem for start-ups that have graduated from incubators and are looking to scale up their R&D activities.

India's Life Sciences cluster



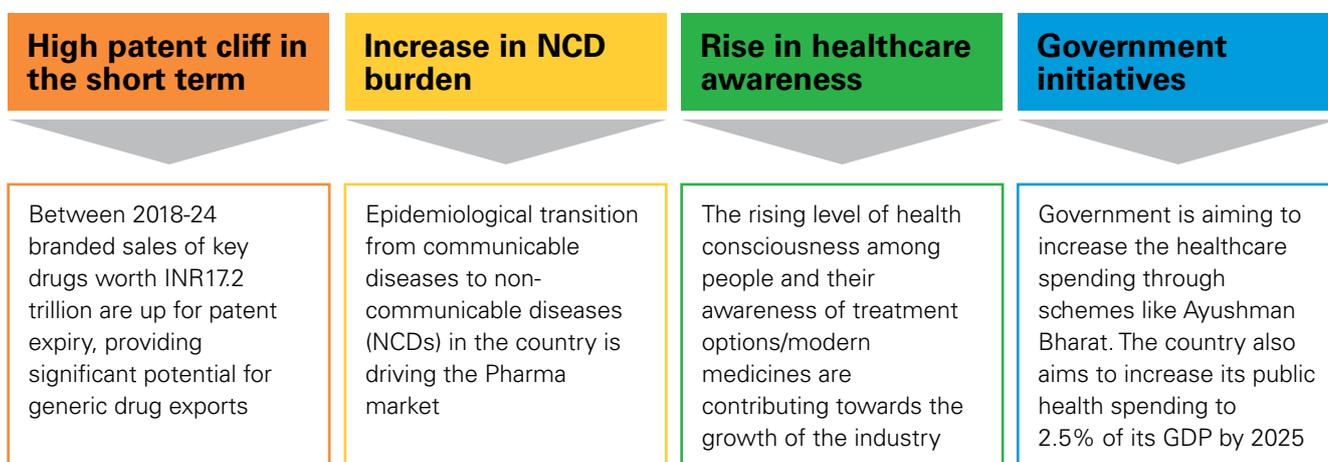
Over the past five decades, Indian Life Sciences has witnessed an exponential expansion in scope and capabilities along the value chain. Extensive measures are being taken at government, state and industry level to further enhance standards and encourage growth.

- **Reducing dependence on Active Pharmaceutical Ingredients (API) imports:** There have been calls for a more robust domestic industry. In March 2020, the government announced a USD1.3 billion fund to encourage the domestic manufacture of Pharma ingredients. This follows severe supply chain disruption

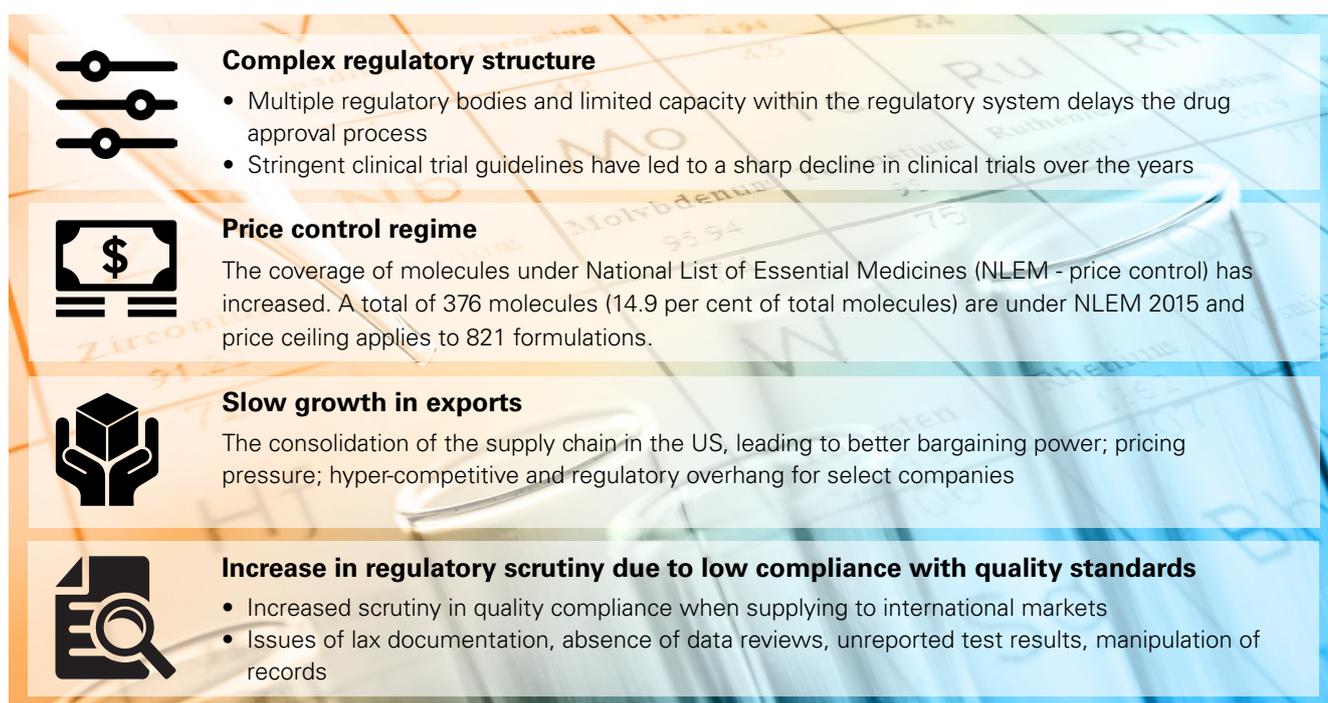
amid the coronavirus pandemic due to India's dependence on imports from abroad. Approximately 70 percent of India's API and 60 percent of penicillin are imported from other Asian countries.

- **Enhancing product liability:** Manufacturers and third-party marketing companies have been liable since 2018 for quality lapses identified by India's Central Drugs Standard Control Organisation (CDSCO). Further, manufacturers of the 300 best-selling brands must print a 14-digit alphanumeric code on the medicine pack together with a contact number. The Indian government is also planning to introduce mandatory barcoding for all drug manufacturers.

Key growth drivers



Key challenges



¹ India to spend \$1.3 billion to boost pharmaceutical production, The Economic Times of India, 22 March 2020

Pharma

India's Pharma market is currently worth USD41 billion, and is expected to be the world's ninth largest market by value by 2023². It is already among the leading global producers of cost-effective generic medicines and vaccines. India's FDA has mutual recognition agreements with 22 EU national drug regulators.

Traditionally focused on manufacturing APIs, many Pharma companies have moved aggressively up the value chain over the past 10-15 years into high potency and complex formulations. As global competition for investment intensifies, India's Pharma industry needs to continuously focus on developing capabilities that generate higher value products and services. Government policy supports this by encouraging collaboration between business and government.

The rise in group insurance schemes has meanwhile helped increase the health insurance penetration from around two percent in 2014 to around 5.4 percent in 2019. The e-pharmacy sector is also growing due to increased digitalization, the convenience of online shopping and the promotion of discounts – helping to secure patient access to prescriptions. In addition, around 4,000 Jan Aushadhi Kendras (outlets that made medicines available at affordable prices to the poor or disadvantaged) have opened across the country.

Biotech

India's Biotech companies have sought to align themselves to meet the rising global demand for biopharmaceuticals. Its manufacturers have a strong position in the international vaccines market, with affordable vaccines reaching over 200 countries.

The 'Make in India' initiative identifies Biotech as one of the country's key industries. In addition, the development of a National Biotechnology Development Strategy 2015-2020, creation of a robust Intellectual Property Rights (IPR) policy, and liberalized Foreign Direct Investment (FDI) norms are among the steps taken by the government to protect and grow the sector.

Medtech

India continues to develop its status as a global hub for the manufacture of medical devices, as the Indian market records solid growth despite a tougher stance on pricing for essential devices.

A comprehensive framework for medical devices, supported by the establishment of a National Medical Devices Promotion Council, should aid domestic manufacturing. Together with the 'Make in India' initiative, this will reduce the country's dependence on medical device imports, which continue to show strong growth despite the threat of further price controls.

The medical devices sector has historically been treated as a branch of the Pharma industry, in which foreign direct investment of 100 percent relating to brownfield investments has required government approval. FDI approval restrictions for medical devices are due to be removed. By doing so, the government hopes to encourage foreign investment in the sector and increase the market share of domestically produced products.

R&D and manufacturing operations

India represents a strong base for multinational Life Sciences businesses. While some have set up local manufacturing bases, most larger players have established local offices and a growing number are carrying out R&D tailored to the local market.

R&D operations

India has risen dramatically up the rankings of the Global Innovation Index, from 81st in 2015 to 52nd in 2019.³ This reflects the efforts being made to accelerate drug discovery and build a stronger research pipeline. This in turn is partly a response to expectations that the Indian government will remove price controls on drugs that use locally manufactured APIs.

Conducting clinical studies in India

Clinical trial approvals for drugs manufactured in India take 30, compared to 90 days for those manufactured outside of the country. A local clinical trial can be waived if the drugs are already approved or marketed in the EU, UK, Australia, Japan or the US.

India announced new rules for clinical trials in 2019 to speed up drug approvals and remove the need for large studies to test the efficacy of drugs that have already been approved in other countries. The new rules apply to all new drugs, clinical trials, and bioequivalence and bioavailability studies. They also aim to promote clinical research in India by implementing a time-bound review of applications, which should improve predictability, transparency and clarity over issues such as post-trial access.

² <https://www.pharmaceutical-technology.com/features/pharmaceutical-manufacturing-companies-in-india/>

³ <https://www.globalinnovationindex.org/gii-2019-report>

Incentives for setting up R&D operations

The Department of Biotechnology has established Biotech parks and incubators across India to help convert research into products and services. These parks offer facilities such as technology incubation, technology demonstration and pilot plant studies. The National Biotechnology Parks Scheme proposes the creation of an ecosystem for startups that have graduated from incubators to give them a platform for scaling up R&D activities in collaboration with state government and industry. A lack of adequate infrastructure remains a challenge, however, and most Biotech parks are not yet fully operational.

Manufacturing operations

Pharma manufacturers in India are one of the world's largest sources of generic drugs. Indian Pharma players have substantially expanded their presence in the generic drugs market, which is reflected in the growing number of entities seeking ANDA approvals, as well as tentative approvals from the US FDA. Mid-sized and small formulation manufacturers, which have traditionally resorted to contract manufacturing, have looked to tap the generic drugs opportunity in regulated markets.

- A huge influx of capital investment into manufacturing is helping Indian Life Sciences to remain cost competitive. Being fairly established in the southern and western regions, the northern region is witnessing investment and growth in its Pharma manufacturing capabilities. To boost the industry further, the Indian government has created a task force to address the challenges faced by domestic Pharma manufacturers.
- Telangana and Andhra Pradesh in the central south have the highest level of Pharma CMO manufacturing of any Indian state. Telangana is a Pharma hub that accounts for 35–40 percent of national Pharma production – this is likely to be strengthened by the completion of Hyderabad Pharma City in 2020. The state has 173 European Medicines Agency (EMA) and/or FDA-approved Pharma facilities. Most facilities in Telangana and Andhra Pradesh are owned by domestic Indian Pharma companies, with most offering small molecule API manufacturing.

Access to capital

The Pharma and healthcare sector recorded the second highest monthly value of private equity and venture capital investments in November 2019 at USD1.2 billion.

Established by the Department of Biotechnology, the Biotechnology Industry Research Assistance Council (BIRAC) is a not-for-profit public sector enterprise that helps to strengthen and empower emerging Biotech enterprises. It has launched the Biotechnology Ignition Grant (BIG) scheme to support early funding to Biotech start-ups.

Make in India

The 'Make in India' program is a progressive move to simplify regulations and eliminate those that are redundant. It has helped to substantially improve business sentiment, reinforcing India's image as a global manufacturing destination. The program is expected not only to attract global companies to set up manufacturing bases in India, but also to encourage domestic players to increase production capacity.

The manufacture of vaccines and biosimilars has been identified as a key opportunity area for Indian Biotech firms, owing to the country's strength in low-cost manufacturing and large pool of qualified personnel. The creation of a single nodal agency for approvals and a single broad expertise based technical committee to simplify clinical trial approvals could go a long way in securing the industry's future.

Majority shareholders interviewed by KPMG India perceive that the ease of doing business has improved and FDI flow has increased in the country following the launch of the initiative. Shareholders also believe the initiative has had a positive impact on investments in infrastructure and financial support for the sector.

Tax environment and incentives for Life Sciences companies

Recent tax reforms have produced significant changes to India's taxation landscape, including replacing multiple indirect tax laws into a single, uniform tax regime.

National tax incentives

In September 2019, the Indian government reduced the effective tax rate from 34.94%⁴ to 25.17%⁵ for companies that forego certain earlier tax exemptions and incentives.

- In addition, a domestic manufacturing company set up and registered on or after 1 October 2019, and that commences manufacturing on or before 31 March 2023, can opt for a concessionary tax rate of 17.16 percent⁶. They must similarly forego other tax exemptions or incentives.

The Indian Government also recently abolished the dividend distribution tax with effect from 1 April 2020 on declaration of dividends. Going forward, dividends will be subject to withholding tax (WHT).

Royalty income in respect of a patent developed and registered in India, earned by an eligible assessee⁷ is subject to a concessional tax rate of 10%⁸, subject to fulfilment of certain prescribed conditions.

To boost employment generation, a deduction of 30 percent of the cost of additional employees is available. This deduction is available for three years, subject to certain conditions and is dependent on an overall increase in the respective company's total number of employees.

State-level tax incentives

A number of states grant incentives to appeal to start-ups, including Gujarat, Telangana, Andhra Pradesh, and Karnataka.

Gujarat: Since 2016, the Gujarat government has aimed to establish 50 incubators to help up to 2,000 start-ups over the following five years. Start-ups receive an interest subsidy and marketing assistance, and potentially other incentives such as subsidies on product development and lease rental.

Telangana: The country's youngest state is looking to become a start-up haven. It plans to bring on board 20 global accelerators and incubators to build plug-and-play workspaces in public-private partnership. It has also made separate provision for seed funding.

Andhra Pradesh: As well as an Initial Innovation Fund for entrepreneurs, the state is setting up a joint incubation center and smart city innovation hub in the city of Kakinada in association with China's ZTESoft.

Karnataka: This state is looking to make incubators part of selected colleges and is offering tax incentives and a reimbursement of some international marketing costs. Under state government rules, a start-up should be technology-based, registered in Karnataka and employing half of its total qualified workforce in Karnataka. In addition, the Karnataka Information Technology Fund will support start-ups by matching funds raised by the incubators from central government.

⁴ 30% tax + surcharge 12% on tax + education cess 4% on tax and surcharge

⁵ 22% tax + surcharge 10% on tax + education cess 4% on tax and surcharge

⁶ 15% tax + surcharge 10% on tax + education cess 4% on tax and surcharge

⁷ An eligible assessee means a person resident in India, who is the true and first inventor of the invention, and whose name is entered on the patent register as the patentee in accordance with Patent Act, 1970.

⁸ plus applicable surcharge and cess





China

Why China – in a nutshell

China is the world's second-largest drug market and the world's largest single payer system, with healthcare spending approaching USD1 trillion at around six percent of nominal GDP. Committed to reforming the healthcare market, the government has set a target to provide affordable and effective healthcare for all its citizens, and to develop its domestic Life Sciences industry to deliver higher quality products and services. Reforms center on reducing drug prices, accelerating the approval process for new drugs, channeling more funding into R&D, and allowing market forces to play a greater role in pricing and the promotion of innovative medicines.

Industry growth and development requires greater levels of manpower, however. The government is providing considerable financial incentives including relocation costs, salaries and start-up funding to encourage Chinese researchers to return home after training abroad. Several government programs are also actively recruiting leading foreign researchers from the US and elsewhere.

As in other Asian countries, there is a move to develop innovation hubs to reinforce a startup and innovation ecosystem. These include the construction of a system of national and provincial government-funded Biotech parks.

China's Life Sciences cluster

The Chinese government's aim to reduce its citizens' personal spend on healthcare may provide opportunities for domestic and international Life Sciences players. Chinese companies are developing increasingly innovative treatments, and new drug approval processes were introduced in 2015 based on those of the US. Since 2017, foreign clinical trials have been enough to secure Chinese approval, as regulatory oversight of clinical trials moves closer to Western norms.

Clinical trials may be waived through special approval for new foreign drugs that are deemed clinically urgent. In some cases, clinical trial applications are being reduced from six to three months.

Since launching its major healthcare reform and pledging to provide all citizens with equal access to basic healthcare of a reasonable quality, the government has quadrupled its health funding.

- In the past ten years, China has made substantial efforts to improve equal access to care and enhance financial protection, especially for people of a lower socioeconomic status. However, gaps remain in quality of care, control of non-communicable diseases, efficiency in delivery, control of health expenditures, and public satisfaction.

Centralized procurement is playing its part in reducing expenditure:

- It is estimated that the 24+7 centralized drug procurement program helps China save 10-19 percent of its total drug spend on at least 25 generic drugs. The program is being rolled out in cities across all provinces in 2020.
- The centralized purchase of high-value medical consumables is being trialed in Jiangsu and Anhui, where it is cited to have achieved significant price reductions for orthopedic implants, CV stents, intraocular lenses and pacemakers in Anhui.

Pharma

China's Pharma sector is estimated to be worth EUR126-153 billion by 2022.⁹ In 2019, 21 of the top 500 companies in China were Pharma companies.¹⁰

Around 97 percent of drugs sold by local Chinese manufacturers are generic. Foreign companies supply almost all innovator (patent protected) products. Traditional Chinese Medicines (TCM) are a significant feature in the domestic market, and are promoted as an export opportunity.

China has a large untapped oncology and infectious disease market compared to other global markets. There is significant demand for innovative cancer therapies, with the result that many start-ups are focused on R&D immune-oncology and CAR-T cell therapies.

⁹ [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(19\)32136-1/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(19)32136-1/fulltext)

¹⁰ http://www.fortunechina.com/fortune500/c/2019-07/10/content_337536.htm

Complementing Chinese government initiatives, foreign Pharma companies are actively constructing incubators in China for new product development.

Biotech

Biotech's development in China used to be largely due to inward FDI. This has changed over the past decade, with it now being characterized by two-way flows including in greenfield investments and venture capital.

Chinese biopharmaceutical companies are responsible for some innovative biologics using cutting-edge technologies such as Chimeric Antigen Receptor T-cell therapy (CAR-T), which can be used to treat cancer.

The government is pursuing a long-term strategy to become a Biotech leader, creating domestic firms that can be globally competitive, and incentivizing the relocation of Biotech manufacturing, design, and operations to China. Biotech has been named a Strategic Emerging Industry, with its development being prioritized by initiatives such as Made in China 2025 and the 13th Five Year Plan. The government is providing further support through R&D programs such as the 863 Program and through investment in infrastructure, the development of research parks, and the recruitment of overseas talent.

Medtech

China is actively encouraging the application of AI to improve productivity and deliver high quality care. It is used across care services, diagnosis and treatment, and health management through wearable devices. Medtech is being promoted through incentives for foreign investment and simpler registration.

- From August 2018 the Medical Device Classification Catalogue has simplified registration for device manufacturers through by the perceived risk levels of 40 types of devices.
- The 2017 Catalogue of Industries for Guiding Foreign Investment added 'intelligent medical rescue devices' to the 'encouraged' category to promote foreign investment by way of reduced taxes and streamlined administration.

Medical device companies are being encouraged to provide innovative diagnostic products at entry-level price points to penetrate rural markets, with the market growing as a consequence.

Universities and technology transfer programs

As Chinese industry moves up the value chain, demand for skilled labor has increased dramatically. The result is an acute skills shortage, which is exacerbated by an aging population and shrinking workforce.

- To attract more highly skilled talent from abroad, China has begun to relax its immigration rules. Twelve new policies aim to attract foreign talent, outstanding youths and overseas Chinese to innovate, start businesses, study and work in China. The policies have been gradually implemented in free trade zones in 16 provinces and municipalities since 2015, including Shanghai, Beijing and Fujian province.
- The city of Shenzhen, for example, has implemented preferential policies and subsidies to attract high-level foreign talent, with a particular focus on Biotech. Measures include simplifying business registration, subsidizing foreigners by up to RMB3 million (around USD450,000) and supporting innovation and start-ups through awards of up to USD15 million¹¹.

Around 250,000 Chinese have returned home since 2013 to work in Life Sciences¹². Science graduates, including returnees from top foreign universities and Big Pharma labs are sharpening its edge in medical innovation.

R&D and manufacturing operations

R&D operations

The Chinese government is encouraging R&D, particularly in Biotech, to develop capacity in biosimilars. Substantial FDI in R&D is also being seen. Foreign companies appear willing to license technologies to Chinese firms and research institutes, thanks in part to the size and dynamism of China's Pharma market.

Two programs are among those being used to promote domestic R&D:

- Made in China 2025. Not specific to Life Sciences, this initiative was launched in 2015 as part of the government's strategy to move the country up the value chain.
- Healthy China 2030. An action plan announced in 2019 sets out 15 goals to be achieved this decade. The plan focuses on promoting public health and disease prevention as a means of moving from treatment to prevention and reducing healthcare needs.

¹¹ <https://www.china-briefing.com/news/incentives-shenzhen-attracting-foreign-talent/>

¹² The Economist, 28 September 2019

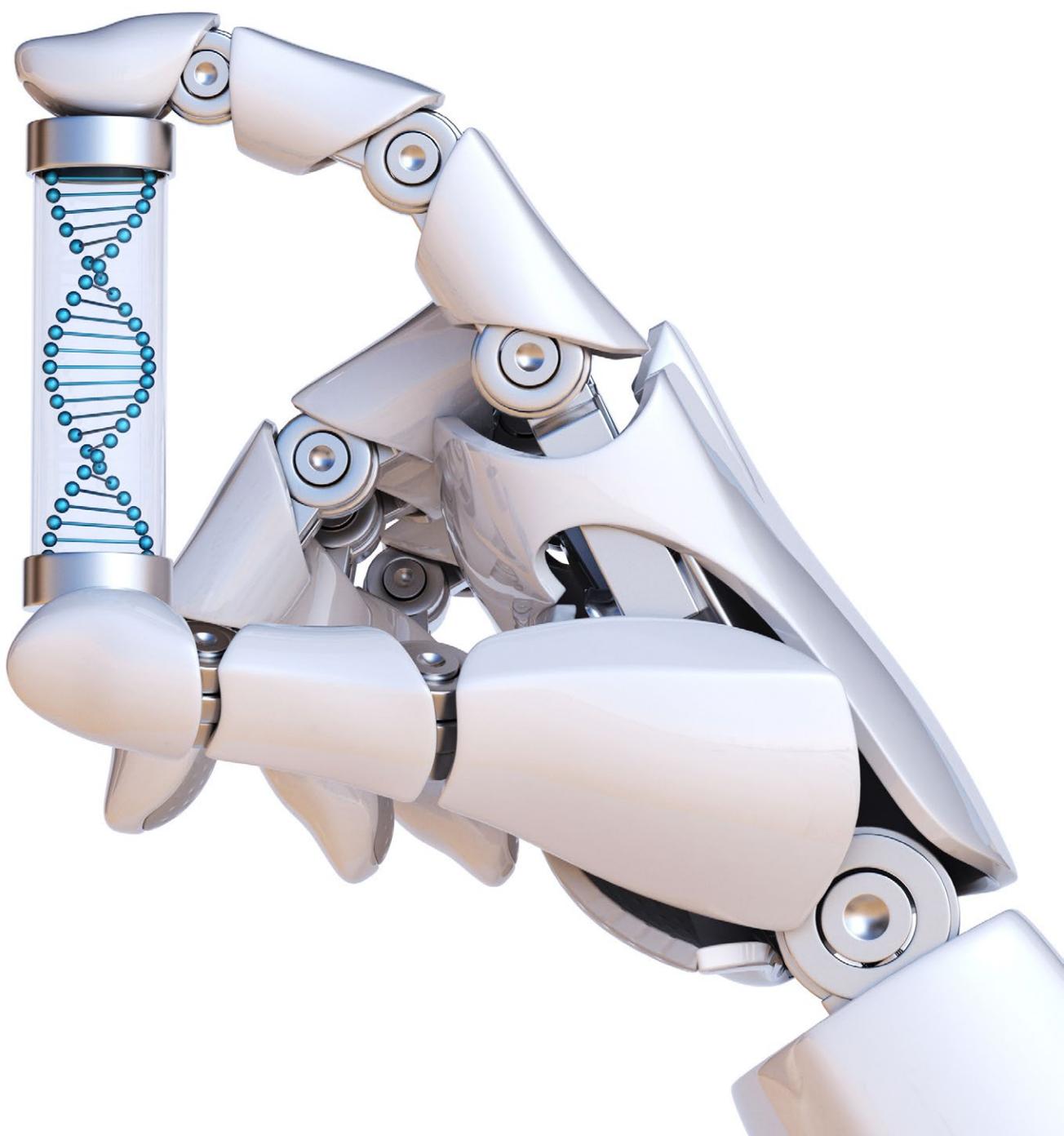
Biotechnology parks and incubator programs

At both national and provincial levels, China's government has invested in the construction of biotechnology parks with the aim of developing major innovation hubs. However, because significant funding has generated a large number of parks and because these parks are geographically dispersed, this results in sub-optimal cluster sizes that would be helpful for collaboration and innovation. In terms of private enterprise, a number of international Pharma groups have set up incubator programs to promote new product development utilizing digitalization and surgical robotics, in areas ranging from diabetes and obesity to lung tumors and kidney diseases.

Opportunities and regulatory requirements for conducting clinical studies in China

There are a number of advantages of conducting clinical trials in China. These include a large patient pool, a homogeneous population, and the existence of more than 100,000 hospitals, clinics and independent outpatient clinics.

Until recently, drugs marketed outside China required full clinical trial data generated in China in order to be approved. Multinational corporations, even those with Chinese ownership, needed to run a separate set of trials for approval to market the drug within China. Chinese companies could not make generic drugs without



performing clinical trials. In the past few years, however, China has reformed its regulatory process to make the approval of imported and new drugs less onerous.

- In February 2016, China's FDA created a new drug classification scheme that includes priority review status for certain innovative drugs, reducing review times to six months. Priority reviews include innovative drugs not approved anywhere else in the world; innovative drugs where the manufacturing site will be transferred to China; global clinical trial applications in parallel with the US or EU; innovative drugs for HIV/AIDS, viral hepatitis, and rare diseases; and newly launched generic drugs.
- In March 2017, China further loosened restrictions by allowing Chinese-produced generics as well as imported innovator drugs to apply for approval without the need for full clinical trials performed within China¹³.

It should be noted that Chinese legislation prevents human samples from being exported from China.

Manufacturing operations

All of the world's leading 20 Pharma companies have manufacturing facilities in China, with many having also established R&D centers in the country¹⁴.

Chinese Pharma manufacturers have until recently concentrated on producing basic chemicals, intermediates and APIs. In a relatively short period, China has become the leading global supplier of APIs by volume. Strict new regulatory standards are being applied to the API manufacturing sector which, while having the potential to raise quality, is causing supply chain issues.



A number of developments are being observed in China's Life Sciences manufacturing:

- Prior to 2016, domestic drug developers were not allowed to use contract manufacturing services; CMOs would only serve foreign customers. In 2016, China introduced the Marketing Authorization Holder (MAH) system, a regulatory change that enabled domestic biologics developers to make use of CMO services. This rapidly expanded the CMO market.
- China is a major API and intermediate manufacturer for the global drug industry and heavily influences other Asian manufacturing markets. Significant investment is taking place to upgrade facilities' GMP levels.

Chinese Life Sciences manufacturing can be analyzed by region:

- Eastern China is more developed and focuses on small molecule API manufacture, while Southern China is more involved in biologics.
- Zhejiang has the most facilities that export to the US and EU.
- Shanghai has a heavy international public Pharma presence, with manufacturing facilities and international contract manufacturers.
- Just south of Shanghai, Zhejiang has long had a reputation for its entrepreneurial spirit. Its capital, Hangzhou, houses facilities for a number of multinationals, though most are owned by domestic Chinese companies.

Environmental protection considerations

Chinese environmental regulations are likely to become ever stronger. Foreign companies seeking low-cost manufacturing need to carefully consider when aligning with manufacturing partners. Appropriate due diligence is a must in avoiding such risks.

Faced with new environmental and regulatory restrictions, some Chinese API manufacturers are exploring moving some production activities outside China, such as to low labor-cost countries in Southeast Asia.

Made in China 2025

Made in China 2025 is a strategic government plan announced in 2015. Its aim is for China to become a driving force in high-tech and high-value industries, including biopharma and medical technologies. The Chinese government has invested billions of dollars into biopharma, as well as seeking to attract overseas-educated Chinese to return home. Estimates put the number of Life Sciences professionals who have returned at 250,000¹⁵.

Tax environment and incentives for Life Sciences companies

High New Technology industries (HNTE) status

This national policy is open to locally-resident Biotech and new medicine companies:

- IP technology must be registered in China and the company must meet minimum personnel, R&D expenses, revenue requirements and enterprise innovation indicators.
- The status can provide a reduced corporate income tax rate of 15 percent, rather than the standard 25 percent, for three consecutive years.

R&D tax super deduction

Including HNTE-certified companies, this nation-wide incentive has been in place for more than ten years and allows for a 175 percent tax deduction on qualifying R&D expenses.

Advanced Service Enterprise (ATSE) status

Chinese companies that provide qualified R&D outsourcing services to overseas business can be eligible for ATSE status.

- A reduced corporate income tax of 15 percent, rather than the standard 25 percent, may be applied, and training fees of up to eight percent of total salaries deducted for corporate income tax purposes.

VAT zero rate /VAT exemption

A zero rate VAT or exemption applies to companies that provide R&D services to overseas businesses.

Technology transfer income

For Chinese-resident companies with eligible technology transfer income, an element of this income is exempt from corporate income tax. Reduced rates are available as income increases.

Financial subsidies

Financial subsidies may be granted by local governments based on the company's local tax revenue contribution. They are typically agreed informally on a case-by-case basis.

¹³ An overview of major reforms in China's regulatory environment, Wang and Davidson

¹⁴ <https://www.who.int/phi/publications/2081China020517.pdf>

¹⁵ <https://www.genengnews.com/a-lists/top-10-asia-biopharma-clusters-2018/>

Clinical trial applications: Comparing China and the EU

Clinical trials are necessary to confirm the safety and efficacy of any new medicinal product prior to market launch. Yet, the procedures and timelines involved in clinical trial applications (CTAs) can vary significantly between jurisdictions. In addition, companies must consider during early stage development which markets may represent the highest value for the drug in question. Where to submit a CTA is therefore a key factor in site selection.

Taking the EU and China as examples, their policy objectives vary considerably and can impact businesses' thinking. Harmonization is central to the EU's principles, for instance. This translates into a single overarching legislation, Directive 2001/20/EC, which will be replaced shortly by EU Clinical Trial Regulation No. 536/2014. Applicable in every EU Member State, the new regulation is extremely detailed and aims to harmonize application procedures across the EU as well as enhancing transparency over trial information.

China, by contrast, is a highly dynamic environment that continues to develop at speed. Unlike in the EU, no single regulation governs clinical trials. Many administrative regulations are announced and supplemented by the State Council (SC) and departments below it. Regulations are updated frequently, with no official translation available in English. These factors add to the complexity of identifying and understanding the relevant information. It should be noted, however, that regulatory changes are usually intended to resolve problems and effect improvements. Since 2015, for example, bioequivalence studies of generic drugs need only be filed instead of reviewed – helping to clear severe CTA backlogs. And revisions to the Drug

Administration Law of the People's Republic of China were approved on 27 August 2019. These implement a range of helpful measures such as the Market Authorization Holder (MAH) system and priority review, bringing China's Pharma industry closer to international standards.

CTA procedures: the same pathway

The overall procedure for CTAs is similar for both China and the EU:

- Approval should be obtained prior to the trial
- The CTA is reviewed by both the competent authority (CA) and ethics committee (EC) / institutional review board (IRB)
- The humanity and interest of participants are protected and prevail
- Internationally accepted ethical principles are obeyed
- The trial must be stopped if unexpected serious adverse events occur, and therapeutic measures must be taken
- Substantial modifications require approval before being implemented
- Accelerated review or conditional approval is available and encouraged under some circumstances, such as orphan drugs and drugs of urgent medical need.

Timelines and procedures for the review of initial CTAs are as follows:

	China – working days		EU – calendar days	
	Maximum duration	If query, maximum extension	Maximum duration	If query, maximum extension
Validation	5 days	5 days	10 days	15 days
Assessment	55 days	Not defined	45 days	31 days
Decision		–	5 days	–

Source: EU Clinical Trial Regulation No. 536/2014 and the Drug Administration Law of People's Republic of China (2019)

In both China and the EU, a tacit approval is granted if no query is raised within 60 days (working days in China or calendar days in the EU) after receipt of application. The assessment time for advanced therapy and biologics is longer.

Some variations exist

Although CTA procedures in China and the EU have many commonalities, there are different requirements to be aware of when considering submitting a CTA. In the EU, the review by the CA and EC happens in parallel, while in China the approval from the CA is prior to the EC's review. While site qualification is a key issue that is reviewed by the EC in the EU, clinical trials in China can only be conducted at selected sites that are qualified by the state and therefore do not require review. There are many other variations, not all of which can be listed here. The support of a local expert can help a sponsor meet geography-specific requirements.

Conducting multiregional clinical trials (MRCTs) is encouraged in both China and the EU and is governed by national regulations as well as international guidelines. Given the improvements taking place to China's legal framework for the Pharma industry and healthcare environment, the choice between China and the EU is less

clear cut than it perhaps used to be. Patients and Life Sciences companies may both benefit from being able to carry out clinical trials simultaneously in China, the EU, and indeed the US. This propels China to the top table when making location decisions for early stage drug development.

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Dr. Regenold GmbH, based in Germany and founded in 1994, specializes in development, regulatory and market access for pharmaceuticals, dietary supplements, cosmetics and biocides. Since its inception, the company has helped many clients progress their product developments by providing scientific and regulatory advice through to gaining regulatory approval and marketing authorization internationally. www.regenold.com

In 2001 Dr. Regenold founded regulanet®, a global network of regulatory affairs professionals with representation in over 90 countries.





Hong Kong SAR

Why Hong Kong – in a nutshell

A renowned financial hub, in 2019 Hong Kong was the world's number one center for IPOs and second-largest for Biotech fundraising.

Its close proximity to mainland China, and growing compatibility with the mainland in areas such as data use for new drug applications, make Hong Kong a natural choice for Life Sciences companies looking to expand in the Chinese market. A series of measures aim to encourage start-ups to use Hong Kong as a bridge to the Chinese market and vice versa. And Hong Kong's location close to markets across Southeast Asia is a driver behind the large number of multinationals that coordinate their regional activities from offices in Hong Kong.

An efficient healthcare center with world-class clinical trial centers and robust IP protection meanwhile make Hong Kong an attractive market in its own right. The territory is seeking to strengthen its position as a Biotech hub: it has designated Biotech a focus sector, has recently relaxed its listing rules, and actively promotes R&D through a range of grants and schemes as well as through incubator hubs to support startups and medium-sized businesses.

Hong Kong's Life Sciences cluster

There are around 250-300 Biotech-related companies in Hong Kong – mainly healthcare businesses in Pharma, medical or healthcare products of traditional Chinese medicine origin, and medical devices and diagnostics.

The medical and healthcare equipment industry contains two distinct markets: household consumer, and professional or institutional (hospitals and clinics). Most companies in Hong Kong are engaged in the OEM business, such as producing massagers and blood pressure monitors for household consumer use, and rubber molding, plastics/resins for institutional use.

To lower production costs, many Hong Kong manufacturers have relocated their production facilities to the Chinese mainland, most of which manufacture mechano-therapy appliances and massage apparatus. However, quality control, marketing, research and development, design, as well as material and equipment procurement continue to be carried out in Hong Kong¹⁶.

Biotech

Alongside artificial intelligence, smart city and financial technologies, Biotech has been identified as one of the four areas of strength for development in Hong Kong, and expenditure on R&D is expected to double as a percentage of GDP in the five years from 2017¹⁷.

The government has introduced various initiatives to encourage further development, including:

- Opening government data to a healthcare data platform: Hong Kong's Hospital Authority is one of the important data sources, with a database of more than 280 terabytes of patient data. It will establish a big data analytics platform to stimulate Biotech research. It has recently set up a data collaboration laboratory on a pilot basis, offering more flexible and interactive data sharing.
- Focusing on the development of genomic medicine: Hong Kong's government has allocated about HKD1.2 billion to the Hong Kong Genome Project, which aims to undertake 40,000-50,000 whole genome sequencing in the six years following its announcement in mid-2019.

R&D capabilities and access to talent

R&D in Hong Kong is fueled by universities, international research organizations, and government-funded support programs. Many of its universities have Life Sciences departments with Biotech-oriented research institutes, centers and programs.

- Hong Kong's universities are also home to Partner State Key Laboratories (PSKLs) - national science and technology development schemes managed by China's Ministry of Science and Technology. PSKLs are laboratories in Hong Kong that are R&D partners of state laboratories in mainland China to carry out R&D, develop researchers, and facilitate collaboration.
- It is estimated that Hong Kong universities produce around 250 high impact biomedical publications each year. The territory has been a key contributor to international,

¹⁶ <https://research.hktdc.com/en/article/MzEzOTQ1MjMz>

¹⁷ <https://hkmb.hktdc.com/en/1X09U6YK/hktdc-research/Innovation-and-Technology-Industry-in-Hong-Kong>

large-scale genomic projects, as well as identifying and characterizing emerging infectious diseases such as SARS and avian flu virus

- The government has committed HKD800 over five years for applied R&D, funding technology transfer offices of designated universities, the Technology Start-up Support Scheme for Universities, State Key Laboratories and Hong Kong branches of the Chinese National Engineering Research Centers.

Research institutes

The Karolinska Institutet Ming Wai Lau Centre for Reparative Medicine was set up following discussions between the Hong Kong government and the Karolinska Institutet. It is the first overseas research branch of Sweden's leading medical university. Established in 2016, it seeks to accelerate research in stem cell biology, biomedical engineering, biotechnology and regenerative medicine. Its opening marked a milestone of collaboration between Hong Kong and Sweden in the field of medical sciences, and enhances Hong Kong's ambition to become a regional hub for medical research.

The Guangzhou Institute of Biomedicine and Health set up a stem cell and regenerative medicine research center at the Hong Kong Science Park in 2017. The research center focuses on enhancing innovation and technology as part of the Greater Bay Area.

The Chinese Academy of Sciences established an affiliate institution in Hong Kong to focus on stem cell research and to promote the transfer of scientific research results, and improve coordination between the academy and local universities.

The Hong Kong Science and Technology Park (HKSTP)

This public corporation was established by the Hong Kong Government in 2001 to foster the development of innovation and technology in Hong Kong. It hosts:

- Incu-Bio, a four-year program to provide business support, networking connections, financial aid and laboratory facilities.
- A number of facilities and services including the Biomedical Technology Support Centre, the Healthcare Devices Innovation Hub, the Chemical Co-Working Centre, Biobank, GMP Facilities (Cell Processing), and the Biomedical Informatics Platform.

HKSTP signed an agreement in 2012 with the Guangzhou Development District to establish a 'Green Channel' to facilitate biological specimen transfer between businesses in the two locations. This is seen as a significant administrative simplification that will support Hong Kong's efforts to become Asia's Biotech hub.

The Hong Kong government has also provided HKD10 billion to establish two innovative clusters in HKSTP. One of these is Health@InnoHK, which aims to attract mainland and overseas universities, scientific research institutions and businesses to carry out R&D in Hong Kong, with a particular focus on healthcare technologies.

Clinical trials and commercialization

Clinical trials are regulated by Hong Kong's Department of Health (DH).

- A Certificate for Clinical Trial/Medicinal Test is needed to conduct a clinical trial on a human being, with the issuing body being the Pharmacy and Poisons Board of Hong Kong. Applicants must receive approval from the hospital's Ethics Committee (EC) before applying.
- The approval timeline in Hong Kong for medical devices and Pharma is rapid.

Supported by mainland Chinese authorities, the DH has put in place various measures to promote Hong Kong as a clinical trial hub.

- China's NMPA recognizes data of clinical trials in more than 30 specialties at the Queen Mary Hospital, the Prince of Wales Hospital, the Hong Kong Eye Hospital and the Hong Kong Sanatorium & Hospital for the purpose of drug registration in China.
- Hong Kong thereby serves as a platform for local and multinational Pharma companies for the Chinese market.

While Hong Kong does not follow the same clinical trial regulations as mainland China for medical devices or Pharma, Hong Kong data can be used to submit new drug applications to China's FDA.

Access to capital/stock exchanges

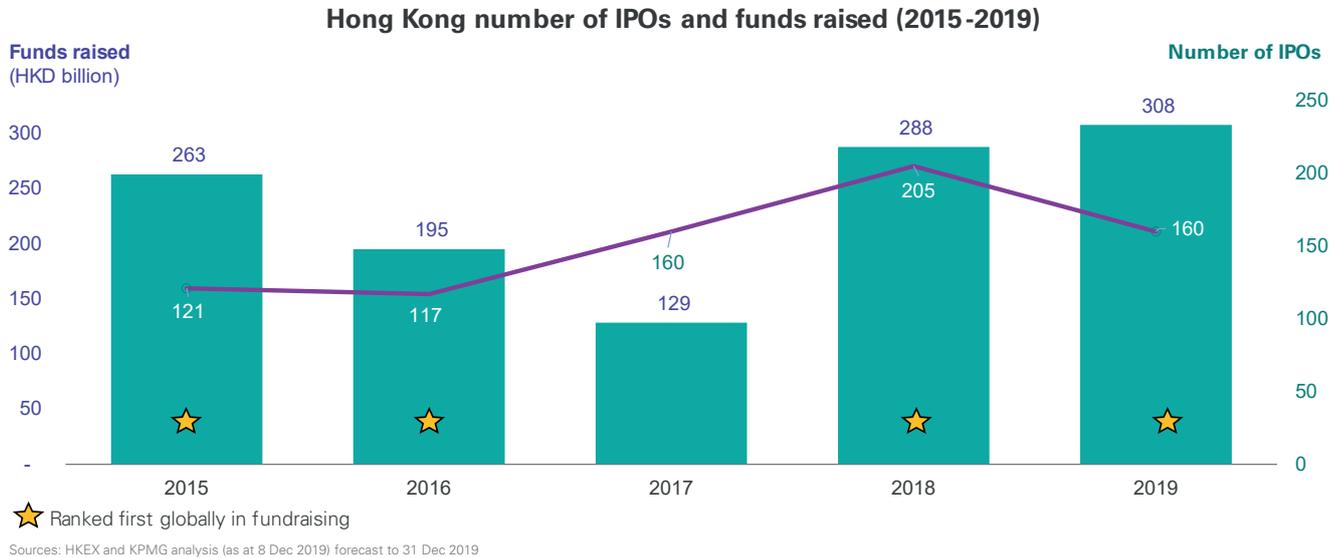
Hong Kong's IPO market ranked first in the world in terms of total funds raised in four of the five years in 2015–2019. 160 IPOs were completed in Hong Kong in 2019, raising a total of HKD307.8 billion. This included a historical high of 145 new Main Board listings.¹⁸

Hong Kong's position as a capital markets hub was strengthened further through the introduction of Chapter 18A in April 2018, which enables pre-revenue/profit biotech companies to list on the Hong Kong Stock Exchange. Since this introduction, 16 Biotech companies have listed on the

¹⁸ <https://home.kpmg/cn/en/home/insights/2019/12/china-hk-ipo-2019-review-and-outlook-for-2020.html?>

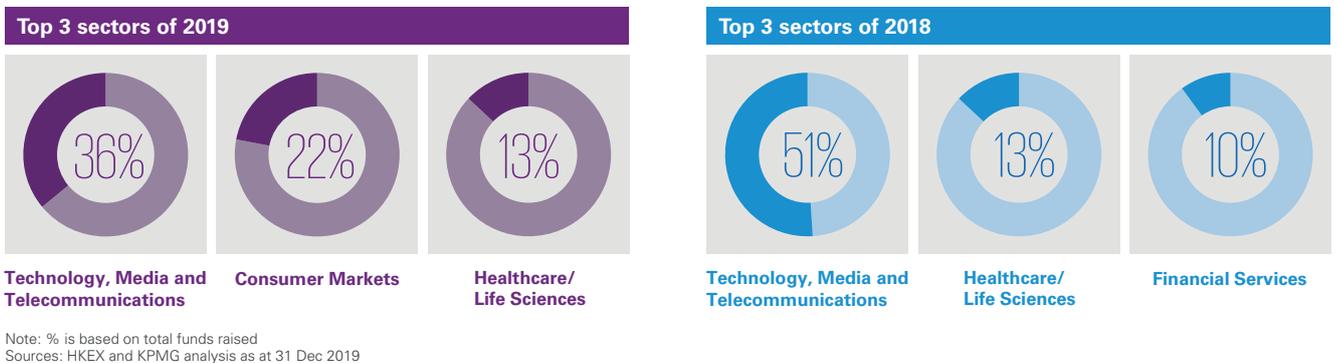
Hong Kong IPO market activity

The **Hong Kong IPO market has ranked first globally** in terms of total funds raised four of the last five years

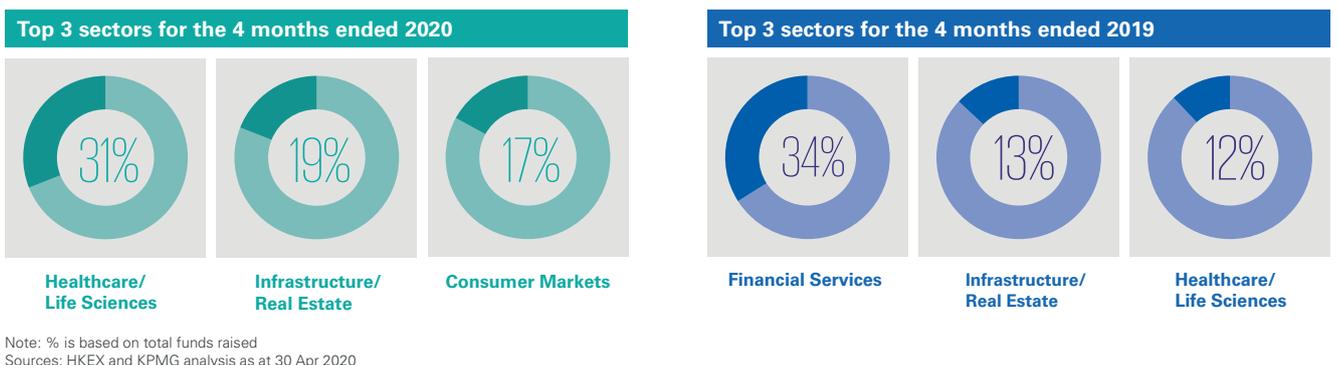


Sector distribution: Hong Kong top 3

The Hong Kong IPO market continues to be driven by several mega-sized listings, while Healthcare / Life Sciences remains a primary driver.



Healthcare/Life Sciences leads the market in terms of fund raised for the first four months of 2020.



Chapter 18A listings

Company	Listing Date	Funds Raised (USD mn)
Asclepis Pharma Inc.	01.08.2018	404.89
BeiGene, Ltd.	08.08.2018	914.17
Hua Medicine	14.09.2018	115.10
Innovent Biologics, Inc.	31.10.2018	490.30
Shanghai Junshi Biosciences Co., Ltd - H Shares	24.12.2018	456.98
Cstone Pharmaceuticals	26.02.2019	331.90
CanSino Biologics Inc. - H Shares	28.03.2019	175.15
Mabpharm Limited	31.05.2019	151.66
Shanghai Henlius Biotech, Inc. - H Shares	25.09.2019	442.00
Ascentage Pharma Group International	28.10.2019	61.82
TOT Biopharm International Company Limited	08.11.2019	76.06
SinoMab BioScience Limited	12.11.2019	178.60
Venus Medtech (Hangzhou) Inc. - H Shares	10.12.2019	384.58
Alphamab Oncology	12.12.2019	271.53
InnoCare Pharma Limited	23.03.2020	332.45
Akeso, Inc.	24.04.2020	332.98
Total raised:		5,120.17

Source: HKEX

Main Board, raising a total of HKD53.5 billion in total as of September 2019¹⁹. Among these, nine pre-revenue Biotech firms listed through the Listing Rules Chapter 18A, raising HKD26.8 billion.

Tax environment and incentives for Life Sciences companies

Taxation

Hong Kong does not levy any sales tax or VAT, withholding tax (except for royalties), capital gains tax, tax on dividends, or estate tax. Rather, its taxes center on a salaries tax (capped at a standard rate of 15 percent), property tax of 15 percent, and corporation tax.

- For corporation tax, the first HKD2 million profits are taxed at 8.25 percent, and any excess is subject to 16.5 percent.
- A two-tiered tax rate exists for unincorporated businesses such as partnerships and sole proprietorships, at 7.5 and 15 percent.

Hong Kong pursues a strong free trade policy. It has free port status and straightforward customs procedures.

Incentives

Enhanced tax deductions are available for qualifying R&D expenditure. These include:

- A 300 percent deduction for the first HKD2 million and 200 percent on amounts exceeding HKD2 million.
- The potential non-qualifying expenditure is subject to a 100 percent deduction. Qualifying expenditure includes direct employee costs and consumables, as well as payments to designated local research institutions.

A range of funding programs and schemes are available to private Biotech companies that are looking to carry out research in collaboration with local public research institutes and R&D centers. Grants are available through:

- The Innovation and Technology Support Program (ITSP), of up to 90 percent of total R&D projects costs for platform projects, and HKD1.4-2.8 million for seed projects.
- The Guangdong – Hong Kong Technology Cooperating Funding Scheme (TCFS), of up to 90 percent of the R&D project, with a specific focus on collaboration between Hong Kong and Guangdong / Shenzhen.
- The Partnership Research Program (PRP), of up to 50 percent of the R&D project.

Further grants are available through:

- The Midstream Research Program for Universities (MRP) of HKD5-10 million, to encourage universities to conduct more midstream research.
- The Enterprise Support Scheme (ESS) of up to HKD10 million to encourage private sector investment in R&D.
- The Research Program, which assists with talent compensation to enable organizations undertaking R&D funded by the Innovation and Technology Fund to recruit graduates from local universities to support R&D.

¹⁹ <https://www.hkex.com.hk/-/media/HKEX-Market/Listing/Getting-Started/Biotech-Newsletter/HKEX-Biotech-Newsletter-Issue-2-EN.pdf>

²⁰ <https://www.scmp.com/news/hong-kong/education/article/2146677/hong-kong-faces-challenge-how-manage-its-ageing-population>



Key trends and opportunities

Aging population

The number of people aged 65 or older in Hong Kong is expected to reach 2.6 million by 2064, almost 36 percent of the population. The workforce, aged 15 to 64, will meanwhile shrink to 3.9 million, or just under 55 percent of the population.²⁰

- This should give rise to rapid growth in treatments for cardiopulmonary disease, diabetes and neurological disorders, as well as a quest for enhanced treatments. This is one of the driving forces behind the government's allocation of HKD1.2 billion in the Hong Kong Genome Project, mentioned earlier.
- A greater awareness of personal wellbeing is also boosting demand for home-based or self-care equipment.

Creating a Greater Bay Area powerhouse

The Greater Bay Area (GBA)'s goal is to combine Hong Kong, Macau and the cities of Guangdong's Pearl River Delta into a region with an economic might that is comparable to the San Francisco Bay Area, Greater New York or Greater Tokyo.

- It aims to do so by improving cooperation in the region, including identifying its constituent cities' core competitive advantages and exploring how they might complement each other.
- One focus is on producing high quality medical and health resources, and optimizing innovation in order to grow new strategic industries around biomedicine, high-end medical equipment, and DNA genetic testing.

As China's leading Pharma province, Guangdong is encouraging local enterprises to develop new-generation biomedicines in the hope of providing more effective medical diagnosis and treatment through more advanced technologies. However, industry players are not only in need of the necessary technologies, but also the talent, clinical test resources, and sustainable financial arrangements to proceed effectively.

Hong Kong has a reputable medical-services system and an extremely strong Biotech cluster. Medical, equipment and diagnostic tools have generally been granted approval and certification by the relevant supervisory institutions in areas such as the US and EU. Hong Kong therefore has a role to play in the GBA by connecting with foreign partners and developing an international Biotech development hub.

Going public in Asia: a shifting Life Sciences landscape

For this report, 457 publicly-listed Life Sciences companies that are headquartered in China, Hong Kong SAR, India and Singapore have been analyzed. They found clear trends in companies' choice of listing jurisdiction. But which sectors have carried out most IPOs over the past decade, and how are regulatory and other initiatives impacting where Life Sciences choose to list?

Of the 457 companies analyzed, activities are weighted heavily towards Pharma and Biotech. Medtech and Healthtech make up the balance of around ten percent, though there are signs this might be changing.

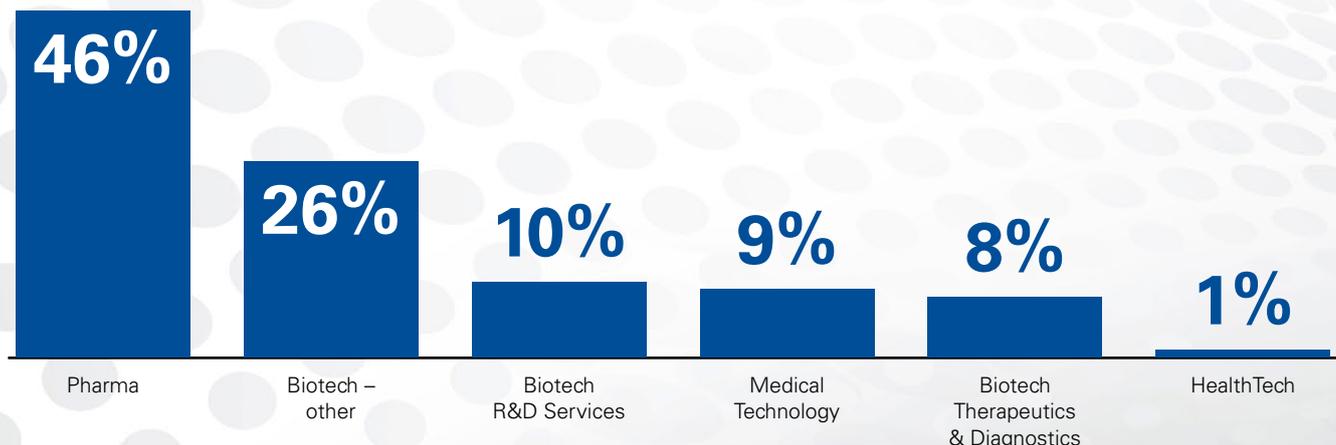
Mainland China and India are home to more than 90 percent of public Life Sciences businesses, though the sector focus between these countries differs significantly. More Biotech companies than Pharma companies are listed in mainland China, while the opposite is the case in India.

Number of public companies in Life Sciences

	Pharma	Biotech Therapeutics & Diagnostics	Biotech other	Biotech R&D Services	Medical Technology	HealthTech	Total
China (Mainland)	130	24	87	23	37	4	305
Hong Kong	14	5	8	1	2	0	30
India	62	4	21	21	1	0	109
Singapore	3	3	2	1	3	1	13
Total	209	36	118	46	43	5	457

Source: Biotechgate / Venture Valuation

Primary activities of public Life Sciences companies in Asia



China leads IPO activity over the past decade

Value and number of IPOs of Life Science companies, 2010-2019

		Pharma	Biotech Therapeutics & Diagnostics	Biotech other	Biotech R&D Services	Medical Technology	HealthTech	Total
China (Mainland)	Number of rounds	54	17	35	20	26	2	154
	Total capital raised (USDm)	8,396	5,147	4,359	2,497	1,228	1,200	24,248
Hong Kong	Number of rounds	3	4	4	0	0	0	11
	IPO financing (USDm)	2,093	347	266	0	0	0	2,707
India	Number of rounds	11	0	3	7	0	0	21
	Total capital raised (USDm)	474	0	6	87	0	0	566
Singapore	Number of rounds	2	3	0	1	3	1	10
	Total capital raised (USDm)	40	71	0	2	71	16	201
Total	Number of rounds	70	25	42	28	29	3	196
	Total capital raised (USDm)	11,004	5,565	4,631	3,907	1,300	1,216	27,623

Source: Biotechgate / Venture Valuation

Due to dual listings, the 196 IPOs in the above table were carried out by 191 companies: 150 in mainland China, 11 in Hong Kong, 21 in India and 9 in Singapore.

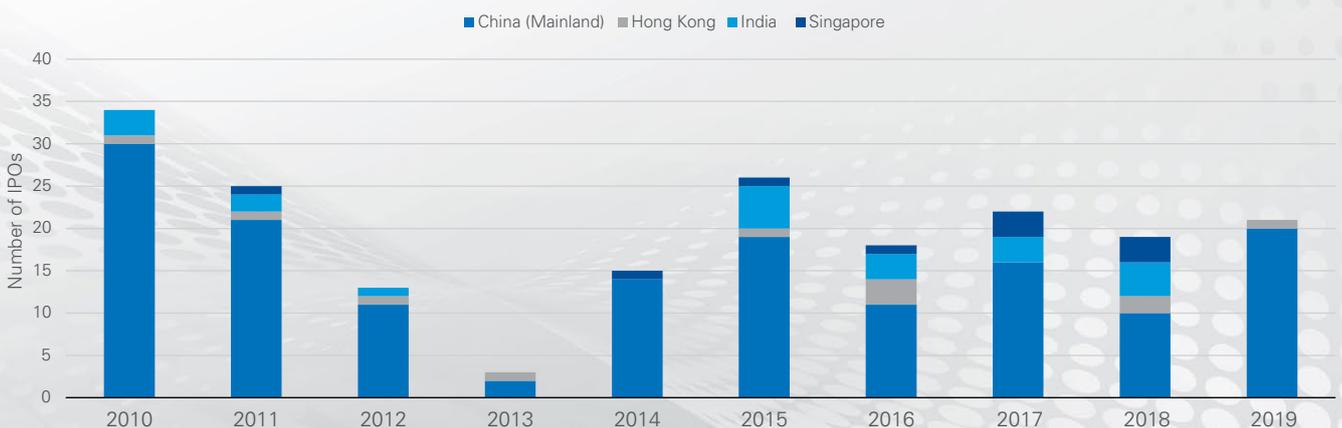
These 196 listings raised a total of USD27.6 billion over the past ten years. The vast majority of the IPOs were Pharma and Biotech businesses. While Healthtech was in the minority at only three listings in this period, it earned by far the highest average value.

China took the lead out of the four jurisdictions noted, at 78.5 percent of all IPOs and raising 87.7 percent of the

capital. In Hong Kong, most IPOs were in Biotech, reflecting the regulatory environment that allows pre-revenue companies to list on the Hong Kong Stock Exchange. In India, the public companies are predominantly generic or API manufacturers, as well as service-oriented businesses. The most valuable IPO in India was carried out in 2015 by Alkem Laboratories, a manufacturer and seller of generics, formulations and nutraceuticals.

Singapore's status as one of the most fertile ecosystems for Life Sciences innovation and start-ups has not translated into a surge of listings... yet.

Number of Pharma and Biotech Therapeutics & Diagnostics IPOs, 2010-2019

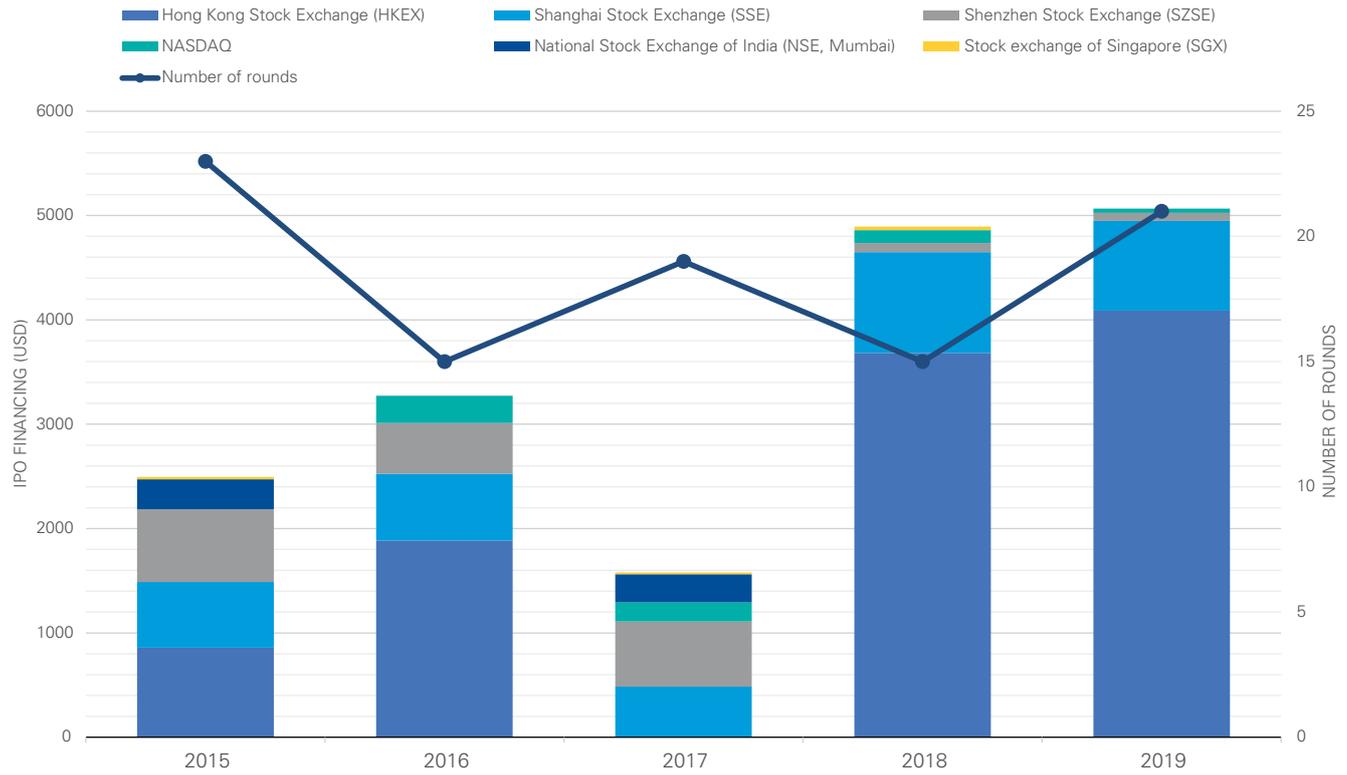


For the first time, there was no Life Sciences IPO in Singapore or India in 2019. While China extended its lead in IPOs, it has suffered its own interruptions to IPO activity in the past: its banking liquidity crisis in 2018 led to the lowest

number of IPOs in the region that year. And in 2015 it introduced a four-month suspension of IPOs to reverse a steep decline in stock prices.

Hong Kong provides stiff competition, but is this about to change?

Value of IPOs per stock exchange and total number of IPOs, 2015-2019



Source: Biotechgate / Venture Valuation



In terms of individual stock exchanges, it was the Hong Kong Stock Exchange (HKEX) that dominated the IPO scene over the past five years. HKEX was followed by the Shenzhen Stock Exchange and the Shanghai Stock Exchange. However, the opening of the Shanghai Star Market may dent Hong Kong’s lead in Biotech listings in particular. Especially as dual listings are permitted in China.

Other factors may also support China’s bio-pharma industry:

- The National Medical Products Administration overhauled China’s regulatory environment. Together with the introduction of ICH complaint guidelines as a result of China becoming a full member of the ICH in 2017, this has increased trust in the Chinese bio-pharma sector.
- The launch of the Nasdaq-style Shanghai Star Market in 2019.

These trends helped China-based BeiGene to raise USD903 million in Hong Kong’s first secondary listing under the new rules, for example.

Pharma has traditionally been the driving force behind listings of Life Sciences companies. Since 2018, however, with the overhaul of the regulatory environment, change in listing requirements for companies on the Hong Kong Stock Exchange, and the opening of the Shanghai Star Board, the number and value of IPOs of Biotechnology Therapeutics & Diagnostics firms has risen (from 13 percent in 2017 to 46 percent in 2018 and 47 percent in 2019).

Proportion of IPO capital raised by sector, 2015-2019

	Biotech other	Biotech Therapeutics & Diagnostics	Biotech R&D Services	Medical Technology	Health Tech	Pharma
2015	11%	4%	14%	0%	18%	54%
2016	20%	8%	4%	0%	5%	63%
2017	16%	13%	9%	1%	7%	54%
2018	0%	46%	27%	24%	0%	2%
2019	1%	47%	30%	0%	9%	13%

Source: Biotechgate / Venture Valuation



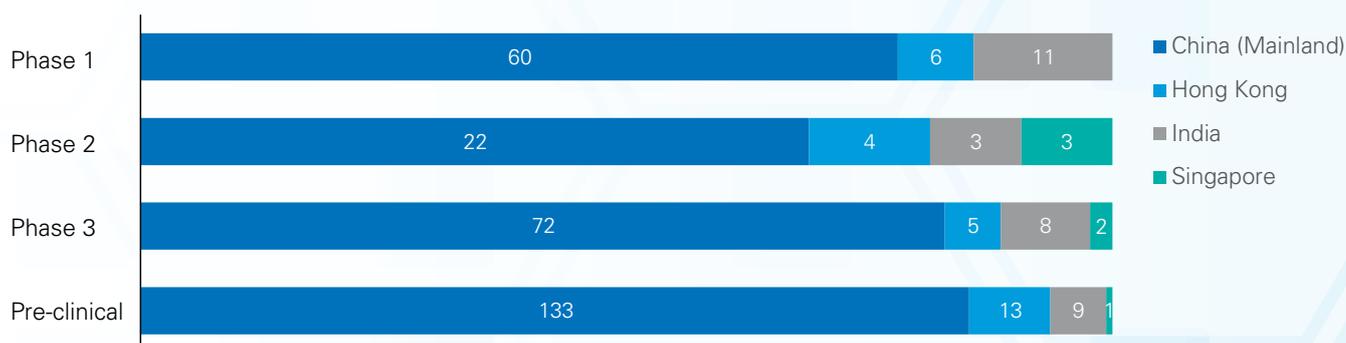
Top five IPOs, 2010-2019

Company name	Based in	Sector	Stock exchange	Year of IPO	IPO USDm raised
China Resources Pharmaceutical Group Limited	Hong Kong	Pharma	HKEX	2016	1,800
Ping An Healthcare and Technology Co.,Ltd.	China	HealthTech	HKEX	2018	1,100
Hansoh Pharmaceutical Co.,Ltd.	China	Biotech Therapeutics	HKEX	2019	1,000
WuXi AppTec	China	Biotech R&D	SSE	2018	967
BeiGene Ltd	China	Biotech Therapeutics	HKEX	2018	764

Source: Biotechgate / Venture Valuation

Maintaining an innovative product pipeline and development

Product pipeline and development of public Biotech – Therapeutics companies



Source: Biotechgate / Venture Valuation

A 2019 highlight was the FDA granting approval to a blood cancer drug from Beijing's BeiGene Ltd. This paves the way for US patients to access a Chinese cancer therapy for the first time.

China has the strongest pipeline, followed by India and Hong Kong. All countries have phase three projects except Singapore. India has a strong phase three pipeline compared to other phases in the country.

Forty-four percent of the number of pipeline products are at the pre-clinical stage, while 22 percent are at phase III. This indicates a significant increase in the value of Asian Biotech companies could be on the cards.

Pre-clinical	44%
Phase1	25%
Phase 2	9%
Phase3	22%

Conclusion

China and Hong Kong are the clear front runners in Life Sciences listings, and look set to remain so for the foreseeable future. Regulatory and government initiatives in India in particular, however, may challenge this pre-eminence over time, especially as Indian companies move up the value chain.

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About Venture Valuation / Biotechgate

Venture Valuation has built up a global Business Development database – Biotechgate – that profiles more than 50,000 Life Sciences companies, over 80,000 potential licensing assets worldwide and licensing deal information. Data from Biotechgate is made available on a subscription basis (www.biotechgate.com, www.venturevaluation.com).





Singapore

Why Singapore - in a nutshell

A strategic location of choice for multinationals, Singapore is home to a wide range of Life Sciences operations. This is due in part to its high-quality R&D environment, which is actively driven by the Ministry of Health and utilizes dedicated parks such as Biopolis.

Singapore boasts a thriving start-up scene, with innovation programs such as the Agency for Science, Technology & Research (A*STAR), with support provided by its infrastructure including the Diagnostics Development Hub and MedTech Park. In addition, Singapore's Economic Development Board (EDB) has set out a clear strategic vision for the country, with the Minister for Finance announcing during the Singapore Budget 2020 that Enterprise Singapore (ESG) aims to work with more than 3,000 small and medium-sized enterprises with cash grants of up to 90 percent to aid in their transformation journey on three core areas: core capabilities, innovation and productivity, and market access. Furthermore, the Smart Nation initiative that commenced a few years ago will continue to harness digital technologies to attract foreign investment, increase business efficacy and enhance employment opportunities for local employees.

At a macro level, Singapore's 25 free trade and economic partnership agreements include the EU-Singapore Free Trade Agreement which will eliminate tariffs on all EU products entering Singapore and all Singapore exports into the EU by 2024, including non-tariff related measures for pharmaceuticals²¹. Additional tax-based incentives include enhanced deductions of up to 250 percent on R&D expenditure and up to 200 percent on investment and market development spend, and reduced corporate income tax rate to as low as zero percent for businesses that carry out significant investments and business activities in Singapore.

²¹ Singapore Economic Development Board, 2019 [<https://www.enterprisesg.gov.sg/non-financial-assistance/for-singapore-companies/free-trade-agreements/ftas/singapore-ftas/eusfta/>] [<https://www.enterprisesg.gov.sg/non-financial-assistance/for-singapore-companies/free-trade-agreements/ftas/Singapore-ftas/EUSFTA>]

²² Global Innovation Index 2018, Bloomberg

²³ World Competitiveness Report 2018, IMD

²⁴ Doing Business Report 2018, World Bank

²⁵ EDB Singapore PharmBio Guide 2019/2020

It is therefore with little wonder that Singapore has been successful in attracting and building Life Sciences companies of all sizes. High living standards, a pool of educated and talented local employees with bilingual command of languages as well as access to nearby growth and thriving ASEAN markets such as Vietnam and Thailand add to its appeal. On top of this, Singapore is ranked top in Asia for innovation²², and second in the world for most competitive economy²³ and ease of doing business²⁴.

Singapore's Life Sciences cluster

As well as being home to the established multinational corporates, Singapore has a fast-growing start-up scene, attracted by a range of features including the country's available talent, access to Asian markets, government support on the various incentives, grants and schemes (subject to meeting relevant conditions), and the presence of venture capital and crowdfunding platforms.

Pharma

Singapore is one of Asia's most advanced Pharma manufacturing and research hubs. A growing number of foreign multinational corporates are choosing Singapore for their regional or global headquarters. Pharma accounts for almost three percent of the country's GDP²⁵ with Pharma manufacturing output trebling between 2000 and 2017 to SGD16 billion (around USD11 billion).

The government's substantial investment helps to foster medical innovation, production, and distribution through the provision of incentives such as reduced corporate income tax rates and/or effective tax rates through partial tax exemption, enhanced tax deductions and cash grants. Extensive investment by the public and private sectors alike will help the industry expand even further at a fast pace, especially as global Pharma firms use Singapore to position themselves for upcoming opportunities in the emerging Asian markets.

Biotech

The Singapore government aims to build capabilities in oncology, diabetes, cardiovascular diseases, infectious diseases, and the central nervous system. This national strategy is delivered in part through the country's role as a source of structured innovation for Biotech start-ups:

- The Agency for Science, Technology and Research (A*STAR) launched the Biomedical Sciences (BMS) initiative, which has gone through three phases since 2000. The third phase, from 2011 to 2015, attracted around SGD350 million in R&D investments.
- A*StartCentral is an incubator lab set up in 2016. Providing support to bring innovations to market, the lab allows Biotechs to operate an asset-light model in their early phases.
- The Experimental Drug Development Centre (EDDC) is a national platform for drug discovery and development, formed by integrating A*STAR's drug discovery and development units and the Experimental Biotherapeutics Centre (EBC). Together, they have forged partnerships with more than 70 academic institutions and 25 companies in Singapore and abroad.

Many companies, including global players, carry out biomedical science research in Singapore. They frequently do so in collaboration with local research and academic institutions.

Medtech

Singapore is one of Asia's leading Medtech R&D hubs²⁶. It is well-placed to manufacture high-value medical technology products, leveraging the country's strong design and engineering capabilities, automation supplier base, and high assurance standards. "Singapore has a legacy in IT, electronics, and software systems. Therefore the adoption barrier for medical technology products has been much lower," said Kim Namyong, CEO of Singapore-based Curiox Biosystems.

According to ESG, there were over 250 homegrown Medtech companies in 2018 – more than double the number in 2014 – with over half of them being start-ups.

- The Diagnostics Development Hub was established in 2014. Operating under A*STAR's enterprise arm, it aims to accelerate the commercialization of technology.
- MedTech Park is a dedicated hub that brings together Medtech manufacturers, product owners, and service providers in the interests of collaboration and synergy creation.

- Catalyst is a Medtech hub that aims to quicken and improve the development of products and services that prevent or cure diseases. It is supported by SingHealth, the National Healthcare Group, and the National Health Innovation Centre.
- Other accelerator programs that focus in Medtech innovation include SGInnovate, Singapore Biodesign, HealthTEC and JUMPstart.
- ESG works with intermediaries to provide early-stage incubation support to encourage more Medtech players to set up in Singapore. One intermediary, Trendlines Medical Singapore, established more than eight Medtech companies in Singapore within two years.

Some Medtech innovators have become well-known far beyond Singapore's borders:

- Biofourmis operates an AI-enabled health analytics platform that helps clinicians deliver personalized care.
- Rosceso Technologies produces wearables to support people's independence.
- Histoindex develops new diagnostics for fibrosis and cancer.
- MiRxes is a spin-off of A*STAR's Bioprocessing Technology Institute that uses microRNA technology for clinical purposes and is looking to launch blood tests for gastric, breast and lung cancers, and pre-cancer screening tests.

Commercial, R&D and manufacturing operations

Commercial operations

A number of multinationals have substantial commercial operations in Singapore, including supply chain management, regulatory affairs and medical affairs. Many businesses base their commercial leaders in Singapore with a remit to cover the entire region. Being in Singapore allows companies to study Asian markets in more detail, such as business development (e.g. payer model that differs significantly from the West), disease states and varying living conditions of patients. Doing so helps to identify appropriate ways to address local challenges (including regulatory difficulties), and can be a basis in the longer term for product launches.

R&D operations

Singapore has dedicated SGD4 billion – more than one-fifth of its national R&D budget – to Health and Biomedical Sciences, in line with its Research Innovation Enterprise 2020 plan. The country aims to further improve innovation capabilities and develop a pipeline of early stage companies through initiatives such as:

²⁶ <https://www.sginnovate.com/blog/snapshot-singapores-growing-medtech-industry-2020>

- Singhealth, a public healthcare cluster that has built a network of early phase clinical research units to support clinical trials, including first-in-human trials.
- Biopolis, which hosts Life Sciences-related R&D from DNA/RNA sequencing to microarray. It is home to public research institutes such as A*STAR and private companies such as Nanopore, Illumina, Takeda, and Procter & Gamble. The sixth phase of its growth, which is due to be completed by mid-2022, focuses on supporting Biotech start-ups.

Clinical trials are key to Singapore's appeal, with around half being oncology-related. The country's recognized track record in clinical trial operations has attracted sizeable multinational Pharma companies to conduct their trials there. A number of local start-ups have also gone on to achieve global status:

- AUM Biosciences leverages latest precision and digital medicine tools to produce a pipeline of small molecule therapies that can rapidly progress into commercially viable drugs.
- Hummingbird pioneers the discovery and development of precision antibody therapeutics for difficult-to-treat conditions.
- Enleofen is a spin-off of NHCS, SingHealth and Duke-NUS Medical School, focusing on the development of new anti-fibrotic therapies.

Regulation of clinical trials

The Health Sciences Authority (HSA) applies a risk-based approach to regulating clinical trials of therapeutic products. Trials are regulated under the Health Products Act and its subsidiary legislation, the Health Products (Clinical Trials) Regulations. These require Clinical Trial Authorization (CTA) or acceptance of Clinical Trial Notification (CTN) prior to the clinical trial being initiated.

All medicinal products imported into, or sold in, Singapore are required to be licensed by the HSA's Health Products Regulation Group. The license holder should be a locally registered company that is responsible for the product's safety, quality and efficacy. Under the Health Products Act, the activity-based licensing framework requires product registrants to hold an importer's license or a wholesaler's license if they intend to import or wholesale their own registered therapeutic products.

Principal Investigators (PI) must conduct clinical trials to obtain ethics and regulatory approvals before initiating a study. The ethics approval is from the hospital's Institutional Review Board (IRB). In order to receive the HSA's approval to conduct clinical trials in Singapore, companies must provide relevant evidence that the investigational drug is acceptably safe, and the design and conduct of the trial provide adequate levels of protection for participants.

The Health Sciences Authority (HSA) set up an Innovation Office in April 2018 to provide a regulatory environment that supports biomedical development. It provides scientific and regulatory advice for early stage clinical development of innovative therapeutic products intended for registration in Singapore.

Manufacturing operations

Singapore is a leading location for world class manufacturing facilities, producing a wide range of APIs, biologics drug substances, and medical technologies.

- Singapore became the first Asian country to join the Pharmaceutical Inspection Co-operation Scheme (PIC/S) on 1 January 2000. Membership facilitates mutual recognition with PIC/S countries with regard to GMP inspection, and promotes global acceptance of the quality of Pharma products manufactured by its members.
- In Medtech, the Singapore Manufacturing Federation's Medical Technology Industry Group aims to facilitate communication between member companies and drive dialog and collaboration with government agencies.

Singapore has also sought to establish itself as a hub for Advanced Manufacturing. The government works closely with companies of all sizes to support the adoption of new manufacturing technologies, as well as expanding capabilities in technology development, testing and industrialization. Some Pharma businesses, for example, have established campuses in Singapore with manufacturing capabilities of small molecule and biologics.

- Launched in 2014, the Singapore Smart Industry Readiness Index (SSIRI) was the world's first Industry 4.0 tool.
- The Pharma Innovation Programme Singapore (PIPS) was launched in 2017. It draws on the combined expertise of A*STAR, the National University of Singapore (NUS), Pfizer, Merck, and GSK. This consortium signed a SGD34 million agreement in 2018 to jointly invest in developing new manufacturing technologies.

The country also has prebuilt, GMP-ready facilities outfitted to accommodate innovations such as single-use technology (SUT) manufacturing platforms. Smaller footprints and significantly reduced upfront capital cost are two key advantages of this approach for companies looking to open such world class manufacturing facilities in land-scarce Singapore.



Access to talent

Singapore's high living standards contribute to it being a popular location for expatriates, including business executives who are focused on international activities across Asia Pacific. More broadly, the IMD's 2019 league table ranked Singapore as the only Asian country among the ten most competitive places for talent. This is further enabled by initiatives such as the following:

- Under the Technology for Enterprise Capability Upgrading (T-Up), run by A*STAR, research scientists can be seconded to local enterprises for up to two years to boost R&D capabilities. In addition, technology transfer offices (TTOs) at various universities help to mentor academics to commercialize research.
- The Workforce Development Agency (WDA) rolled out the Development and Apprenticeship (DNA) program to support the costs of trainees undergoing local on the job training. In 2014, the Biologics Overseas Skills Training (BOOST) training program was launched to create a buffer talent pool in anticipation of future demand for the biologics industry.

The Development and Apprenticeship (DNA) program rolled out by Singapore's Workforce Development Authority aims to support the cost of trainees in the industry. It forms part of the government's promotion of the biologic industry, with the goal of creating an additional 700-1,000 jobs in Singapore. Singapore works closely with industry partners to support its biopharmaceuticals industry. Initiatives to develop talent include the Sectoral Manpower Development Fund for the biologics manufacturing industry. The fund collaborates with a number of major multinationals.

Universities and technology transfer programs

Singapore boasts two major international universities with significant medical and scientific faculties:

- The National University of Singapore (NUS) is ranked second in Asia and 25th in the world.
- Nanyang Technological University (NTU) is ranked 48th in the world.²⁷

Singapore is a collaborative ecosystem where universities work with industry to ensure research is purpose-driven and has international scale-up in mind. In this regard, these two universities are often directly involved in Life Sciences R&D. Various universities and polytechnics operate technology transfer programs with other universities or industry. The government announced three initiatives in 2017 to spur innovation through such programs, as well as through talent development and smart capital. These include the launch of the National IP Protocol, which encourages research agencies and businesses to work more closely together to develop IP into products and services.

Labor regulations and the cost of labor

Singapore's labor regulations and workforce are consistently rated highly by leading international organizations such as the World Economic Forum and Washington-based risk consultancy agency, Business Environment Risk Intelligence (BERI).²⁸

Tax environment and incentives for Life Sciences companies

Taxation

Singapore has Asia's most extensive double tax treaty network:

- Eighty-seven comprehensive tax treaties and an additional six that are signed but not ratified.
- While there is no double tax treaty between Singapore and the US, Singapore has tax treaties with most Asia Pacific and EU countries, including China, India, Australia, Switzerland, Ireland, and the UK.

Singapore is generally a tax-efficient holding jurisdiction:

- Quasi-territorial basis of taxation.
- No income tax levied on certain foreign sourced income unless received or deemed received in Singapore.
- No capital gains tax or withholding tax on dividends irrespective of the recipient's tax residency.
- No foreign exchange regulations or thin capitalization rules that limit the amount of debt funding required.
- Extensive list of allowances available on the acquisition of capital assets.
- Certainty of non-taxation of companies' gains on disposal of equity investments on exit.

Incentives

At 17 percent, Singapore has a competitive prevailing corporate income tax rate. Tax exemption schemes, corporate income tax rebates and incentives that offer a reduced corporate income tax rate, all aid in lowering the effective tax rate of a corporate tax payer, making it even more attractive compared to countries with a lower prevailing corporate income tax rate.

Tax incentives/ schemes available in Singapore include:

- 250 percent enhanced tax deduction for qualifying R&D expenditure.

²⁷ The Times World University rankings 2020 www.timeshighereducation.com

²⁸ <https://www.mas.gov.sg/development/why-singapore>

- Up to 200 percent tax deduction on qualifying investment and market development spend.
- Allowances for investments in productive equipment buildings.
- Potential for concessionary tax rates as low as zero percent on qualifying income if the activities carried out in Singapore are considered to be substantial and in line with the Government's directions for development.
- Reduced or nil withholding tax rate on royalty payments to access advanced technology and know-how.
- Writing-down allowances on capital expenditure incurred in acquiring Intellectual Property Rights (IPRs).
- Potential suspension of Singapore GST via certain schemes, bonded warehouse, etc.

A number of pools govern the incentives/ schemes via a negotiation-driven process that are available, including:

- International/ Regional Headquarters Award.
- IP Development Incentive (IDI).
- Approved Royalties Incentive.
- Pioneer Certificate Incentive (PC).
- Development and Expansion Incentive (DEI).
- Writing Down Allowance for Acquisition of IPRs .
- Investment Allowance (IA).
- Land Intensification Allowance (LIA).
- Major Exporter Scheme (MES).

In addition to the above tax incentives, there are cash grants available for companies that carry out R&D activities in Singapore, or training programs that impart new technologies and industrial skills to staff. Other programs are also available, such as schemes that facilitate the employment of staff.

The following are relevant to preclinical and clinical research

R&D Enhanced Tax Deduction: Businesses can enjoy tax deductions on qualifying expenditure incurred on qualifying R&D activities, including a tax deduction of 100 percent for R&D and an enhanced tax deduction of 150 percent for R&D carried out in Singapore.

IP Development Incentive (IDI): The IDI encourages the company to undertake R&D activity in Singapore. It offers a concessionary tax rate of five percent or 10 percent on a percentage of qualifying IP income, such as income for the commercial exploitation of IPRs. In order to qualify, a company is required to commit to additional employment as well as fixed asset expenditure or total business expenditure.

Writing Down Allowance for Acquisition of IPRs (S19B):

The S19B is a writing down allowance granted on the economic and legal acquisition of IPRs, and is intended to enhance Singapore's attractiveness as a location for businesses to hold and commercialize IPRs. Where only economic rights to the IPRs are acquired, approval is required from the relevant authorities. The writing down allowance is granted over a five, 10 or 15 year period.

Approved Royalties Incentive (ARI): The ARI is intended to encourage companies to access cutting-edge technology and know-how for substantive activities in Singapore. It offers a reduced or nil withholding tax on qualifying royalty payments for access to advanced technology and know-how. In order to qualify, the technology and know-how must be used in Singapore, e.g. employed in manufacturing and/ or R&D activity.

Research Incentive Scheme for Companies (RISC) and Innovation Development Scheme (IDS):

These grants encourage companies in Singapore to conduct or expand their R&D activities in science and technology, as well as to undertake strategic innovation activity in Singapore. Supportable project costs on approved projects include expenditure on manpower costs (up to 50 percent support), training cost (up to 30 percent support), equipment, materials, consumables and technical software (up to 30 percent support), Singapore-based professional services (up to 30 percent support), and IPRs such as licensing, royalties, technology acquisition (up to 30 percent support).

Training Grant for Company (TGC): This grant encourages the development of manpower capabilities in applying new technologies, industrial skills and professional know-how by supporting employee training programs. Benefits include up

to 30 percent support on qualifying costs such as trainee salaries and overseas trainee expenses, subject to caps.

Tech@SG Programme: The Tech@SG Programme provides company-level endorsement to the Ministry of Manpower (MOM) by the relevant authorities, reducing the risks of rejections for Employment Pass applications made by the company to MOM. The purpose of the program is to allow fast-growing companies with digital or technology offerings (e.g. Medtech, Biotech) to more readily access global talent, so as to establish their core teams in Singapore and more quickly capture business opportunities.

The following are relevant to manufacturing

Pioneer Certificate Incentive (PC) and Development and Expansion Incentive (DEI): These incentives provide concessionary tax rates of between zero percent to 10 percent (reducing tax outlay as the normal tax rate is 17 percent aiming to encourage companies to grow capabilities and carry out new, or expand, activities in Singapore. To qualify, companies must meet quantitative and qualitative criteria, including employment created, business expenditure that generates spin-off benefits to the economy, and a commitment to growing capabilities in Singapore, among others.

To be eligible for the PC, the company must also introduce technology, skillsets or knowhow that are substantially more advanced than that which currently prevails in Singapore, and may be subject to additional assessment criteria at the discretion of the relevant authorities.

Investment Allowance (IA) is intended to support the capital expenditure, such as equipment purchases, on a qualifying project. To qualify, companies must undertake high value-added activity in Singapore, such as the manufacture of new products or expansion of existing manufacturing capability, or R&D.

Land Intensification Allowance (LIA) is intended to support the productive and efficient use of industrial land for higher value-added activities. It offers an allowance on the

cost of constructing a new building, or renovation of an existing building, as well as other related qualifying costs. In order to qualify, the building must meet certain land productivity benchmarks and must be used for qualifying activity (e.g. manufacturing or logistics activities).

The ACSS Consortium (Australia, Canada, Singapore, Switzerland)

Four medium-sized regulatory authorities - Australia's Therapeutic Goods Administration (TGA), Canada's Health Canada, Switzerland's Swissmedic, and Singapore's Health Sciences Authority (HSA) - have banded together into the ACSS Consortium. The Consortium aims to better align regulatory systems and reduce unnecessary duplication and differences, as well as exploring opportunities for information and work-sharing initiatives.



Digitalizing Singapore's healthcare market

The Singapore government allocated SGD11.7 billion (USD8.5 billion) to healthcare in the 2019 financial year. This represents an increase of SGD1.1 billion or 10.3 percent over 2018. According to Singapore's Deputy Prime Minister, Heng Swee Keat, the amount is expected to "rise quite sharply" by at least SGD3 billion by 2020 as the nation addresses the challenges of an increasing elderly population, a growing prevalence of chronic disease, an increased usage of long-term care facilities, and limited healthcare labor²⁹.



Together with infrastructure investment in six new hospitals and 14 new polyclinics, an additional 30,000 healthcare workers will be required by 2030 to meet the rising demand for healthcare services. The Singapore government began about ten years ago to embrace the use of digital healthcare technology to improve the quality of care. Adopting digital technologies will be vital to ensure a sustainable, cost-effective healthcare system.

“Technology is a key enabler in our efforts to improve productivity by using it strategically to digitize, connect and analyze,” according to Chee Hong Tat, Minister of State for Health, the Singapore Budget Debate 2017³⁰.

Driving digitalization in the public sector

The Integrated Health Information Systems (IHiS) body was set up in 2008 under the Ministry of Health to oversee the development of digital healthcare technology in the public sector. As the CIO for all six regional health systems in Singapore, IHiS is responsible for providing digital IT services for all public healthcare establishments, and standardizing digital IT resources and functions. Around 800 digital IT systems have been designed, trialed or implemented. These include systems for electronic medical records, medical imaging, laboratory test records, medication dispensing, patient registration, billing, financial aid, community care, telehealth and videoconferencing for long-distance doctor-patient consultations across 46 public healthcare institutions³¹. IHiS’s objective is to move Singapore’s healthcare sector away from a fragmented, provider-centric care delivery system towards a more integrated, patient-centric healthcare delivery system within an integrated healthcare masterplan.

A focus on improving care for the elderly

To advance the use of digital IT technology further, Prime Minister Lee Hsien Long launched the Smart Nation Vision (SNV) initiative in 2015. Developing assistive technologies and monitoring systems in the homes of the elderly is one of its key objectives. The Housing and Development Board (HDB), which houses more than 80 percent of Singapore’s population, was the platform to trial the Smart Elderly Monitoring and Alert System (SEMAS). Sensors were placed in 12 flats rented by the elderly to collect data about their present locations, sleeping patterns and time spent in the bathroom. Alerts are sent by SMS to the caregiver when unusual routine changes are detected so that help can be dispatched³².

There is significant potential for manufacturers to adopt technology solutions that ensure, or update on, the safety of the unsupervised elderly. Or that alert the caregiver or healthcare provider to intervene when necessary, such as the Elderly Care Monitoring Systems (sensors at home, applications, wearable devices).

Addressing labor-intensive tasks

A further initiative under the SNV is the Smart Health Assist (SHA) project. Its focus is to tackle the growing demand for hospital beds, and investment in hospital infrastructure. Healthcare providers interact with patients by using digital IT technology, including remote consultation. The SHA also allows healthcare providers to provide timely and effective healthcare services by leveraging instant, wireless access to patient data. Cumulatively, there is significant potential for wide-scale adoption of technology in the fields of telehealth, remote monitoring, IoT infrastructure for seamless device communication, and strengthening communications between hospitals, hospitals and ambulances, and other healthcare institutions. The business opportunities in this sector will be for multiple types of players, many of which will be non-traditional healthcare players such as telecommunications, social media and consumer products companies.

Automation of labor-intensive work in hospitals will also continue. Pilot projects were trialed to see if productivity could be enhanced by utilizing robots for menial tasks such as: delivering linen, drugs and documents; bed transporters to reduce the number of people required when transferring patients; and using robotics to reduce wound assessment from 30 minutes to 30 seconds per patient.

The use of digital technology will be part of the wholesale shift in Singapore’s healthcare landscape, from prevention to treatment and management of diseases. Optimizing the flow of information between healthcare providers and individuals, as well as within the healthcare ecosystem, is set to cause a seismic shift in Singapore’s healthcare landscape³³.

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About Montrose R+ Pte Ltd

Montrose R+ Pte Ltd www.montroser.com is a Singapore based company providing healthcare regulatory services and market entry services for pharmaceutical products, dietary supplements, medical devices and cosmetics across Asia. Montrose R+ Pte Ltd is a sister company of Dr. Regenold GmbH www.regenold.com and CE plus GmbH <https://www.ceplus.eu/> and a member of regulanet® www.regulanet.com, a global network of regulatory affairs professionals.

²⁹ <https://www.mof.gov.sg/singapore-budget/curated-budget-reads/injecting-more-into-singapore-s-healthcare-as-we-age>

³⁰ https://www.ihis.com.sg/Latest_News/News_Article/Pages/Health_Ministry_reveals_plan_to_increase_productivity_with_digital_and_data.aspx

³¹ <https://www.ihis.com.sg/projects-programmes>

³² <https://www.todayonline.com/singapore/hdb-completes-semas-test-bed>

³³ [https://www.google.com/search?q=Future+Health+Index+by+Dutch+technology+company+Royal+Philips.&aqs=chrome..69l572341j0j8&sourceid=chrome&ie=UTF-8](https://www.google.com/search?q=Future+Health+Index+by+Dutch+technology+company+Royal+Philips.&aq=Future+Health+Index+by+Dutch+technology+company+Royal+Philips.&aqs=chrome..69l572341j0j8&sourceid=chrome&ie=UTF-8)

Emerging markets of Southeast Asia: Indonesia, Malaysia, Philippines, Thailand, Vietnam

Having identified Southeast Asia as a growth market, Life Sciences companies are investing significantly in R&D efforts to cater to its population. Genomic studies on Asian populations in areas such as oncology for targeted therapies, infectious diseases, genetic disorders and pharmacogenomics are on the rise, with Pharma and in-vitro diagnostic device companies actively seeking to develop and provide innovative solutions. The growing interest in Southeast Asia is being accelerated by the COVID-19 situation, which is driving a greater focus on supply chain diversification and resilience, and a need to move close to end-markets.

At present, however, demand for healthcare outstrips supply across many parts of Southeast Asia. This gap looks set to widen due to further rises in incomes, populations, disease burdens and general health awareness. And as changing lifestyles and higher life expectancies fuel incidences of non-communicable diseases.

As more countries move towards universal healthcare coverage, healthcare expenditure is expected to soar. This will contribute to transforming Life Sciences in the region, supported by:

- Improving access to healthcare in rural areas and historically under-served populations.
- The application of new digital and automation technologies which could change the way medicines are manufactured and delivered.
- The 2015 ASEAN Medical Device Directive that harmonizes medical device regulations, facilitating market penetration and encouraging efforts to meet the growing demand for innovative equipment.





Indonesia

Indonesia's Life Sciences cluster

Southeast Asia's largest Pharma market faces a number of challenges:

- The Pharma sector is dominated by domestic manufacturers, with 90 percent of drugs in Indonesia being produced in the country. These companies tend to produce low-cost generics and have little focus on R&D.
- The country is heavily reliant on the import of APIs for Pharma production, at around 90 percent. This creates exposure to foreign exchange fluctuations.
- Low levels of foreign participation in the market is partly due to generally weak IP protection. Indonesia is on the US's priority watch list for inadequate law enforcement of Pharma patents and counterfeit drugs.
- A lack of public healthcare infrastructure has contributed to a large under-served healthcare market.

To help address these challenges, the government has opened up the sector to private investment.

- Expenditure on healthcare was USD41 billion in 2018, being approximately 40 percent public and 60 percent private. This is projected to increase to USD120 billion by 2028.
- Private providers are establishing a growing number of hospitals, private practices, midwifery clinics, clinical laboratories and pharmacies – particularly in Tier 2 cities such as Makassar, Pekanbaru and Balikpapan.
- The number of hospital beds and doctors remains low relative to the size of population, however. Of 2,776 hospitals, 1,767 are privately managed and 1,009 managed by the public sector. Combined, they offer 1.16 beds per thousand people.

In addition, the ongoing roll-out of National Health Insurance (JKN) is having a considerable impact. As of September 2019, JKN covered 223 million people - around 83 percent of the country's population.

Progress is also being driven by Indonesia's sizeable and growing middle class, who have tended to travel abroad for their care in the past. They are now beginning to demand more sophisticated healthcare services at home.

And there is a vibrant digital healthcare scene as inadequate geographical coverage and high smartphone penetration has driven a number of telemedicine start-ups such as Halodoc and Alodokter to bring healthcare to tens of millions of Indonesians.

Key players

- Key government agencies are the Ministry of Health (MoH), Ministry of Home Affairs, Social Security Managing Agency (BPJS Kesehatan) and the National Board of Population and Family Planning.
- Indonesia is seeing a rise in the number of private healthcare providers, which are dominated by five major groups: Awal Bros Group, Rumah Sakit Mitra, Siloam Hospital Group, Hermina Hospital Group, and Sari Asih Group.
- The largest Pharma players include Kalbe Farma, Sanbe, Dexa Medica, Pharos Indonesia, Tempo Scan Pacific, Kimia Farma, Fahrenheit, Sanofi, Soho and Novell Pharm, which tend to be located in West Java. Kalbe and Sanbe have invested in expanding their manufacturing activities.
- Major private laboratory chains are extending their geographic presence and capacity, including Prodia, Kimia Farma, Pramita, Cito, BioMedika and Parahita.
- Medical device players comprise local manufacturers, foreign manufacturers that import products into Indonesia, and distributors that work with either.
 - Major foreign participants in the market include GE healthcare, Philips, Roche, Siemens and Pfizer.
 - Local manufacturers include Indo Health Medical, PT Andini Sarana and PT Trimitra Garmendindo Interbuana (TRIMED).

Regulatory framework

The Ministry of Health's Food and Drug Supervisory Board oversees Pharma production quality. The National Agency of Drug and Food Control (NA-DFC) is the primary government agency for regulating medical devices and Pharma.

Regulation No. 1010/XI/2008 on Registration of Medicines is the main legislation governing the manufacture, license and sale of Pharma products.

Pharma companies registered in Indonesia are supervised by the Food and Medicine Supervisory Board (BPOM). BPOM also regulates clinical trials, which can be conducted

directly by the sponsor or by a contract research organization if the latter is based in Indonesia and complies with good clinical trial practice standards.

Law No. 33/2014 took effect in October 2019 with regard to halal certification. This mandates the Halal Certification Agency (BPJPH) to implement halal law for medicine manufacturers. It will work with the country's highest clerical body, the Indonesian Ulema Council Food and Drug Analysis Agency (LPPOM MUI) to do so. Implementation is being carried out in phases, such as the need for companies to comply with labeling laws by 2026.

To prepare for its integration with ASEAN's medical products regulations, Indonesia has introduced an online medical device registration system that requires the Common Submission Dossier Template (CSDT).

- Device distributors and manufacturers apply for distribution licenses, production licenses and product registration through the online portal, which is integrated with the Indonesian customs database. Registration generally take 6-12 months to obtain:
 - A distributor's license: Companies must have a distributor's license and a product license before their products can enter Indonesia or be sold. Government regulations require a local distributor – either a domestic distributor or a local office.
 - Medical device registration: Following receipt of a distributor's license, the company must apply for product licenses.

Following incorporation, a company must apply for a manufacturer license to confirm compliance with Indonesian and international standards of quality, effectiveness and safety. This license must be obtained prior to applying for a special distribution permission (IPAK) or a medical distributor license, which is issued according to the usage of the medical device in question.

If a foreign company wishes to use a local office instead of appointing a local distributor, it must establish a limited liability company with foreign direct investment (PT PMA).

- To do so, the company needs to apply for a permanent business license issued by the Investment Coordinating Board (BKPM).
- The Negative Investment List restricts foreign ownership of healthcare company shares to a maximum of 49 percent.

Tax environment and incentives for Life Sciences companies

Indonesia provides income tax relief for business sectors that are considered to be a national priority, especially for boosting exports.

- Pharma raw materials industries qualify for full corporate income tax exemptions on investments of at least IDR500 billion (around USD35.5 million) and a 50 percent corporate income tax reduction on a minimum investment of IDR100 billion (USD7.1 million).

There are no R&D incentives available in Indonesia.

Key trends and opportunities

Pharma/Biotech

Indonesia's changing epidemiology of chronic illnesses such as diabetes, obesity and cardiovascular diseases is reinforcing demand for safe and effective medications.

The country imported USD990 million of pharmaceuticals in 2018. This is low relative to its population size. The local Pharma manufacturing industry is highly dependent on imported raw materials, and halal considerations are becoming increasingly important.

But the universal insurance scheme, JKN, prioritizes the use of low-cost generic drugs and is leading to more intense competition and diminishing profit margins in the generics market. As a result, there is a need for local manufacturers to explore higher-value drug manufacturing.

While Indonesia's Biotech is still in the nascent stage, the country's rich biodiversity (it is home to more than 30,000 medicinal plants out of the 40,000 that are known globally) points to untapped market potential.

Medtech

The growth in the number of private hospitals is fuelling demand for advanced medical equipment as they seek to better serve clients' needs.

- Demand for medical devices such as surgical equipment, CT and MRI scanners, x-rays and medical imaging equipment is forecast to grow.
- Other products such as treatment equipment for cancer, dental equipment, laboratory and diagnostic equipment, and medical disposables are also expected to see strong demand.

Indonesia relies on imports from countries such as the US, Germany, Japan and the Netherlands for more than 95 percent of its medical and surgical instruments.



Malaysia

Malaysia's Life Sciences cluster

Healthcare demand is expected to grow with the country's growing non-communicable disease burden: Malaysia has the highest levels of obesity and diabetes in Southeast Asia, and a rapidly aging population. To address health challenges and improve efficiency, the government plans to adopt an Electronic Medical Record (EMR) system in 145 hospitals by 2022.

Total public and private healthcare expenditure is expected to rise to USD22 billion by 2022.

- In its 2019 budget, Malaysia allocated USD6.9 billion to healthcare, up 7.8 percent on 2018.
- Budget plans include:
 - A USD490 million Health Protection Fund to provide free protection against 36 critical illnesses.
 - A pilot national health screening program for the lowest income groups.
 - USD2.6 billion to upgrade aging public health infrastructure.

Malaysian healthcare services consist of tax-funded and government-run primary healthcare centers and hospitals. These are administered by the Ministry of Health (MoH), the main regulator.

- The public sector is the largest provider, with 42,300 beds across 135 hospitals, together with 1,085 health clinics and 1,796 community clinics.
- The fast-growing private sector offers 200 hospitals and 7,570 clinics but only 14,800 beds.
- Private services play an increasingly important role, particularly in specialist fields, and are experiencing growing demand due to shorter waiting times and higher-quality services. They are typically concentrated mainly in urban areas to cater to the upper-middle income population.

Malaysia is a major destination for medical tourism in the region, with around two million per annum expected by 2020.

- The Malaysia Healthcare Tourism Council (MHTC) was established in 2019. Under the MoH, it helps to raise the

country's profile by coordinating collaboration within the industry and building public-private partnerships locally and internationally.

- Medical tourism receipts from international travellers were poised to grow by 25 percent to USD430 million in 2019, outperforming the industry's global average growth of 10-12 percent.

Key players

- KPJ Healthcare (KPJ) is Malaysia's largest private hospital chain. IHH Healthcare Berhad (IHH) is the second largest player, operating under the Parkway Pantai and Gleneagles brands.
- Major local Pharma companies include Pharmaniaga Manufacturing Berhad, Hovid Berhad, CCM Duopharma Biotech Sdn Bhd, and Kotra Pharma (M) Sdn Bhd. These focus on generics.
- Foreign-owned companies that manufacture in Malaysia include Y.S.P. Industries (M) Sdn Bhd (Taiwan), Sterling Drug (M) Sdn Bhd (the manufacturing arm of GlaxoSmithKline) and Ranbaxy (M) Sdn Bhd from India.
- Multinationals such as Pfizer, Schering Plough, Novartis and Astra Zeneca are mainly licensed importers.
- Medical device companies include Agilent, B. Braun, St Jude Medical, Symmetry Medical and Toshiba medical systems. These are mainly located in Penang and Selangor.
- Infrastructure support is strong, such as through industrial parks. The primary Biotech parks are Bio-XCell in Nusajaya in the Johor region, Penang Science Park, and Kulim High Tech Park in the North-West of Peninsular Malaysia.

Regulatory framework

The National Pharmaceutical Regulatory Agency (NPRA) under the MoH is responsible for drug registration, quality control and regulation. It issues licenses for wholesalers, importers and manufacturers. All registered Pharma companies must be either manufacturers or sellers of medical products. Under regulation 7(1) of the Control of Drugs and Cosmetics Regulations 1984, only registered products can be sold, supplied, manufactured or imported.

Halal certification is not mandatory, but preferential treatment is given in government procurement to medicines with halal ingredients.

- The Department of Islamic Development Malaysia (JAKIM) granted the world's first halal license for prescription medicine to Chemical Company of Malaysia in 2017.
- The halal certification process is straightforward, with applications for a Halal Confirmation Certificate being submitted online to the JAKIM halal hub.

Clinical trials are regulated by the Medical Device Authority (MDA) or the National Pharmaceutical Control Bureau (NPCB).

- Trials are reviewed by Institutional Review Boards. Trials using MoH facilities are reviewed include the Medical Research & Ethics Committee (MREC), while those using non-MoH facilities use local boards.
- License requirements include a Clinical Trial Import License (CTIL), issued to import any product for clinical trial purposes, and a Clinical Trial Exemption (CTX), which authorizes the manufacture of samples for clinical trials.

The MDA is responsible for the regulation, quality control, licensing and registration of medical devices. Since January 2018, the Medical Device Act 2012 covers all medical devices exported from, imported into, and distributed within Malaysia.

- As well as registering their products with the MDA, medical device suppliers must have an establishment license, which involves having a local presence - either a manufacturing plant or through local agencies or appointed local distributors.
- In addition to MDA registration, foreign manufacturers must obtain a Conformity Assessment Body (CAB) certification in order to receive MDA approval for product registration.

Foreign businesses may register a company in Malaysia with 100 percent foreign ownership. Alternatively, they may set up a joint venture with a Malaysian partner, whereby the local company has at least 50 percent ownership. Joint ventures in Malaysia can also be set up as partnerships; the director of the company must be Malaysian, and the business would be eligible for government grants.

Tax environment and incentives for Life Sciences companies

Numerous tax incentives encourage companies and institutions to carry out R&D activities in Malaysia.

- The main R&D incentives are granted in the form of Pioneer Status (PS), Investment Tax Allowance (ITA), Double Deduction or Tax Exemption.
- There are also some forms of R&D grants available.

Key trends and opportunities

Pharma/Biotech

Foreign multinationals dominate the Pharma industry.

- Malaysia imported USD1.5 billion of products in 2018, with Germany and the US being key source markets.
- Local companies are mainly small and medium-sized enterprises that produce generic drugs, traditional medicines and herbal supplements, as well as carry out contract manufacturing for multinational corporations.

IP protection legislation in Malaysia is strong, and the legislation generally conforms with international standards.

Patented medicines account for 37 percent of domestic sales, while generics account for 63 percent. The market for prescription drugs is 80 percent, and OTC 20 percent.

The 11th Malaysian plan is set to fast-track the country's emerging Biotech industry. Government support, tax incentives and access to halal markets give rise to opportunities, particularly in R&D for priority areas.

- The government has identified halal nutraceuticals as a major growth segment, and has mandated the certification of halal manufacturers.
- Malaysia is one of the world's top halal Pharma producers and is a leader in terms of standards. Demand remains niche, however, despite government support to boost the sector.

Collaboration opportunities exist with local companies and research institutions to produce herbal medicines, such as supplying APIs and excipients (the inert substance) for generic drug manufacturers.

Medtech

Malaysia's medical device market relies mainly on imports, in particular technologically-advanced platforms and systems. Imports of medical devices have more than doubled in value over the past decade to reach USD725 million in 2018. The US is the largest source country.

As befits its role as one of Southeast Asia's electrical and electronic manufacturing centers, plans are underway to raise Malaysia's profile as an advanced Medtech manufacturing hub. This should help it diversify from latex-based consumable supplies such as gloves to more advanced equipment.

The government is focusing on equipping public hospitals with specialist departments and equipment that allow them to deal with more complex health issues. In addition, plans by the public and private sectors to construct more hospitals should boost demand for MedTech.

The Philippines

The Philippines' Life Sciences cluster

There are more than 500 drug traders, 700 importers, and 5,000 distributors in Southeast Asia's third largest Pharma market.

It is estimated that the Philippines spent USD15 billion on healthcare in 2018, of which 65 percent was by the private sector. Expenditure is set to grow to USD22 billion by 2023, driven largely by government spending.

The Philippines' dual healthcare system contains public and private elements, with the Department of Health (DoH) being responsible for national health policy and regulations. Provincial government units manage government-owned hospitals and health offices, while city government units are responsible for providing healthcare services in the respective city.

- The country has around 800 private hospitals, 430 government hospitals, 2,600 rural health units and 20,216 village health stations.
- Uneven geographical coverage across 7,641 islands has led to local health facilities in remote areas being poorly equipped and staffed, and two-thirds of hospital beds being on the largest and most populous island, Luzon.

The government enacted the Universal Health Care Act (UHC) in 2019.

- This will reform the current PhilHealth coverage which does not provide comprehensive services, has high co-payments and suffers from difficult reimbursement procedures.
- Reforms include automatic enrolment, expanded coverage, improved health facilities, closing the human resource gap, and designating PhilHealth as the national purchaser of health commodities and services.
- Medical professionals have expressed hopes that the UHC could spur the adoption of Electronic Medical Records, which would allow hospitals to provide faster and quality healthcare services.

The government encourages the use of generics, on which domestic production is focused.

In October 2018, the Philippines' FDA began to implement a policy requiring pharmacies to use a mobile app from Singapore-based mClinica to digitalize logbooks by 2020.

IP protection laws are generally weak. This is largely due to the Bolar provision, which has allowed unauthorized third parties to commercialize products prior to patents expiring through using the patented innovation for R&D purposes and to obtain the required regulatory approvals.

Key players

- The main government healthcare regulator is the DoH. Its regulatory agencies consist of the FDA, the Bureau of Health Facilities and Services (BHFS), and the Bureau of Health Devices and Technology (BHDT).
- The Metro Pacific Group is the largest hospital chain, with 14 hospitals, many of which are among the Philippines' largest and most modern. The other prominent player is real estate developer Ayala Group, which operates a chain of hospitals and clinics under the QualiMed brand in partnership with Mercado Medical Group. The Allied Care Experts Group (ACE) is another key player.
- Some multinationals that had manufacturing plants in the country have closed their facilities over the years. They import from corporate production centers abroad or use local contract manufacturers such as Hizon Laboratories, Lloyd Laboratories, Swiss Pharma and Ace Pharmaceuticals.
- Of the world's top 20 Pharma companies, over 14 have manufacturing facilities in the Philippines, including Sanofi, Pfizer and GSK. The fastest-growing companies for generics include Sandoz, Taiwan's Orient Europharma (OEP) and Getz Pharma of Pakistan.
- Manufacturers with a local presence tend to be located on Luzon, primarily in and around the Manila metropolis. These include United Laboratories (with its subsidiaries Asian Antibiotics, Amherst, and Westmont), Pascual Laboratories, AMEuropharma, AD, Drugstel, and Euro-med.

Regulatory framework

Medical devices and Pharma are both regulated by the FDA. There are no barriers to the sale or purchase of medical equipment of acceptable international standards.

Two key documents are required for registration: a License To Operate (LTO) and product registration.

- Any establishment in the Philippines – from single proprietorship to public and private limited companies - can apply for an LTO as long as they are engaged in the healthcare field as importers, distributors, wholesalers, manufacturers, traders, etc.
- The approval timeline is one to three months. A company with an LTO can then apply for the product registration certificate.

While the Philippines is transitioning to the ASEAN medical device directive, current regulations mean that the Philippines follows a registrable/non-registrable classification system. In future, registration will follow the CSST format (Common Submission Dossier Template) for class B, C, and D devices, according to the new risk-based classification.

Foreign companies do not need to establish a legal presence in the country, but are advised to work with a licensed local distributor.

- Under the Foreign Investments Act of 1991 (FIA), a foreign investor is generally allowed to own 100 percent of any local business enterprise.
- Some limitations on foreign ownership are imposed by the Philippine Constitution and certain statutes. The 11th negative list clarifies that pharmacy may be practiced by foreigners in the Philippines provided their home countries allow Filipinos the same right.

Tax environment and incentives for Life Sciences companies

Foreign and local businesses in the Philippines that qualify and are registered for tax incentives may take advantage of income tax holidays. And a special tax rate of five percent in lieu of any and all taxes if the business is located in a Philippine Special Economic Zone (PEZA).

The Philippines has introduced changes in the R&D tax incentive regime in recent years. The present government will likely enact additional tax reform laws that may generally restrict the availability of tax incentives.

Key trends and opportunities

Pharma/Biotech

Spending on Pharma is expected to increase due to the UHC Act, urbanization and the growing disease burden.

Patented medicines account for 37 percent of domestic sales, while generics account for 63 percent. The Philippines has a higher utilization rate of lower-cost generics than other Asian countries with comparable GDPs. The market for prescription drugs is 73 percent, and OTC is 27 percent.

Around USD1.6 billion of Pharma was imported in 2018, with India being the largest supplier at a 12.6 percent share. India

is the largest provider of generic medicines globally, and is in talks with the Philippines government to set up manufacturing zones in the Philippines for Indian Pharma companies wanting to access the ASEAN market.

Among Southeast Asian countries, the Philippines has been one of the more active promoters of the adoption of Biotech and Life Sciences innovations for health. The sector is opening up with the expansion of R&D activities and the establishment of new facilities, offering opportunities for R&D collaboration, the provision of related products and technology, and the development of genetic and genomic databases.

Medtech

The Philippines produces basic medical devices and disposables such as surgical gloves, syringes, and needles.

- Nearly all medical equipment, and around half of medical disposables, is imported – being around USD258 million in 2018.
- As a price-sensitive market, imports are largely from countries such as China and South Korea, with other major suppliers being Singapore, the US and Germany.

The expansion of hospital groups in the Philippines is generating Medtech market demand. There is also demand for medical equipment replacements as the Philippines has launched an ambitious program to develop and upgrade its healthcare facilities to ensure equitable access across the country.

High incident rates of heart, kidney, and respiratory diseases as well as hypertension have prompted hospitals to purchase equipment that provide specialized services, especially devices such as CT Scans, x-ray machines, ECGs, and dialysis machines.

With 100 million Filipinos spread across more than 7,000 islands, the country's fragmented geographical nature is driving the rapid adoption of telemedicine as well as interoperable Health Information Systems.



Thailand

Thailand's Life Sciences cluster

Thailand is often held up as an example of a successful emerging-market healthcare system.

- It offers universal coverage to 99 percent of its 69 million citizens at a cost of less than four percent of GDP.
- Healthcare expenditure was an estimated USD25.3 billion in 2016, with approximately 77 percent coming from the public sector.

The country is experiencing a rapidly aging population, with 15 percent of the population being 60 years of age and above, and a growing non-communicable disease burden. The government is seeking to address these challenges by increasing healthcare spending, supported by growth in healthcare personnel and infrastructure. More broadly, the government's Thailand 4.0 policy aims to make Thailand a medical hub for ASEAN countries.

The government's implementation of a national eHealth strategy from 2017-2026 is expected to increase efficiency. It is also expected to reduce waiting times and bed occupancy rates, which have been driving middle income consumers to private sector services that use high-tech diagnostics and digital technology.

The Ministry of Public Health is responsible for the organization, management and administration of health services.

- The country has over 38,000 health facilities: including 9,800 public primary centers, 24,800 private clinics, 249 public hospitals and 347 private hospitals.
- Around 70 percent of hospitals are small. Larger facilities target richer Thais and tourists in Bangkok.

Thailand is renowned for its excellent and low cost medical services, particularly for cosmetic surgery, dentistry, and cardiovascular diseases, among others.

- In 2017, it attracted around two million international patients and earned USD1.5 billion in medical tourism receipts.
- It ranks sixth most attractive medical tourism destination in the world.

Key players

- Bangkok Dusit Medical Services is the largest private hospital group in Thailand, operating 45 hospitals under six hospital brands – Bangkok Hospital, Samitivej Hospital, BNH Hospital, Phyathai Hospital, Paolo Hospital, and The Royal Hospital. Other key healthcare players are Bumrungrad International Hospital and Thonburi Healthcare Group.
- Leading Pharma companies that are active in Thailand include Pfizer, GlaxoSmithKline, MSD, Novartis, Roche, and Siam Bioscience. Key manufacturers include Takeda, Siam pharmaceutical, Olic, Meiji, and Mega.
- Medical device companies include Hoya Optics, Nipro, Kawasumi Laboratories, Reckitt Benckiser Thailand, Meditop, GE medical systems, Emerald Nonwovens International, Roche Diagnostics, Siemens, Semparmed Hoya, Tyco and Molnlycke Healthcare. Head offices tend to be located in Bangkok with manufacturing sites in neighboring provinces such as Pathum Thani and Nakhon Ratchasima.

Regulatory framework

The FDA's Medical Device Control Division (MDCD) is responsible for protecting consumer health by ensuring the quality, safety and efficacy of Pharma and regulating, controlling and monitoring the use of medical devices. All devices are regulated under the Medical Device Acts BE 2531 and 2551.

- Unlike for Pharma products, there is no requirement for clinical efficacy evaluation from randomized control trial before market approval.

The assessment of social, economic and ethical impacts of medical devices that cost more than THB100 million (USD3.3 million) is mandatory prior to market authorization.

- The Ministry of Public Health (MOPH) designates health technology assessment (HTA) units within and outside the country to conduct the assessments, the costs of which are borne by the medical device manufacturer.
- There is neither a price ceiling nor a reference set for medical devices such as orthopedic instruments or services provided such as CT scans. The price is subject to the conditions of market demand and supply.
- There is no reimbursement list for medical devices – their distribution is controlled by suppliers.

The Drug Act (1987) requires all those who wish to sell, produce or import drugs into Thailand to obtain a license from the Thai FDA.

Foreign medical device companies wishing to sell their products in Thailand must first register them according to a risk-based classification system based on ASEAN harmonized standards. In Thailand, Class I devices – licensed devices – have the highest risk classification.

- To import medical devices into Thailand, an importer must have an import authorization and registration permit from Thailand's FDA prior to shipment.
- Thailand prohibits the import of used/refurbished medical equipment.
- Devices that cannot be marketed or sold in the country of origin will not receive permission to be registered in or imported into Thailand.
- If all required paperwork is properly completed and submitted in a timely manner, it takes the Thai FDA three to five months to issue an import license for a Class III general device.

The Thai FDA's Secretary-General is permitted to control drug research study activities by issuing temporary suspensions, requesting specific improvements, or discontinuing a study that fails to comply with the Minister's published guidelines. While there are no regulations governing clinical trials, researchers who wish to import drugs into Thailand for the purpose of conducting clinical trials must submit their Clinical Trial Protocol to the Ethics Committee of the institution conducting the trial.

Tax environment and incentives for Life Sciences companies

R&D-related incentives and tax concessions are generally available under the Revenue Code and the Board of Investment (BOI) regulations.

The Thailand 4.0 national economic growth strategy targets industries including agriculture and biotech, biofuels and biochemicals, and health, wellness, and biomed.

- Biotech companies enjoy corporate tax exemptions of up to eight years, with a five-year additional 50 percent tax exemption for businesses that locate in science and technology parks.

Since 2015, Thailand has encouraged cluster development in Ayutthaya, Pathum Thani, Chonburi, Rayong, Chacheongsao, Prachinburi and Nakhon Ratchasima for electrical appliances, including medical devices.

In this super cluster is a minimum eight-year corporate income tax exemption and an additional five-year 50 percent reduction, as well as an import duty exemption on machinery.

Key trends and opportunities

Pharma/Biotech

Thailand is the second-largest Pharma market in Southeast Asia and has an extremely strong healthcare infrastructure. It is a leading developer of vaccines in the ASEAN region.

Patented medicines account for 51 percent of domestic sales, while generics account for 49 percent. The market for prescription drugs is 80 percent. OTC is 20 percent.

Pharma imports amounted to USD2.6 billion in 2018, with the US (16.5 percent) and Germany (14.8 percent) being the two largest source countries. Around 75 percent of Pharma producers in Thailand are domestic companies. The majority of Thai conventional medicine manufacturers are final-stage producers of finished generic drugs. Only five percent of ingredients are GMP-accredited. Thailand imports over 90 percent of its active substances.

The Thai Board of Investment (BOI) strongly encourages growth in Life Sciences. This has led to a focus on the sector by numerous companies and R&D hubs, as well as university and hospital research laboratories. Laboratories typically have ambitious research goals and the ability to create proof-of-concept platforms to license proprietary Pharma assets to international biopharma producers.

Medtech

Thailand has more than 160 domestic medical device manufacturers and exports more than 80 percent of its total production.

- Most of its products are lower-end devices such as disposable test kits and syringes, however, as well as latex products including surgical gloves.
- It is beginning to produce more high-value products such as dental equipment, orthopedic appliances and artificial respirators.

Approximately two-thirds of medical devices are imported, especially high-grade and sophisticated devices. Imports of medical devices totaled USD629 million in 2018.

- The US is the country's biggest source, accounting for more than 23 percent of imported devices.
- Imported medical equipment covers cardiology, clinical diagnostics, dentistry, dermatology, neurology, orthopedics, ophthalmology, rehabilitation, ultrasounds and x-ray devices.

Demand for, and spending on, assistive technologies is expected to increase with Thailand's aging population. Products expected to be in demand include devices such as wheelchairs, wristbands, robotic assistants, and hearing aids.



Vietnam

Vietnam's Life Sciences cluster

Healthcare expenditure in Vietnam was estimated at USD16 billion in 2018, with 50 percent by the government. This is expected to grow to USD43 billion by 2028, driven by public spending to expand universal healthcare. The government aims to cover 95 percent of the population under its national health insurance scheme by 2025.

Despite significant expenditure on healthcare, Vietnam's healthcare system continues to struggle with issues such as a lack of medical equipment, infrastructure degradation, uneven distribution of professional doctors and expertise. This leads to around 40,000 Vietnamese travelling abroad annually for healthcare, spending USD2 billion.

The government has approved the Vietnam Health Program (2018-2030) which includes measures on non-communicable disease detection, environmental sanitation, reduction of tobacco and alcohol consumption, and improvement of care delivery.

The government is also supporting the digitalization of healthcare, rolling out an Electronic Medical Record system nationwide since July 2019 that aims for 90 percent coverage of the population by 2025.

Government reform has led to the development of a private healthcare sector, which has seen remarkable growth over recent years.

- There is a large number of newly established private hospitals through public-private partnerships. Fifty-two new private hospitals and 44 public hospitals have been built in the past five years alone.
- The 1,160 public hospitals continue to outnumber the 184 private hospitals.

The country's high-caliber 'central-level' hospitals are located in major cities and are generally recognized as employing the country's best doctors. Their specialized wards and modern equipment tend to draw patients from outlying provinces, while lower-level under-equipped district hospitals struggle to attract patients.

Looking ahead, a number of factors will support the development of Life Sciences in Vietnam, including:

- Vietnam's integration into new generation Trade Agreements such as Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTTP) and EU-Vietnam Free Trade Agreement (EVFTA). These should strengthen its position within the Asian market.
- Vietnam has one of the fastest growing middle class in Asia. It is driving strong growth in demand for quality health products and services, including innovative medicines.

Key players

- Hoan My Medical Group is the largest private hospital and clinic group in Vietnam, with 14 hospitals and six clinics in the country. Well-established private hospitals in Vietnam include the Hanoi French Hospital, Vinmec, FV Hospital, Hanh Phuc Hospital and Hoan My Hospital.
- The main players in the Pharma sector include Abbott Laboratories, Bayer HealthCare pharmaceuticals, Nipro Pharma Corporation, Sanofi and B. Braun Melsungen. These are typically located in Hanoi, Danang and Ho Chi Minh City. Some are located in the Saigon High Tech Park in Ho Chi Minh City, which offers investor incentives such as exemption on corporate income tax for the first four years, exemption on import duty, land rental and housing and immigration assistance.
- Only 50 domestic manufacturers of medical equipment licensed by the Ministry of Health, with the majority manufacturing simple and low value-added products such as medical beds, cabinets, dressings, plastic gloves and syringes. Vietnam's Industrial Development Strategy Through 2025, With Vision toward 2035 (Decision No. 879/QĐ-TTg) prioritizes the development of the medical electronics sector after 2025.

Regulatory framework

The Department of Medical Equipment and Health Works (DMEHW) regulates medical devices in Vietnam. The MoH Drug Administration of Vietnam (DAV) regulates Pharma.

Medical devices are subject to regulation and licensing requirements set by the MOH. Only companies with a legal business entity registered in Vietnam and that have an import license are eligible to distribute medical equipment.

- To fulfil this requirement, foreign suppliers often sell through local distributors or agents.

- Both imported and domestic devices must also be granted a marketing authorization (MA) license prior to being sold in Vietnam. MA licenses must replace all import licenses upon expiration of the import license.

Foreign companies may wish to work with a local distributor. If a company wishes to incorporate in Vietnam, there are requirements based on the type of legal entity the company chooses.

Foreign investors may participate in the manufacture of Pharma products by establishing a joint venture with a Vietnamese partner or establishing a wholly foreign-owned company. Foreign investors are permitted to sell Pharma products to Pharma wholesalers in Vietnam that have been certified by the MOH as qualified to buy such from a foreign Pharma provider.

Clinical trials are regulated by the Administration of Science, Technology and Training of the MoH.

- Following approval, companies should submit a clinical trial protocol and product dossier, after which two examinations are conducted.
- Any company seeking to conduct clinical trials must conform with Good Clinical Practice (GCP).
- Only central-level health institutes are able to conduct clinical trials.

In December 2018, the Vietnamese government promulgated Decree No. 169/2018/ND-CP, amending Decree No. 36/2017/ND-CP on medical device management. This allowed risk classification results from qualified foreign entities to be recognized in Vietnam without conducting a separate local classification. An amendment in 2019 means the results must come from qualified local entities. In addition, government-approved entities will use the highest risk threshold for the final classification result, irrespective of the uses of the device and how it may be used alongside other devices. This would raise compliance costs for foreign equipment suppliers.

In January 2019, Decree No. 155/2018/ND-CP was issued to simplify procedures for drug imports. Commitments made by Vietnam under the European Union Vietnam Free Trade Agreement (EVFTA), signed in June 2019, will make the Vietnam market more accessible to pharmaceutical imports from the EU by eliminating import duties and strengthening intellectual property rights. They also remove the criteria that are stricter than international practices in clinical research and open up the government drug procurement market to EU businesses.

R&D incentives

The government has issued various policies to encourage enterprises in all sectors to invest in R&D activities with a number of tax incentives available.

Key trends and opportunities

Pharma/Biotech

Domestically manufactured medicines account for only 48 percent of the total Pharma market. Local drug production is insufficient to meet domestic demand. Foreign enterprises are responsible for around 20 percent of domestic Pharma production.

The prevalence of counterfeit medicines and lack of inspection and quality control means that trust in local pharmaceuticals is limited. Imported goods with strong brands can benefit from this situation.

Patented medicines account for 20 percent of domestic sales, while generics account for 80 percent. The market for prescription drugs is 75 percent, while OTC makes up 25 percent.

Vietnam imported USD2.2 billion of pharmaceuticals in 2018, with Switzerland (14.4 percent), France (11 percent) and Germany (9.7 percent) being the largest sources.

Vietnam has had some success in developing green Biotech for application in its agricultural sector.

- It is now making rapid progress in developing Biotech for medical applications – developing and manufacturing own solutions to be used in therapeutics, diagnostics and vaccinations.
- Vietnam is looking at Biotech as a potential solution to address challenges such as the growing incidences of cancer, diabetes, and antibiotic-resistant infections.

Medtech

Imported medical equipment dominates the local market by up to 95 percent, with imported goods coming mostly from Japan, the US, Germany and China. Demand is driven by a need to replace obsolete hospital equipment. The government applies low import tariffs and no quotas. Particular growth areas include operating theaters, orthopedics, and diagnostics and monitoring equipment.

To meet growing demand, Vietnam has eased market access and reduced regulations on imported medical devices. Increases in healthcare spending are expected to support the continued growth of imports, offering significant opportunities for foreign companies.

Domestic production of medical devices is on the rise as Japanese, US and European companies utilize Vietnam's low labor costs as well as import tax exemptions on materials used for domestic production or assembling of medical equipment.

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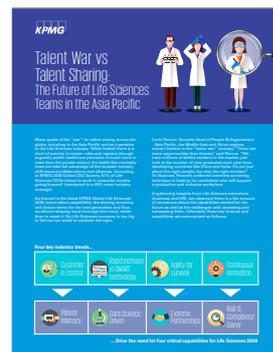
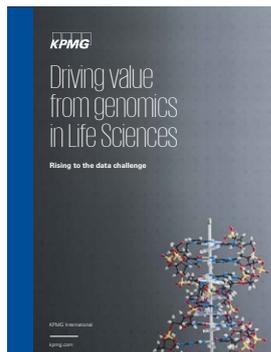
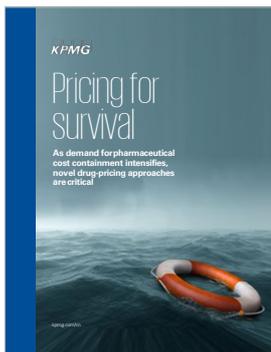
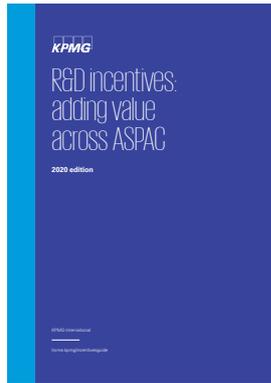
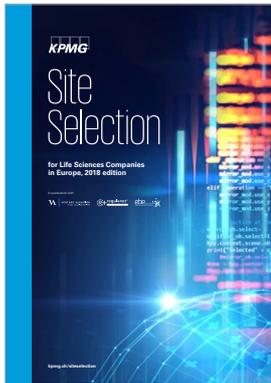
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