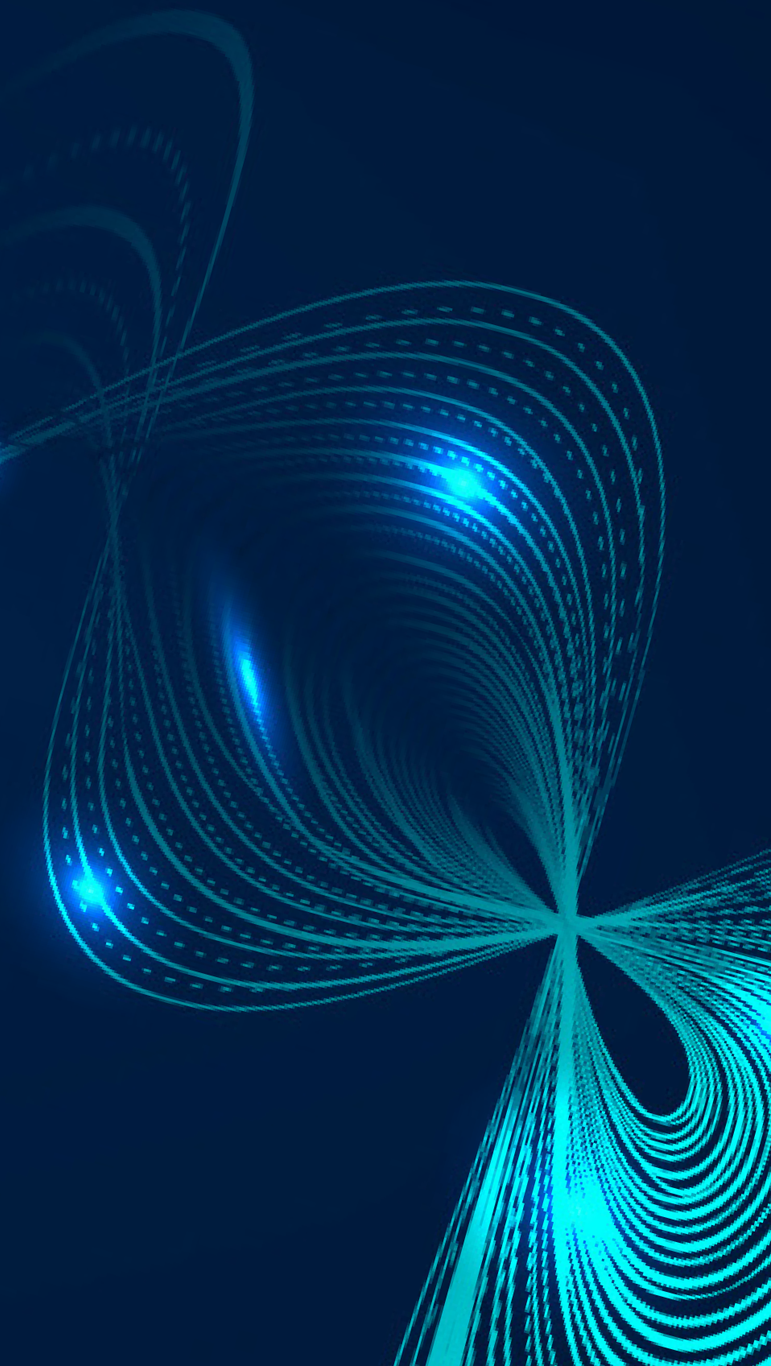
Baker McKenzie.

Improving the Top Line Through Healthcare Transformation

Unlocking and Accelerating Growth:

Healthcare and Life Sciences in Asia Pacific



Contents

01

Welcome from Baker McKenzie's healthcare and life sciences team

Innovation is flourishing in Asia Pacific. Unique population demographics, digitally savvy citizens and an overburdened healthcare system combine to create exciting and urgent opportunities for development.

From governments to private investors, established pharmaceutical companies to biotechs, organizations inside and outside the region are reimagining healthcare and life sciences to improve access, outcomes and affordability. This requires capital investment, collaboration and change at levels rarely seen before.

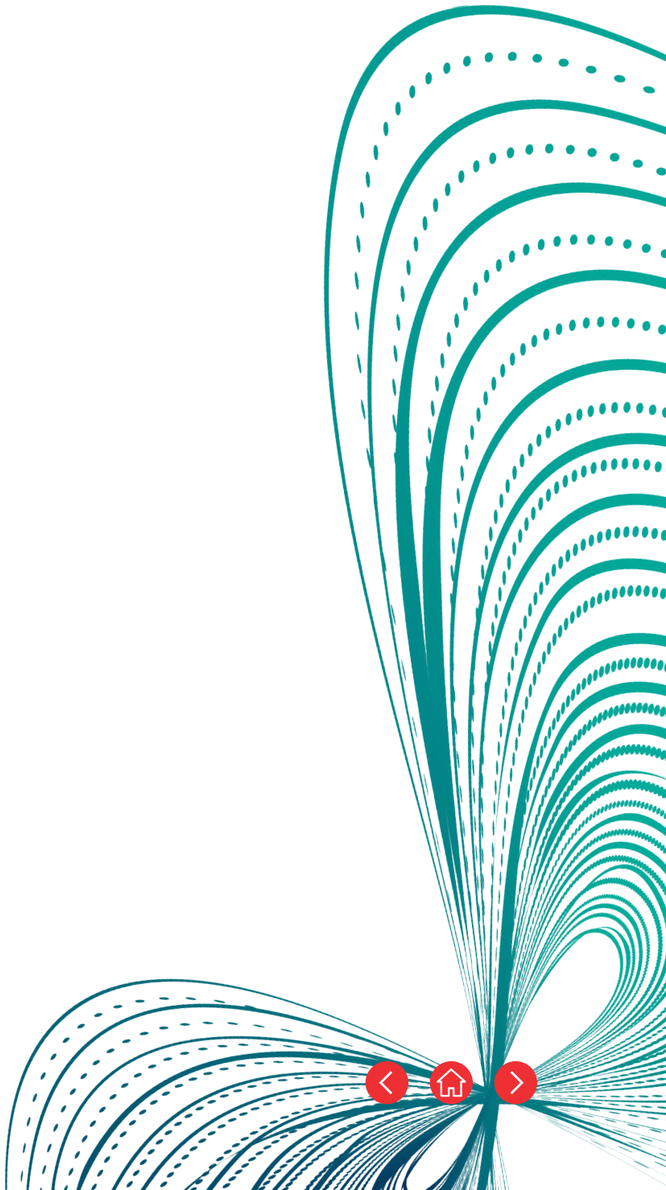
Harnessing opportunities in Asia Pacific relies on deep knowledge of local nuance when it comes to corporate transactions, regulation and compliance. Continue reading to discover:

A macro view of **Asia Pacific's unique market dynamics** and what this means for investors and innovators in healthcare and life sciences.

The **top three market opportunities** attracting cross-border investment interest and innovation.

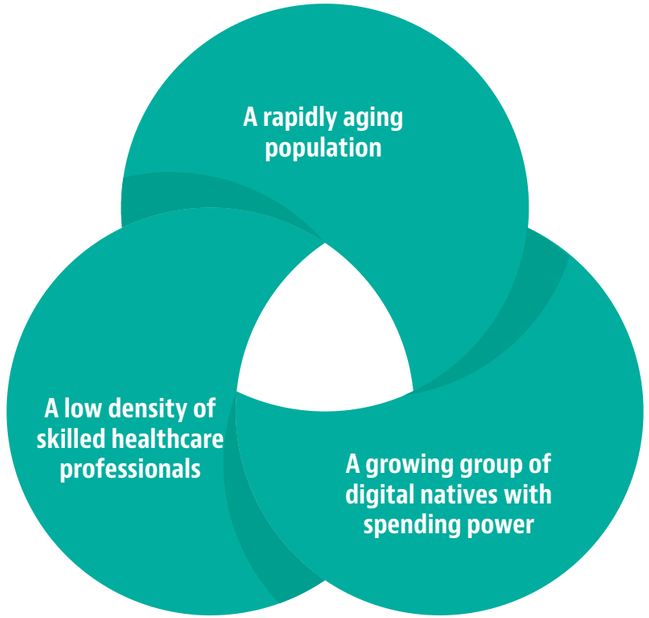
Legal insights and practical takeaways to help you unlock and protect growth – including cross-border deals, commercial collaborations, IP protection, data protection, takeover bids, and more.

Healthcare transformation starts here.



02 Why Asia Pacific is a magnet for innovation and investment

Three unique dynamics are key forces in the healthcare industry in the region, which reinforce the need to expand access, quality and affordability:



These regional nuances are drivers of transformation. Players across the ecosystem are revolutionizing the personalization of care, predicting patient outcomes with greater accuracy and preventing ill health with targeted, early intervention.

A rapidly aging population.

By 2050 one in four people in Asia Pacific will be over 60[1], placing additional strain on healthcare systems already feeling the effects of increasing chronic conditions and labor shortages.

A growing group of digital natives with spending power.

Asia Pacific is home to half of the world's internet users[2] and by 2030 two in three members of the middle class will be in Asia[3]. These tech savvy, affluent consumers expect digitally enabled end-to-end solutions to more proactively manage their health and wellbeing.

A low density of skilled healthcare professionals.

Countries in the region have an average of 1.5 trained healthcare professionals per 1,000 people compared to the OECD average of 3.4(2022)[4]. They are under pressure to deliver more with less.

1 Asian Development Bank https://www.adb.org/what-we-do/topics/social-development/aging-asia

2 McKinsey https://www.mckinsey.com/industries/healthcare/our-insights/the-future-of-healthcare-in-asia-digital-health-ecosystems

3 Brookings Global Economy and Development https://www.brookings.edu/wp-content/uploads/2017/02/global_20170228_global-middle-class.pdf

4 Philips https://www.philips.com.au/a-w/about/news/archive/standard/news/articles/2022/20220915-the-digital-innovation-wave-is-coming-to-the-asia-pacific-region.html

03 Where is transformation happening and who are the key players?

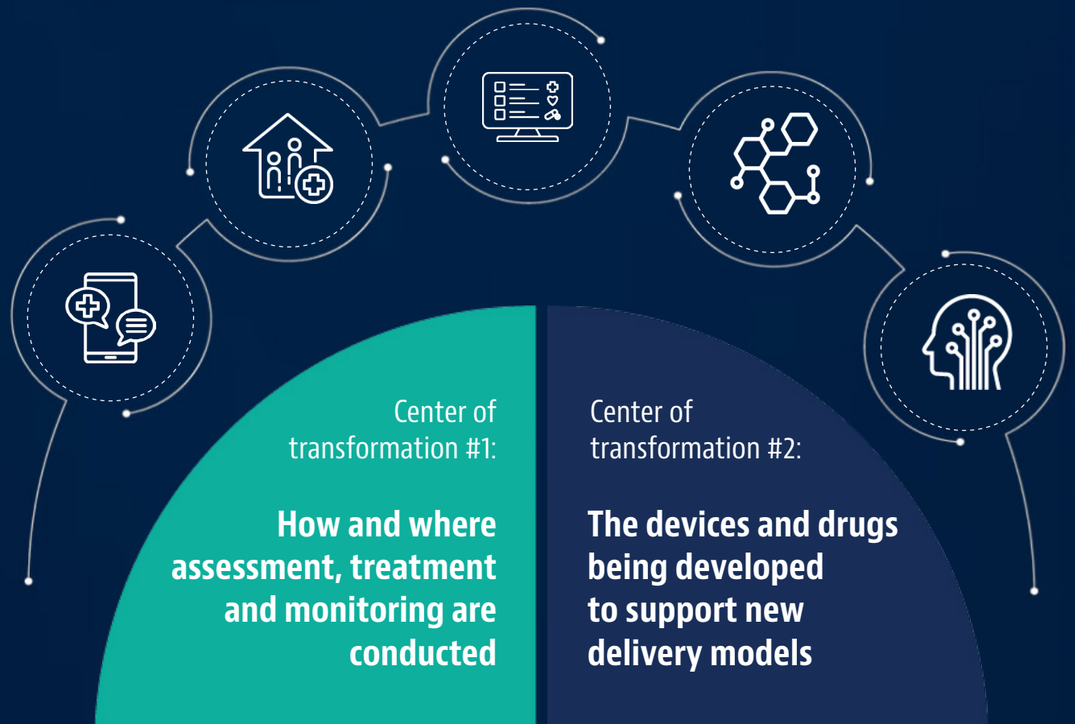
Digital therapeutics companies are delivering increasingly sophisticated and connected devices that empower patients to monitor their own conditions and provide real-time custom health recommendations.

Hospital-at-home care providers are increasingly meeting patient needs flexibly, quickly and efficiently outside of clinical settings, to improve patient outcomes while reducing costs.

Biotech and pharmaceutical companies are powering advancements in cell therapies, synthetic biology, gene sequencing and editing.

Next generation telehealth players are building a wider ecosystem of online and offline providers that provide patients with personalized tools for behavior change and self-monitoring.

AI technology platforms are accelerating the discovery of new molecules and antibodies, and enabling prediction and personalization in cutting edge devices.



04 What you need to know to unlock and protect growth

Organizations around the world are looking to Asia Pacific's healthcare transformation to drive growth. At the same time, governments are actively seeking partners to accelerate change in three critical areas: innovation, personalization and easing pressure on existing healthcare systems.

But with large-scale transformation inevitably comes a shifting regulatory landscape. A proactive approach to risk is essential for anyone unlocking growth in this dynamic region.

Three key market opportunities for healthcare transformation

Market opportunity #1

Attracting investment to Asia Pacific's innovative companies

Market opportunity #2

Accelerating the shift to personalized and preventative medicine through AI

Market opportunity #3

Easing pressure on healthcare systems through virtual and remote care delivery

Market opportunity #1: Attracting international investment for critical innovation

The ability to finance large-scale, long-term innovation will define the success of healthcare transformation in Asia Pacific. As public debt rises and capital markets remain erratic, attracting investors and private finance is mission critical.

What you need to know about the investment landscape

Share price volatility and faltering investor confidence saw IPO activity remain depressed in 2023. As a result, innovative biotechs in particular are struggling to raise capital and are increasingly turning to established pharmaceutical companies to fund development milestones. For pharmaceutical companies, collaboration with emerging players is key to addressing innovation deficits.

Meanwhile, lower valuations and strong market conditions mean that innovative enterprises in the region are particularly investable. This, combined with the promise of untapped growth markets and incentivized Foreign Direct Investment (FDI), is proving attractive for cash rich US and EU acquirers ready to deploy capital to acquire 'bargain' assets in Asia Pacific. The global top 25 pharmaceutical companies hold a combined USD 130 billion on their balance sheets and are ready to deploy.[5]

Opportunities for key market players to drive growth

Established pharmaceutical companies:

- Pharmaceutical companies can leverage more nimble innovative market players to outsource clinical trials and R&D.
- Opportunity to invest in acquiring the rights to new technologies and products that better serve end customers via collaborations and licensing agreements.

Biotechs:

- Faced with higher interest rates and tightening credit conditions, biotechs are in a race to reach the next clinical milestone before cash runs out. Data shows that even listed companies are struggling. 29 per cent have less than a year of cash on hand (2023).[6]
- Opportunity to source crucial funding via M&A, collaborations and licensing agreements, venture capital, private equity and IPO to advance drug approvals, run large scale clinical trials, acquire supply agreements and take drugs to market quicker with scale.

Investors:

- Private capital and institutional investors continue to pursue robust returns in the dynamic life sciences sector. Private equity deal value in the region has experienced a strong multi-year growth trajectory, bucking the slowdown in global activity.[7]
- There are extensive opportunities to invest directly in Asia Pacific's growing number of innovative players, or as part of consortia or co-investment agreements.

5 Bain https://www.bain.com/insights/healthcare-life-sciences-m-and-a-report-2023/

6 EY https://www.ey.com/en_us/news/2023/06/beyond-borders-2023-biotech-is-facing-a-complex-path-forward-says-ey-report

7 Bain https://www.bain.com/insights/asia-pacific-global-healthcare-private-equity-and-ma-report-2023/

Regional Spotlight: Government Incentives to encourage foreign direct investment (FDI)

Acquisitions, collaborations (and foreign interest in M&A activity) are bridging innovation deficits and raising much needed capital to accelerate development, approvals and get to market. Across the region, governments are also introducing various incentives in place to encourage foreign direct investment.

Mainland China

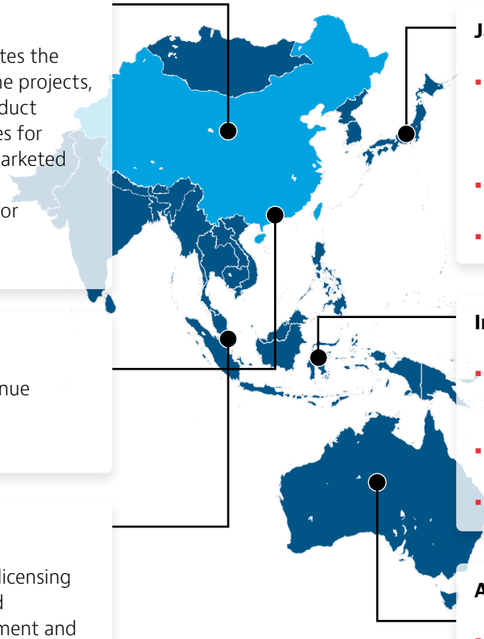
- Government policy announced in 2023 accelerates the implementation of foreign-invested biomedicine projects, encourages foreign-invested companies to conduct clinical trials in China and streamlines procedures for drugs manufactured in China that have been marketed overseas.
- Investment tax credits and foreign tax credits for international investors.
- Venture capital tax offsets.

Hong Kong SAR

- Chapter 18A rules to encourage global pre-revenue biotech IPO.
- Foreign tax credits.

Singapore

- Tax deductions on R&D set up costs, acquiring licensing rights, Intellectual Property (IP) registration and innovation projects to support clinical development and value creation.
- Tax incentives for pioneer companies and firms expanding or upgrading local operations.
- Tax exemption on profits generated from capital investment.
- Generally no restrictions on levels of foreign ownership of Singaporean companies.



Japan

- Special support available to global companies conducting R&D projects in Japan, including fundraising assistance for small and medium sized businesses, faster patent examinations, residency applications and review periods on new investments.
- New M&A rules to discourage defensive tactics from domestic companies.
- Tax breaks for companies enhancing headquarter locations.

Indonesia

- Tax holidays and allowances for foreign companies making significant capital investment plans, including firms in pioneer industries delivering value to the national economy.
- Creation of free trade zones and special economic zones, including income tax facilities and non-collection of VAT and import taxes.
- Support for training local workers.

Australia

- Foreign income tax offsets to help avoid double taxation.
- Concessional tax treatment for investments made in qualifying early stage innovation companies, including tax offsets and a ten year exemption on capital gains tax.
- Clear system of approval for foreign bidders via the Foreign Investment Review Board.

> As the Philippines undertakes reforms to provide universal healthcare, there is a real need for private sector investments in healthcare services and facilities, such as clinics, hospitals, specialty centers and laboratories, to scale up access for the wider public.
>
> Health Management/Maintenance Organisations (HMOs) - which are unique to the Philippines in Asia reflect the still progressive implementation of public healthcare and create interesting opportunities for non-traditional players.

Christina Macasaet-Acaban
Partner, Quisumbing Torres*,
the Philippines

**Quisumbing Torres is a member firm of Baker McKenzie*

Key legal considerations for investments, acquisitions and collaborations

As capital flows into Asia Pacific and new partnerships are established, what are the top legal considerations?

1. Biotechs should prepare for opportunistic bids to stay in the negotiating driver's seat

Share price fluctuations generally mean the time is ripe for prospective acquirers to make unsolicited and opportunistic bids. Given that current volatile market conditions look set to continue for the foreseeable future, biotechs that want to ensure shareholders are delivered maximum value should 'be ready'. The board needs to have a firm view on the company's longer term value and a well-developed response strategy, which requires planning and advance consideration .

How can biotechs protect their interests when faced with takeover bids?

1. **Understand your position.** It is crucial to have a clear understanding of your company's current position in the market and a realistic valuation, which includes being aware of the value of your product portfolio, IP rights and pipeline.
2. **Develop a clear strategy**. Know what you want out of a deal and have a clear strategy for achieving it. This could involve remaining independent, finding a partner for co-development, or being fully acquired.
3. **Secure key talent.** Human capital is a major value center in biotech. Retain your key researchers and other staff through employee contracts and incentives.
4. **Due diligence preparation.** Be prepared for intensive due diligence by having all necessary documents and information readily available. The ability to move quickly will be an advantage.
5. **Protect IP.** Intellectual property is usually the key value driver for acquirers. Ensure you have robust protection for your IP and that patents are secure.
6. **Regulatory awareness.** Understand the regulatory environment and any restrictions that could impact the rapid progress of the deal in relevant markets. For example, foreign ownership rules.
7. **Strengthen your negotiating team.** Create a team of experienced negotiators who understand the industry and the intricacies of M&A deals, especially in relation to regulatory, merger control, data and IP.

"With spending constraints curtailing further transformation, governments are increasingly looking to the private sector investment to fill the gap. As a result, private capital investors including the superannuation, pension and infrastructure funds, private equity and venture capital firms and high net worth individuals are driving much of the healthcare and life sciences transactional activity in Asia Pacific."

Tracy Wut
Managing Partner, China

2. Leverage innovative deal structures to maintain and grow revenues

Joint ventures, strategic alliances, licensing transactions and collaboration agreements have a long history in the healthcare and life sciences industry. However, in recent times, as healthcare and life sciences companies are looking for alternative ways of maintaining and growing revenues, the industry has borne witness to the development of more novel and innovative structures.

We expect to see continuing use of Co-Development, Co-Marketing and Co-Promotion Agreements, Co-operative Research Agreements and other innovative forms of collaborative structures moving forward.

> "We are seeing strong interest in Asia by global pharmaceutical and biotechs, including billion dollar plus global deals involving platform technologies and regional deals targeting specific Asian markets."

Oren Livne
Partner, New York

How can organizations structure effective collaborations and licensing agreements?

- **Dual licensing.** Dual licensing is growing ever more popular as a means of driving co-creation and transformation in the industry. Under a dual license, the licensee can offer academic institutions and open source collaborators access to software, databases, techniques and protocols, while offering proprietary licenses to commercial partners. If your agreement includes dual licensing, ensure that both licenses are clearly defined, don't conflict with each other and that all parties involved understand the terms.
- **Therapeutic combinations.** When combining novel therapies in new ways, as is increasingly common in life sciences innovation, it is crucial to check if there are existing IP (notably patents or copyrights) that could be infringed. Also consider the regulatory approvals required for such combinations. A comprehensive due diligence process should be carried out to ensure that all legal and IP-related issues are addressed.
- **Fee arrangements.** A variety of fee arrangements can be applied to collaboration and licensing agreements to best serve the circumstances of the deal parties and the focus of the collaboration, including upfront payments, milestone payments, royalties or equity stakes. The arrangement should clearly specify what each party is entitled to and when payments are due. It's also important to set clear milestones and outline what would happen in the event of missed milestones, payment issues as well as the need for retesting or new trials.
- **Intellectual property rights.** Companies need to carefully consider how to protect their intellectual property rights and know-how in dealings with third parties. Parties who have access to or are using such intellectual property and know-how, both present and in future, should be clearly defined, as well as how and for what purposes such parties can use the intellectual property and know-how. Ownership of background and foreground intellectual property should be clearly defined, along with non-disclosure and confidentiality obligations. With regard to trade secrets, key practices companies should adopt are identifying trade secrets, recording, reviewing, and securing these, and training employees on cybersecurity measures to prevent leaks. This is crucial to successful collaborations.
- **Liability and indemnification.** These clauses protect parties from potential legal action resulting from the agreement. They should be carefully negotiated and drafted, including any contingencies and warranties.
- **Antitrust compliance.** Such collaborations and arrangements, particularly between competitors, can raise antitrust issues. These risks should be considered and managed from the outset, when negotiating and structuring your agreements and joint initiatives. This includes interactions connected to a transaction; also be aware that many deal structures can trigger regulatory filings and approvals.

3. Understand the regulatory considerations in M&A

Merger control rules are expanding and becoming more unpredictable and interventionist, while foreign investment screening is increasingly geo-political. Under these regimes, transactions that meet particular financial or economic thresholds may be subject to regulatory approval, often prior to closing. This includes share or asset acquisitions; new greenfield joint ventures or investment vehicles; changes in shareholdings, and potentially various types of structures other than mergers and acquisitions.

To mitigate disruption to transaction timelines and to ensure deal certainty, it is important to map out issues as early as possible. This entails planning for and running a multi-jurisdictional assessment in advance, to determine where and which filings and approvals may be required.

> “Filing obligations across multiple jurisdictions can be triggered easily and filings need to be made quickly to keep to deal timetables. Good planning can prevent delays as most regimes around the world are mandatory and require parties to standstill until formal clearance.”

Stephen Crosswell
Partner, Hong Kong

How should organizations navigate these regulatory layers when contemplating a transaction?

- **Consider the regulatory hurdles on every deal.** Merger control and foreign direct investment (FDI) rules can be triggered easily and require filings to be made quickly. Most regimes around the world are mandatory and require parties to standstill until formal clearance. The most common trigger is a change of control.
- **Think global.** It is irrelevant where the deal is being done or where parties are based. What matters is who the parties are, and often the revenues of the parties involved. No filing in one jurisdiction does not mean no filings elsewhere. Some parties may need to file in multiple jurisdictions.
- **Assess early.** Work out which filings need to be made as early as practicable, so that the impact on deal strategy, budget and timetables can be considered. Filings take time to prepare, and require significant amounts of data and input. While many commonly take a pragmatic approach as to whether or not to file in some cases, depending on the deal and enforcement environment, it is important to revisit your risk appetite on each transaction. For transactions which may raise substantive concerns from regulators (for example, where the parties are close competitors in a concentrated market), it is strongly advisable to develop a plan to pre-emptively identify and address these issues, including potential remedies (which may take the form of a divestiture) upfront. Be aware that internal documents are disclosable and will be scrutinized by regulators, especially on such deals, so put in place document creation guidelines.
- **Manage regulatory risk.** Merger control and FDI requirements can lead to a delay between signing and completion, and a transaction can be conditional on these approvals. For notifiable deals, transaction documents need to reflect how this risk will be allocated and managed, and to align timing with the M&A timetable / longstop date.
- **Be mindful of dealings with competitors.** Parties typically exchange a wide variety of information when negotiating a transaction, and access to competitively sensitive information is often necessary for planning and valuing the deal. Be aware that this is high risk, when such exchanges are between competitors or potential competitors and are not appropriately managed. “Competitors” can include buyers, sellers and other investors.

Market opportunity #2: Accelerating healthcare transformation through AI

Rapid advances in AI and data processing have enabled a new generation of solutions, from gene sequencing and diagnostic imaging to health monitoring and workflow. Collaboration between technology platforms, industry players, private investors and public organizations is powering transformation and, as AI matures, all will play a pivotal role in developing the drugs, devices and delivery infrastructure of the future.

What you need to know about the investment landscape

AI is a key part of the revolution in healthcare and life sciences, and will play a critical role in addressing the biggest challenges facing healthcare systems in Asia Pacific. We already see AI improving patient outcomes, accuracy and accessibility – from diagnosing diseases earlier and predicting treatment efficacy, to helping identify novel drugs and bring them to market faster.

Asia Pacific is home to a growing number of promising start-ups and established leaders in the AI space. This dynamic market is seeing robust deal activity, including venture capital finance, collaborations and licensing agreements between digital players and established pharmaceutical companies, and public-private partnerships. This will only increase as AI matures, existing applications scale and new use cases are discovered.

Opportunities for key market players to drive growth

- **Platforms and digital service providers.** Large technology companies are making bold plays in healthcare and life sciences, leveraging their development capabilities to build industry specific solutions. Behavior monitoring, workflow management, data compliance and electronic health record solutions are key growth areas. Partner with established pharmaceutical companies and public institutions to advance digitization and harness anonymized patient data for future innovation.

- **AI-first healthtechs, biotechs and digital therapeutics.** There are approximately 570 AI healthtech start-ups across Australia, China, Japan and Singapore[8] – the 'big four' AI markets in Asia Pacific. These agile, highly specialized players target problem areas and unmet needs across the ecosystem with innovative new solutions, and similar to biotech, funding development milestones and scaling market access are top priority. Collaborate with insurers, established pharmaceutical companies and public institutions to transform drug discovery, bioinformatics, diagnosis, treatment, monitoring and outcome predictions.

- **Established pharmaceutical companies and medical device companies.** For leading global multinationals looking to enhance existing offerings and operations with AI, it is more time and cost efficient to buy rather than build. Invest in the capabilities of both specialist and generalist digital players to create new revenue streams.

8 Tracxn data https://tracxn.com/d/explore

- **Public institutions.** Access to population data and clinical infrastructure is key to AI development in the industry. Increasingly, collaborations between government-backed agencies and private organizations are powering change. For example, more than 20 research institutes operate under Singapore's A*STAR initiative, which aims to advance scientific discovery and innovation, fund innovation and enable successful spin offs from academic institutions via government incubators and programs.

- **Venture capital.** We are seeing an uptick in global venture capital firms entering the Asian market and a general increase in cross-border deal flow, which will lead to increased competition for venture deals in the region. But investors remain selective. Liquidity is a key concern and investments are increasingly likely to be structured with more flexibility for investor-driven exit requirements – preferred equity, convertible notes and SAFE instruments. Look for high potential companies in the region with the scope to scale.

"Governments across the Asia Pacific region have identified the power of AI to help address national healthcare challenges and turbocharge innovation, investment and economic growth. Favorable government policies have been and will remain key to growth."

Yee Chung Seck
Partner, Vietnam

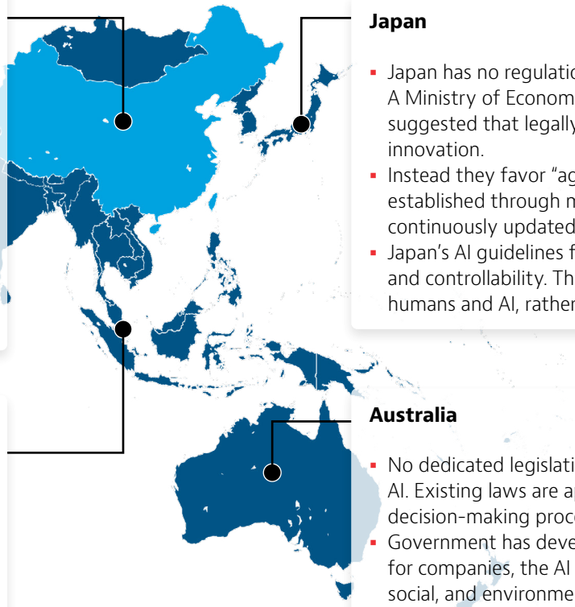
Regional Spotlight: AI regulation across different Asia Pacific jurisdictions

Mainland China

- In 2023 the Cyberspace Administration of China released their Interim Measures for the Management of Generative Artificial Intelligence Services, which stipulates rules to regulate generative AI.
- The law includes traditional AI safety measures such as IP protections, transparency and discrimination, as well as others that are unique to China, such as adherence to the values of socialism and the prohibition of generating incitement against the State.
- Several laws related to data protection, cybersecurity, and e-commerce also indirectly impact AI applications.

Singapore

- Government encourages responsible AI governance over specific regulations. But existing data privacy laws apply.
- The Infocomm Media Development Authority and the Personal Data Protection Commission (PDPC) has developed a Model AI Governance Framework, providing detailed guidance to private sector organizations deploying AI.
- The PDPC also recently launched a public consultation on the proposed clarifications on how data protection law applies to the collection and use of personal data to develop and deploy predictive AI systems. These clarifications will take the form of non-binding Advisory Guidelines.
- Singapore launched the world's first AI testing toolkit, AI Verify.



Japan

- Japan has no regulations that generally constrain the use of AI. A Ministry of Economy, Trade, and Industry report in July 2021 suggested that legally binding, static regulation could stifle innovation.
- Instead they favor "agile governance" – guidance and frameworks established through multi-stakeholder dialogue, which can be continuously updated.
- Japan's AI guidelines focus on transparency, user assistance, and controllability. They also emphasize collaboration between humans and AI, rather than replacement of humans by AI.

Australia

- No dedicated legislative framework specifically for regulating AI. Existing laws are applied as relevant to AI and automated decision-making processes.
- Government has developed voluntary, high-level ethical principles for companies, the AI Ethics Framework, which emphasize human, social, and environmental wellbeing.
- Momentum is building for more specific AI regulation in Australia, with proposals for potential bans on deep fakes and other high risk AI applications.

"As AI is integrated into drug and patient pathways, risks and uncertainties are emerging. Regulation is evolving piecemeal behind the technology, data privacy, accuracy and bias are significant concerns, and existing frameworks around IP and competition are being challenged by the new. Managing these issues will be critical to realizing safe and sustainable growth."

Isabella Liu
Partner, Hong Kong

Key legal considerations for AI

As AI technology matures and markets adopt new standards, what are the top legal considerations?

1. Protect value in collaborations and agreements

Collaboration between data providers, developers, public institutions, life sciences and healthcare providers is common in digital health. But in entering into collaborations, companies must ensure appropriate treatment of intellectual property, know-how, trade secrets and confidential information.

In particular, it is important to consider how IP is protected and exploited at the end of the agreement. For example, whether this will need to be returned or destroyed, or if the parties will be subject to continuing obligations. Codifying terms into agreements helps to avoid infringement risk and contested ownership later.

How can organizations take a proactive approach to IP protection?

- **Legal mechanisms.** Companies should: (a) investigate IP infringement risk (b) carefully document AI use and programs to formalize IP protection for AI inventions; (c) implement non-disclosure agreements in relevant contracts; (d), secure physical and digital access to proprietary information; (e) implement policies that take into consideration the security capabilities of specific AI systems; and (f) train employees on confidentiality protocols.
- **Active management.** Companies should: (a) develop training protocols (including contractual measures, where appropriate) to minimize infringement risk; (b) regularly conduct patent and trademark searches to establish freedom to operate and monitor for possible infringements; (c) review licensing agreements to ensure they clearly define rights and responsibilities and are keeping up with product enhancements; and (d) be aware of any changes to IP law in relevant jurisdictions, as laws evolve to take account of the impact of new technologies including AI.
- **Enforcing IP rights.** The IP enforcement landscape around AI and AI-facilitated innovations has emerged around certain key issues. Litigants are beginning to explore core questions: (a) can works created by AI models be eligible for IP protection?; (b) does the training of AI models amount to infringement of underlying IP rights in such data?; and (c) what is the role of trade secrecy in protecting AI assets? The answers to these questions will shape the commercial landscape of AI in this pivotal moment in its development.

> “Creating safe and effective AI products can be an expensive and complex venture, particularly in AI drug discovery, where IP is diverse – from datasets and algorithms to molecules and antibodies. As such, the commercial protection of these innovative technologies has become a pivotal issue. Collaboration between data providers, technical experts, developers and end users is also common here, which gives rise to complex issues of IP ownership and liability for potential infringement. Due to these complexities, we expect to see a rise in disputes as technology evolves and more players enter the market.”

Isabella Liu
Partner, Hong Kong

2. Manage confidentiality and bias risk when collecting and processing healthcare data

Data is essential to developing effective AI solutions. But in healthcare and life sciences the stakes are particularly high. Training models to diagnose, recommend and predict medical outcomes requires highly sensitive personal health information, and patient safety rests on accuracy. As such, how data is collected, processed and protected is subject to close regulatory oversight.

In respect of confidentiality, companies should be particularly mindful of sharing data in the course of collaborations, and put robust data handling protocols and encryption in place to limit the chance of a breach. Similarly, fairness metrics, adversarial testing and sensitivity analysis can help address hard-to-detect bias, incomplete or flawed data sets early.

3. Embrace ethics-based governance to mitigate regulatory complexity

AI defies national boundaries and effective governance demands a collective regulatory approach. Instead we are seeing a patchwork of national AI policies, sectorial codes of conduct and corporate responsibility standards.

As AI matures, a more formal global framework may emerge that reconciles ethical and legal imperatives with the need to foster innovation and economic progress. In the meantime, organizations can look to "soft law" principles and adopt ethical governance frameworks to guide AI adoption.

"The present global landscape of AI regulation is varied and focused on addressing the new risks posed by AI systems, such as bias in decision making and new privacy risks. As countries introduce new rules, they will need to balance these risks with the imperative to promote business certainty and attract jobs and investment. As the impact of AI on commerce will be multifaceted, don't assume that there will soon be a harmonization of AI regulation. Businesses should pay close attention to developments in various jurisdictions of interest to stay attuned to change."

Oren Livne
Partner, New York

Principles for an ethics-based governance model for AI

"Soft law" is the dominant approach governing AI, outside existing data privacy, IP and patient safety regulation. Taking the lead from proposals endorsed by policymakers at the OECD and in the recent Bletchley Declaration on AI safety, what principles should companies consider as they develop their own AI governance models?

- **Human-centricity.** Design AI that adheres to human rights, improves human wellbeing and coexists harmoniously with people. Include mechanisms for human invention in AI.
- **Justice.** AI systems shouldn't create or reinforce bias. Ensure AI promotes democratic values, inclusive growth and maintain fairness in all AI processes.
- **Transparency.** Companies should establish transparent AI algorithms, decision making processes and governance structures that clearly identify roles, expectations and accountability. Responsible individuals should be able to understand and challenge AI-driven outcomes.
- **Safety and accountability.** AI systems should be built and tested for safety, with mechanisms in place to ensure accountability for any adverse outcomes or harm caused by AI.
- **Privacy.** AI must respect privacy rights and provide data protection. The use of AI should not infringe upon an individual's right to privacy.
- **Strategic integration.** AI should be integrated strategically into business operations, including considering its impact on the workforce.

Market opportunity #3: Improving patient outcomes and containing cost through virtual and remote delivery

Asia Pacific is under pressure to meet the disparate needs and expectations of elderly and digital native populations without adding cost or clinical professionals. To achieve this ambitious goal, doing more of the same is not an option. The region is counting on a growing ecosystem of telehealth platforms, remote care providers and digital devices to transform healthcare delivery.

What you need to know about the investment landscape

Telehealth and hospital-at-home innovation is transforming the delivery of healthcare in Asia Pacific, meeting patients' care needs flexibly, quickly and efficiently. The convenience of being assessed and treated remotely has led to better patient outcomes for both immobile elderly groups and busy millennials, leading to higher levels of satisfaction and reduced costs.

New offerings are developing at speed, powered by a new ecosystem of service providers, digital therapeutics companies, technology players and investors. But as the industry matures and competition grows, simple digital consultation business models alone are unlikely to offer sustainable long-term growth.

Consolidation is growing across the region, as larger players acquire local telehealth platforms to access new markets and grow the user base. Deal activity is also being driven by virtual providers buying up in-person clinical facilities to augment their offerings.

Opportunities for key market players to drive growth

- **Global and regional telemedicine providers.** Innovators at the forefront of the virtual health trend are now looking for new growth opportunities in vertical integration and expansion to physical facilities. Companies are integrating products and treatment plans into online consultation models, blurring the lines between health providers and retailers.

- **Hospital groups and care providers.** There are 730 home health care companies in Asia Pacific, with a total funding amount of USD 640 million from 189 funding rounds.[9] With so many players operating in this space and such huge potential in operating scale, private equity buyouts and acquisitions by hospital groups and elderly care providers seeking synergies are on the rise.

"Hospital-at-home programs offer financial advantages for healthcare institutions due to the reduction in required bed space. Although they must invest in the technological infrastructure to allow 24/7 remote monitoring of patients. In Singapore, hospital-at-home programs have been largely offered by public hospitals, but it's likely similar programs will be increasingly offered by private healthcare institutions, which will impact payment models and investment patterns."

Isabella Liu
Partner, Hong Kong

9 Crunchbase https://www.crunchbase.com/hub/asia-pacific-home-health-care-companies

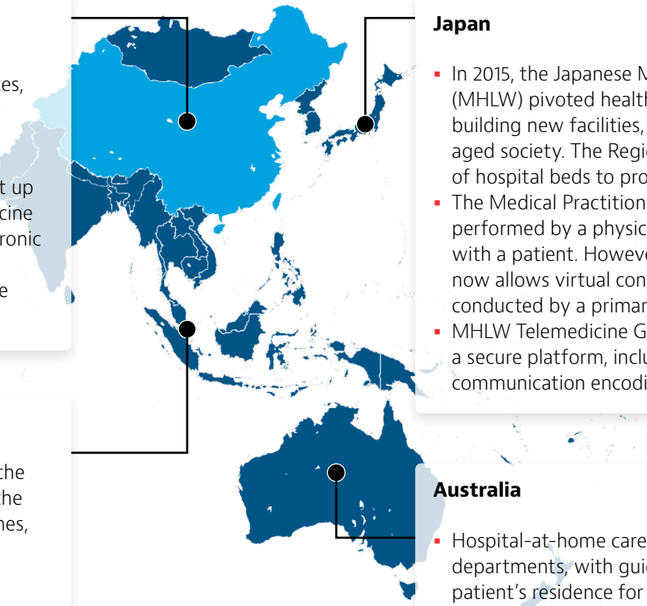
Regional Spotlight: Virtual and remote care regulation across different Asia Pacific jurisdictions

Mainland China

- The National Health Commission has issued several guidelines and standards for home healthcare services, covering areas such as service delivery, staffing, and patient rights.
- China is a leader on telehealth. As far back as 2018, a policy was issued to allow medical institutions to set up internet hospitals and to directly carry out telemedicine services for revisiting patients with common and chronic diseases.
- Government approved more than 1,600 telemedicine platforms as of the first half of 2021.

Singapore

- Home healthcare providers must be licensed under the Private Hospitals and Medical Clinics Act and meet the standards set out in the Ministry of Health's guidelines, which cover patient safety, quality of care and the qualifications of healthcare professionals.
- With respect to telehealth, the Ministry of Health introduced the LicenceOne portal to fast-track applications for telemedicine licenses.
- It also issued National Telemedicine Guidelines to provide clarity on the standards expected of healthcare practitioners when conducting teleconsultations. For example, only qualified doctors registered with the Singapore Medical Council can provide virtual care, to ensure quality equivalent to traditional face-to-face consultations.



Japan

- In 2015, the Japanese Ministry of Health, Labor and Welfare (MHLW) pivoted health policy to facilitate home medical care over building new facilities, as a way to meet the needs of its super-aged society. The Regional Healthcare Vision limits the expansion of hospital beds to promote in-home services.
- The Medical Practitioners' Act requires medical diagnosis to be performed by a physician through a face-to-face consultation with a patient. However, relaxation of telemedicine rules in 2022 now allows virtual consultation from the first visit providing it is conducted by a primary care physician.
- MHLW Telemedicine Guidelines also require providers to provide a secure platform, including multi factor authentication and communication encoding.

Australia

- Hospital-at-home care is regulated by individual state health departments, with guidelines outlining the provision of care in a patient's residence for conditions requiring clinical governance.
- In relation to telehealth, new guidelines from the Medical Board of Australia came into force in September 2023 to combat so-called 'tick and flick' services, which offer prescriptions without a real-time consultation with a doctor.
- Medicare Benefits include reimbursement for telehealth services and all registered health practitioners can use telehealth as long as it is safe and clinically appropriate.

"Improving accessibility to healthcare has been a key priority for governments across Asia Pacific. Governments have increasingly invested in telehealth infrastructure and put in place regulatory and reimbursement frameworks to encourage its use – with resulting advantages to patients, healthcare providers and Governments around the region. These shifts recognize the importance of equitable healthcare access and affordability of healthcare."

Elisabeth White
Partner, Australia

Key legal considerations for virtual and remote care

As the industry consolidates and evolves, what are the top legal considerations?

1. Build a robust data governance framework to mitigate compliance risk

The sensitivity and volume of personal data being processed in virtual and remote environments means that the commercial impact and regulatory consequences of non-compliance are high.

This is a complex area for organizations to manage. Data is often stored and processed via different operating systems, providers and jurisdictions, and regulatory regimes overlap. Therefore, the scope of security flaws, and cyber events is significant.

How can organizations mitigate data risk?

1. **Be well prepared.** Consider the legal requirements and consent required for data processing in key markets. Develop privacy notices and ensure transparency over secondary uses in these communications.
2. **Conduct data protection impact assessments.** If you are unsure how the organization is collecting, processing, storing and sharing information, impact assessments can highlight potential risk areas. This may be particularly relevant at the start of a new collaboration or following a merger or acquisition. In some jurisdictions, conducting such assessments is a statutory requirement.
3. **Protect against third party risk.** Include language in contractual agreements with third party suppliers that clearly defines liability and employment of reasonable risk management precautions in the event of a cybersecurity breach. Consider the use of insurance coverage. Additionally, conducting due diligence over the third parties handling data is also recommended.
4. **Maintain a dynamic view.** Regularly test and review security measures, including encryption, systems and governance protocols.

“Getting data security right is paramount for continued transformation of health.”

Ren Jun Lim
Principal, Singapore

2. Anticipate patient safety class actions and claims with proactive risk assessment

The shift to virtual and at-home care can amplify patient safety risks, including misdiagnosis, poor quality advice and inconsistent treatment. Data sharing challenges and lack of interoperability between digital platforms, electronic health records and hospital providers may also be compounding these issues. As a result, we are likely to see a rise in class actions and damages claims associated with patient safety.

For telehealth and digital therapeutics, these risks are primarily associated with accuracy of information, patient confidentiality and the ability to accurately report and monitor adverse outcomes. In hospital-at-home services, regulators are particularly concerned with avoiding unsafe care, including infection control, staffing levels and training and equipment failure. The development of standardization guidelines is a priority here.

How can organizations minimize patient safety risks?

1. **Design for safety.** Involve clinical experts, health professionals and care organizations in the creation of new products and services to anticipate issues. Integrate safety into product development and ensure compliance with all relevant safety standards.
2. **Establish license to operate.** Understand the rules for providing virtual care, including where healthcare professionals should be licensed and requirements for in-person consultation before remote care and monitoring can be introduced.
3. **Create rigorous guidelines and protocols.** Set operational protocols and standards, such as confirming patient location, hand offs between clinicians, escalation processes and workflows. Test and update them regularly.
4. **Educate patients.** Disclose potential risks to patients and healthcare professionals upfront and communicate consistently as interventions progress. Keep everyone in the loop.
5. **Report and learn from issues.** Actively monitor patient outcomes, report on adverse events and find learnings. Ensure these are shared within the organization to prevent repeat occurrences.

05 Key takeaways

Asia Pacific is a dynamic region with a unique imperative to transform healthcare. Population demographics, robust market conditions and headroom for growth combine to create a magnetic destination for innovation and investment. The rest of the world is looking at how organizations in Asia Pacific are pioneering drug development, digital devices, AI and healthcare delivery to meet the specific needs of the region.

Whether you are an investor who wants to deploy capital with favorable investment prospects, a pharmaceutical company looking to augment R&D, or a biotech or digital player seeking funding for your next milestone, you can unlock growth here.

But realizing this potential means navigating regulatory, competitive and compliance nuances across the region and in your target jurisdictions. A proactive approach to manage these evolving legal considerations, and the support of an experienced legal partner, is key to success.

Our top four key legal considerations for investors and innovators transforming healthcare

- **Data compliance.** Telehealth and digital therapeutics are the new normal, and regulators are strengthening rules to protect patient data, ensure safety and support positive patient outcomes. Cybersecurity is also front of mind in an increasingly digital industry. Use our framework to coordinate a robust approach.
- **AI governance.** Regulators are weighing regulatory approaches to AI, with different jurisdictions favoring different regimes. For example, Singapore will rely on existing data protection and medical device rules to regulate AI, while China has created AI-specific rules. Keep up to date on the big shifts.
- **Antitrust and FDI regimes.** Numerous jurisdictions are enforcing against failures to file. Identify these regulatory hurdles as early as possible in transaction discussions so you can incorporate these considerations into your transaction strategy, budgets and deal timetable. Remember that many deal structures can trigger filings around the world, and the most common trigger is a change of control: it is irrelevant where the deal is being done or where parties are based.
- **Protecting value.** Protecting IP and managing liability to avoid disputes should be high on the agenda, particularly as collaboration between digital players, established pharmaceutical companies and public institutions grows. Consider how these agreements are structured upfront to create clear ownership, controls and dispute resolution mechanisms.

What to expect next in this series

Here we have focused on opportunities to finance innovation and accelerate transformation in Asia Pacific – growing the top line. Next we turn our attention to strategies for remaining sustainable, resilient and profitable – protecting the bottom line.

Expect insights on ESG governance, supply chain efficiency, carve-outs and more.

How Baker McKenzie can help you unlock growth

Baker McKenzie's unique view on the healthcare and life sciences industry in Asia Pacific enables our clients to grow in a rapidly changing environment. Clients trust us because we have over 60 years' experience in the region and know the legal landscape like no other.

Our key legal expertise

Collaborations and licensing agreements
DISCOVER MORE

Strategic M&A
DISCOVER MORE

IP protection
DISCOVER MORE

Cross-border data privacy compliance and cyber-security
DISCOVER MORE

Dispute resolution
DISCOVER MORE

Competition compliance, merger control and foreign direct investment
DISCOVER MORE

06

Key Contacts

Asia Pacific Healthcare & Life Sciences Chair

Elisabeth White
Partner, Australia
+61 2 8922 5386
elisabeth.white
@bakermckenzie.com

Intellectual Property

Isabella Liu
Partner, Hong Kong
+852 2846 1689
isabella.liu
@bakermckenzie.com

Elisabeth White
Partner, Australia
+61 2 8922 5386
elisabeth.white
@bakermckenzie.com

Kherk Ying Chew
Partner, Malaysia
+603 2298 7933
kherkying.chew
@wongpartners.com

Ren Jun Lim
Principal, Singapore
+65 6434 2721
ren.jun.lim
@bakermckenzie.com

Anti-Trust & Competition

Stephen Crosswell
Partner, Hong Kong
+852 2846 2599
stephen.crosswell
@bakermckenzie.com

Transactional (M&A)

Kate Jefferson
Partner, Australia
+61 2 8922 5302
kate.jefferson
@bakermckenzie.com

Panyavith (Taro) Preechabhan
Partner, Thailand
+66 26662824#4360
panyavith.preechabhan
@bakermckenzie.com

Zhang Hong
Partner, China
+ 86 21 6105 8588
hong.zhang
@bakermckenziefenxun.com

Safari Watanabe
Partner, Japan
+81 3 6271 9480
safari.watanabe
@bakermckenzie.com

Yee Chung Seck
Partner, Vietnam
+84 28 3520 2633
yeechung.seck
@bakermckenzie.com

Tracy Wut
Managing Partner, China
+852 2846 1619
tracy.wut
@bakermckenzie.com

International Trade & Compliance

Anne Petterd
Partner, Australia
+61 2 8922 5888
anne.petterd
@bakermckenzie.com

Christina Macasaet-Acaban
Partner, the Philippines
+63 2 8819 4947
christina.macasaet-acaban
@quisumbingtorres.com

Cahyani (Icay) Endahayu
Partner, Indonesia
+62 21 2960 8515
cahyani.endahayu
@hhplawfirm.com

Kevin Wang
Partner, Taiwan
+886 2 2715-7322
kevin.wang
@bakermckenzie.com

Andrew Martin
Principal, Singapore
+65 6434 2507
andrew.martin
@bakermckenzie.com

Vivian Wu
Partner, China
+86 10 6535 3860
vivian.wu
@bakermckenziefenxun.com

Dispute Resolution

David McCredie
Partner, Australia
+61 2 8922 5358
david.mccredie
@bakermckenzie.com

Celeste Ang
Principal, Singapore
+65 6434 2753
celeste.ang
@bakermckenzie.com

Baker McKenzie delivers integrated solutions to complex challenges.

Complex business challenges require an integrated response across different markets, sectors and areas of law. Baker McKenzie's client solutions provide seamless advice, underpinned by deep practice and sector expertise, as well as first-rate local market knowledge from more than 70 offices globally. Celebrating its 75th anniversary in 2024, Baker McKenzie works alongside clients to deliver solutions for a connected world.

bakermckenzie.com