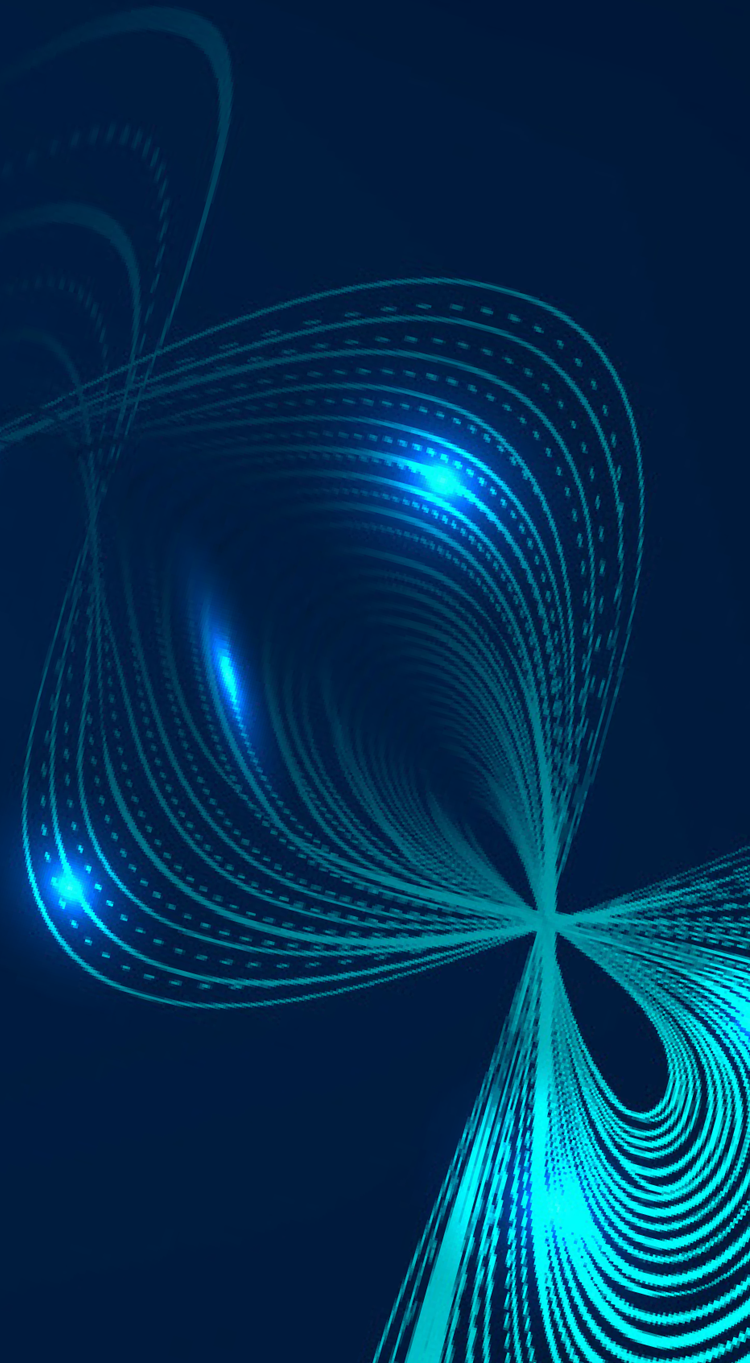
Baker McKenzie.

Protecting the Bottom Line Through Operational Resilience

Unlocking and Accelerating Growth:

Healthcare and Life Sciences in Asia Pacific



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01

Welcome from Baker McKenzie's healthcare and life sciences team

Healthcare and life sciences companies are striving for future-proof performance. Positioning for long-term success by achieving a healthy balance sheet, a strong innovation pipeline, optimized product portfolio and agile, sustainable supply chains.

The healthcare industry has a sharp focus on unlocking growth and the Asia Pacific region is a key focus. Our insights on healthcare transformation highlight the region's strengths as being increasingly dominant in manufacturing and distribution, capitalizing on growing local demand and high tech, lower cost production capabilities.

Global companies are building resilience through transactions, partnerships and inward investment in the region. But realizing the value of these gains 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.

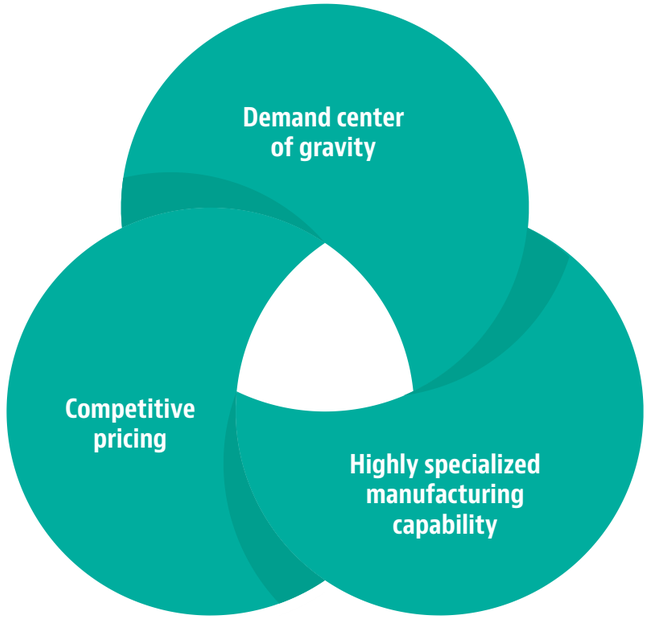
The **top three market opportunities** driving investment and change.

Legal insights and practical takeaways to help you unlock and protect growth – including cross-border deals, executing effective corporate divestitures and carve-outs, trade compliance best practice, IP protection, data protection, supply chain due diligence, preparing for ESG-driven litigation, and more.

Operational resilience starts here.

02 Why Asia Pacific is a magnet for innovation and investment

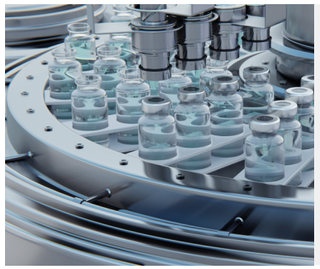
Three unique factors are generating resilience-driven investment in Asia Pacific, reflecting the industry's urgent need for cost saving and flexible solutions:



These dynamics create significant opportunities for global companies to optimize operations.

Demand center of gravity.

Asia Pacific is among the fastest growing medical markets in the world, expected to reach USD 138 billion in spending by 2027.[1] As a result, industry organizations are bringing clinical trials, manufacturing and distribution closer to patients in high demand markets to maximize speed and agility, while minimizing cost and supply chain risk.



Highly specialized manufacturing capability.

To accelerate development and production of innovative new drugs and devices, global players look to Asia Pacific for its strength in manufacturing.[2] Digital manufacturing is also becoming a larger component of GDP in the region. Among the world's top 10 economies with the largest ICT to GDP ratio, seven are in Asia Pacific, including Thailand, and Singapore.[3] This region-wide strength is allowing global companies to diversify supplier relationships.

Competitive pricing.

Pricing transparency and efforts to reduce healthcare costs is also driving action and decision making. Companies are looking to preserve margin wherever possible, making the relatively low cost of production in Asia Pacific a draw.

1 IQVIA Global use of medicines 2023, https://www.iqvia.com/-/media/iqvia/pdfs/library/presentations/presentation_global_meds_2023_webinar.pdf

2 McKinsey, https://www.ft.com/partnercontent/mckinsey/asias-technological-path-to-growth.html

3 IMF, https://www.imf.org/en/Publications/fandd/issues/2018/09/asia-digital-revolution-sedik

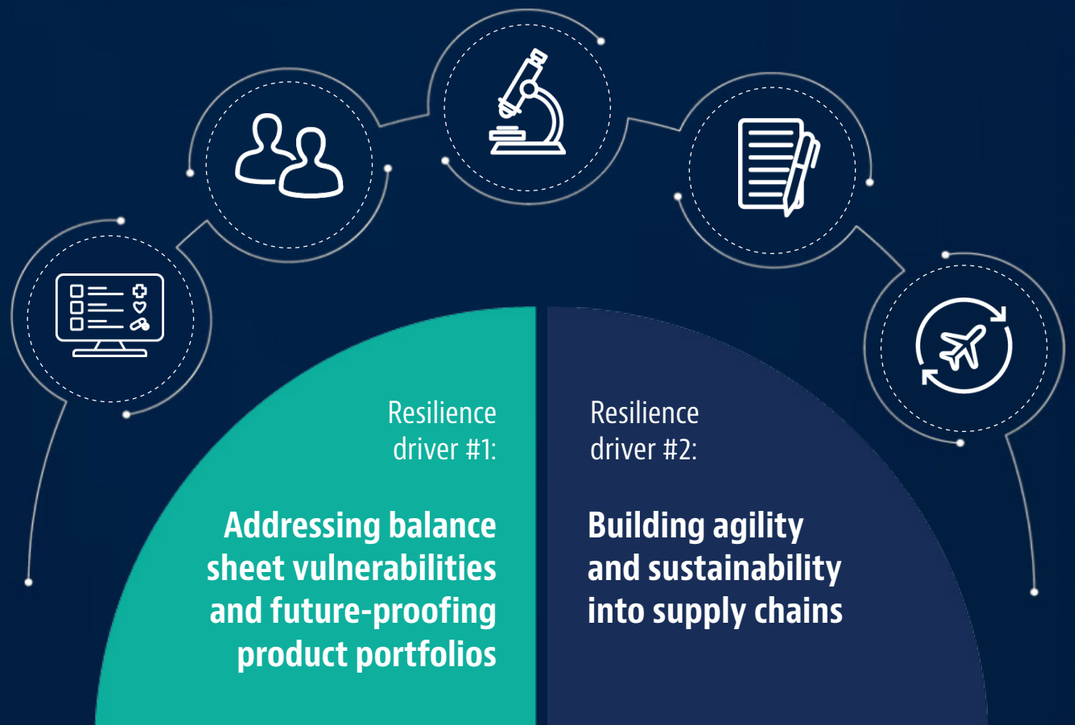
03 Where are the big opportunities to build resilience and who are the key players?

Global pharmaceuticals and medical device companies are feeling the effects of inflation, pricing pressure, patent cliffs and trade shocks. Market conditions are driving divestment and carve-out activity as they offload debt, realize value and focus on core business/assets. Many are actively looking to acquire their next big winners through M&A[4] – building product portfolios that defy the healthcare spending squeeze. For example, vaccines, innovative treatments involving cell and gene therapy, and AI-powered solutions represent significant new revenue streams. Global pharmaceuticals and medical device companies are also pivoting supply chains to cope with volatility and sustainability concerns – developing, manufacturing and tracking in more streamlined, local and agile ways.

Private equity investors will play an increasingly important part in this landscape, as the trend for restructuring and divestment continues. The size and scope of carved-out assets are often particularly attractive to PE buyers and sponsors, with opportunities to transform assets to realize future value.

Smaller biotech, healthtech and digital therapeutics players in Asia Pacific are leading the development of next generation healthcare and life sciences solutions. Facing sluggish capital markets, M&A is a strategic lever to finance growth and optimizing balance sheets in anticipation of takeover bids is key to attracting strategic buyers.

4 Financial Times, https://www.ft.com/content/325b75d9-5148-4635-b9c2-63244fa74936



Contract Development and Manufacturing Organizations (CDMOs) are growing particularly rapidly in Asia Pacific. The market is projected to reach USD 140 billion by 2031.[5] Outsourcing via CDMOs is increasingly used to access specialist knowledge, mitigate manufacturing bottlenecks and make regional supply chains faster. This is especially relevant to healthcare and life sciences today, as companies launch increasingly complex products, balance small and large scale production, and navigate divergent regulatory compliance, particularly in relation to environment, social and governance (ESG) factors.

5 Research & Markets data, https://www.researchandmarkets.com/reports/5855132/global-healthcare-contract-manufacturing-market#cat-pos-10

Contract Logistics Providers (CLPs) are also expanding in Asia Pacific, providing an inside track to local markets for products manufactured in the region and imported from the US and Europe. Asia Pacific is expected to be the highest growth market for contract logistics every year to 2027.[6]

6 Global Transport Intelligence, https://www.ti-insight.com/whitepapers/global-contract-logistics-market-size-forecasts-2023-2024-2027/

04 What you need to know to unlock and protect growth

Building resilience represents an exciting chance for organizations to drive long-term growth while combating short-term uncertainty. 59 per cent of global healthcare companies say building resilience is a top priority for their business.[7]

As portfolios and operations are reshaped, staying on top of geopolitical nuances and local regulations is essential to protecting value.

Three key market opportunities for operational resilience

Market opportunity #1

Restructure and divest non-core assets to unleash capital in growth areas

Market opportunity #2

Embrace regional outsourcing to build agile supply chains and protect margins

Market opportunity #3

Ensure longevity through ESG leadership

7 McKinsey, https://www.mckinsey.com/industries/life-sciences/our-insights/resilience-in-life-sciences-emerging-stronger-from-the-downturn

Market opportunity #1: Optimizing the balance sheet

The mission to unleash capital is driving significant transactional and investment activity in Asia Pacific – from carve-outs and spin-offs to PE-backed public-to-private deals. Global life sciences companies are prioritizing healthy balance sheets and new revenue streams to maintain a strong growth trajectory.

What you need to know about the investment landscape

Global healthcare and life sciences companies are keen to position for future growth, overcoming current margin and reimbursement pressures. This means divesting unprofitable or non-strategic assets, restructuring debt and realizing value to unleash capital in high potential areas. Carve-outs, spin-offs and take-private deals are increasingly important features of the market – rising from 12 percent of all healthcare deals in 2021 to 46 percent in 2022.[8]

Opportunities for key market players to drive growth

As products become more complex, companies require a broader range of capabilities and talent to develop, manufacture and launch products. We are seeing companies use transactions to pivot:

- **Pharmaceuticals and medical devices.** Large players are divesting for the future – leveraging carve-outs and spin-offs to refocus on core activities and access capital. Volume-based procurement has led to significant price cuts, as city and province-wide contracts are awarded to organizations offering the lowest cost products. Companies are responding by accelerating the pipeline for diversified products, looking for portfolio efficiencies and rethinking market entry strategies.

- **Biotechs and healthtech.** Smaller innovators are benefitting from investment in high potential niches, particularly as some pharmaceutical players shift from "blockbuster" to "nichebuster" product strategies. Larger strategics are targeting companies in high potential therapeutic areas and with sought after digital expertise via early-stage minority investments, M&A and licensing deals.

8 Bain Capital, https://www.bain.com/insights/life-sciences-tools-global-healthcare-private-equity-and-ma-report-2023/

- **Alternative finance, including private equity.** At the heart of strategic transactions is alternative finance, particularly involving private equity sponsors. Companies of all sizes are leveraging different types of financing, such as royalty deals, Special Purpose Acquisition Companies (SPACs) and clinical development finance to fuel innovation and build pipeline. Competition for prize assets will increase demand for creative financing strategies from PE players. Private credit arrangements, joint ventures that include a PE and strategic player and club deals, where multiple PE buyers pool capital, are becoming more common.

- **CDMOs.** The CDMO value chain is stretching out in both directions – from traditional manufacturing operations to research and development at the start of the journey and commercialization at the end. They are moving toward a "one-stop-shop" service portfolio. In this context, CDMOs are leaning on M&A to build out capabilities and scale capacity and capability and are seeing high valuations consummate with demand. Between 2017 and 2021, 244 publicly announced M&A transactions involved CDMOs.[9]

9 EY, https://www.ey.com/en_au/strategy/how-cdmo-companies-are-leading-innovation-for-pharmaceutical-partners

"A variety of strategies are being adopted by companies to ensure operational resilience, including M&A. Some are shedding 'non-core' business units to focus on building specialty platforms. Others are using M&A to acquire expertise and R&D for innovative treatments and patient experience solutions. An analysis of how to maximize the advantages of technology and digital capabilities is also fueling resilience-driven activity."

Kate Jefferson
Partner, Australia

"Private equity interest in healthcare assets, particularly core plus' assets, remains strong in Asia Pacific. Some Asian healthcare focused private equity firms are engaged in capital raising for new funds focused on investing in the healthcare sector in southeast Asia. Moreover, continuation funds are being deployed by some private equity firms to roll over the ownership of existing well performing healthcare assets."

Zhang Hong
Head of Private Equity, China, Baker McKenzie Fen Xun*

* FenXun established a joint operation office with Baker McKenzie in China as Baker McKenzie FenXun, which was approved by the Shanghai Justice Bureau in 2015

Key legal considerations for strategic transactions

As portfolio restructuring and strategic pivots drive deal activity, what are the top legal considerations for corporate reorganizations?

1. Maximizing gains from cross-border corporate reorganizations

Ensuring seamless transition, supply chain continuity and value capture from large corporate reorganizations and subsequent carve-outs, spin-offs and divestments requires a significant amount of planning and know-how. This is particularly important in the context of the highly regulated healthcare and life sciences industry.

Considerations for planning and implementing effective reorganizations

- **Define scope of assets and liabilities.** Identify the universe of assets and liabilities to be transferred – particularly in the context of shared contracts and co-mingled services where a clean split is not straight forward – and determine where transitional services or contract manufacturing may be required to facilitate and support ongoing business operations.
- **Minimize supply disruptions.** Map the extent to which critical healthcare products need to be stockpiled or other steps taken to ensure continuity of supply whilst complying with the regulatory requirements of a change to the ownership. In the supply chain for those products, consider the impact local regulations may have on the timing of completion of steps globally and the need to plan for delayed markets, including labeling, import/export logistics and distribution arrangements. Ensure that you have a plan for how you will develop business functions and stand up operations to enable you to turn off services being provided under a transitional arrangement or contract manufacturing services in an orderly and timely manner.
- **Stay on top of regulations and obligations.** Where the reorganization causes a change in the regulatory landscape, prepare the business for new regulatory requirements. Ensure that both businesses continue to have the relevant knowledge, expertise and regulatory personnel to operate in their markets, particularly where employees transfer in, and more importantly, where employees transfer out of the respective businesses.
- **Shore up IP rights.** Ensure that IP rights are transferred alongside relevant products, or that IP license arrangements are in place for the transitional period, to ensure the respective businesses have the right to develop, manufacture and sell such products immediately post-reorganization.
- **Ensure medical data security.** Where healthcare businesses are split, thought needs to be given as to how data is shared to enable compliance with regulatory requirements whilst balancing against patient confidentiality and data protection. Careful consideration should be given to the long-term arrangements that must be implemented and consents acquired to ensure compliance.
- **Reflect on governance structures.** Consider the specific jurisdictional requirements concerning governance. Questions should be asked early on as to whether certain qualifications are mandatory for those sitting on the boards of companies or holding key positions within the business, particularly in terms of ESG. Are your local boards aware of their duties, obligations and responsibilities locally?

2. How buyers and sellers can *both* win via effective carve-outs

Effective carve-outs should be a positive sum game – aligning deal parties in success. What are the principles buyers and sellers should adopt?

Sell-side

Prepare the asset properly. Preparation is key to achieving a robust valuation and facilitating a smooth sale process. Assemble the relevant materials on supply chain partners and contractual obligations. Clearly delineate IP, including patents or trademarks, that belong to the asset.

Balance deal certainty and price. Consider the regulatory restrictions you might encounter and your ability to get the deal done in a timely and compliant way versus achieving the highest price.

Consider continuity. Ensuring the carved-out business can operate independently without disruption is essential, including customer retention. Consider staying in the asset for a period of time to make the carve-out a success and optimize downstream value.

Buy-side

Establish the rationale. Ask whether you can do what you need to do to realize the value of the asset, understanding that tax, regulatory or compliance issues that could erode value.

Don't skimp on due diligence. Comprehensive due diligence can identify potential issues early on and enable informed negotiation. This includes financial, operational and regulatory and compliance fact finding.

Consider continuity. Ensuring the carved-out business can operate independently without disruption is essential, including customer retention. Consider keeping the seller in the asset for a period of time to make the carve-out a success.

Market opportunity #2: **Building agile supply chains**

Flexible supply chains that tap into regional manufacturing and distribution capabilities are a source of competitive advantage for global healthcare and life sciences players. There are short and long-term performance opportunities to build resilient supply chains in Asia Pacific.

What you need to know about the investment landscape and supply chain resilience

Supply chain resilience is a key indicator of overall business health in the healthcare and life sciences industry. The ability to meet demand seamlessly, responsibly and efficiently is the foundation of growth. Today digitalization, rising costs and underlying market volatility is driving a reevaluation of supply chains, as 88 per cent of companies in the sector cite production or logistics issues and reduced capacity as key commercial challenges.[10]

Efforts to diversify from single-source suppliers and capitalize on local, digital approaches to manufacturing and logistics is driving outsourcing deals and collaborations across the region, offering new opportunities for players outside China and in contract industries. Markets across Asia Pacific are promoting their credentials as efficient, safe and sustainable destinations for sourcing, clinical development, manufacturing and distribution.

Opportunities for key market players to drive growth

- **Pharmaceuticals and medical devices.** During the COVID-19 pandemic, larger global players identified critical supply chain vulnerabilities. Many identified opportunities to build resilience in Asia Pacific and are prioritizing visibility of the end-to-end supply chain, shoring up supply of key materials, manufacturing capacity and distribution channels. Almost half of companies have kicked off a transformational supply chain deal in the last 12 months and 30 per cent plan to do so in the next 12 months.[11] Navigating trade compliance is also shaping new networks.

- **CDMOs**. Outsourced innovation is exploding in Asia Pacific. The region's CDMOs have specialized expertise and cutting edge technology to develop and produce increasingly complex products and therapies, helping partners to achieve precision, quality and efficiency without investing in owned regional infrastructure. CDMOs are often best able to meet huge demand for biologics and biosimilars while also accommodating small runs of more niche products, and are well versed in the regulations and manufacturing standards required by local health authorities.

- **CLPs.** Asia Pacific is also emerging as a formidable destination for contract logistics, supporting global pharmaceuticals, biotech and medical device companies to streamline, accelerate and integrate distribution in the region. CLPs are often able to offer greater transparency on sustainability and integrate with cold chain networks, making them particularly valuable to international companies trying to reach patients across the region.

10 Deloitte, https://www.deloitte.com/global/en/Industries/life-sciences-health-care/perspectives/global-life-sciences-sector-outlook.html

11 Baker McKenzie, https://www.bakermckenzie.com/-/media/restricted/healthcare-life-sciences/hls-supply-chain-brochure.pdf

Regional Spotlight: Regulatory approach – how governments are strengthening manufacturing and distribution capabilities in healthcare and life sciences

Vietnam

- Vietnam is transforming into a global manufacturing hub, benefiting from the "China plus one" diversification strategy favored by global companies.
- Manufacturing made up around 25 per cent of Vietnam's GDP in early 2023 and has been increasing to the end of 2023.[12]
- FDI into manufacturing dominated overall inflow to the tune of around 82 per cent in the first three quarters of 2023.[13]
- While the country has one of the most rapidly growing markets in Asia for pharmaceutical products, it still relies heavily on imports for its needs. More than 90 per cent of medical equipment in the country is imported.[14] To address this issue, the Vietnamese government has been taking action:
  - Actively promoting FDI in the healthcare sector. The government offers various incentives such as tax breaks and simplified administrative procedures to attract foreign investors.
  - Working to strengthen its international trade relations. The EU-Vietnam Free Trade Agreement ensures the use of international standards, practices, and guidelines developed for pharmaceutical products and medical devices, to help Vietnamese products gain wider acceptance in international markets and boost exports.
  - Improving the regulatory framework for the pharmaceutical sector to ensure high quality domestic production, robust IP protection and licensing will also support growth. Vietnam benefits from its membership to ASEAN and coordinated efforts to harmonize regulation across the region.

12 General Statistics Office Vietnam, https://cafef.vn/quy-mo-gdp-viet-nam-dat-2300-nghin-ty-dong-nganh-nao-dong-gop-lon-nhat-trong-quy-1-2023-188230406133259406.chn

13 Foreign Investment Department, Ministry of Planning and Investment, https://kinhtevadubao.vn/9-thang-dau-nam-2023-nha-dau-tu-nuoc-ngoai-do-2021-ty-usd-vao-viet-nam-27179.html

14 International Trade Administration, https://www.trade.gov/market-intelligence/vietnam-medical-device-registration

"It's encouraging that foreign investors continue to invest in Vietnam's manufacturing sector. These investments reflect the broader trend of shifts in supply chain and manufacturing operations away from China and into Southeast Asian countries. This is driven in part by geopolitical dynamics and global trade reform among major markets. Vietnam is well-positioned in terms of geography and political stability as it deepens its role in global supply chains, and remains cost competitive whilst also focusing on up-skilling the workforce."

Yee Chung Seck
Partner, Vietnam

Thailand

- Thailand's strategic location as a gateway to Asia Pacific, skilled workforce and supportive government policies have seen the value of foreign investment rise by 43 per cent to USD 11.5 billion for the first nine months of 2023. This reflects investors' confidence in Thailand's infrastructure, supply chains and long-term growth potential.
- The Thailand 4.0 growth model identifies biopharmaceuticals, bio-economy and medical equipment as key industries for development, and the Thai government actively promotes investment in manufacturing, logistics and medical facilities as part of its plan to become a leading medical hub:
  - The Board of Investment (BOI) provides exemptions from corporate income tax to certain industries, including those involved in manufacturing and logistics, and has approved incentives to support the adjustment of existing production lines to manufacture medical devices or parts, including exemptions from import duties. This can significantly lower the cost of setting up or expanding manufacturing facilities.
  - The Eastern Economic Corridor (EEC), an area-based development initiative, also offers efficient infrastructure, connectivity and incentives to attract knowledge-based industries, including biosciences, artificial intelligence and robotics into Thailand.
  - The government has participated in international medical and wellness exhibitions, simplified the process of getting visas for medical purposes and developed marketing campaigns to attract medical tourism.
- Thailand's logistics infrastructure and comprehensive cold chain network is also suited to the specific needs of the life sciences and healthcare industry. The government continues to make improvements to resilience and sustainability, including a recent grant from the US Trade and Development Agency (USTDA), which will accelerate more sustainable distribution routes like road to rail.

"Thailand is emerging as a key manufacturing, logistics and research hub for healthcare and life sciences. Apart from its strategic location as a gateway to Asia Pacific, skilled workforce and supportive government policies, what makes Thailand a destination for high potential growth is the plethora of well-established, high-quality hospitals and medical facilities in the country, many of which are expanding internationally, and not only serving the demand for healthcare in Thailand, but international demand through medical tourism The COVID-19 pandemic demonstrated the R&D capabilities of the domestic players, with significant advances particularly in vaccine R&D and production."

Panyavith (Taro) Preechabhan
Partner, Thailand

Key legal considerations for building agile supply chains

What legal issues should organizations consider as they transform supply chains?

1. Take a proactive approach to manage third party IP risk

There are inherent IP risks in outsourcing arrangements, especially across borders. Any contract that requires companies to share important intellectual property outside the organization carries an increased risk of infringement, disclosure or theft. This is amplified where different jurisdictions take different approaches to enforcing IP rights.

IP infringement in the context of outsourcing arrangements is often the result of poor handling or protection of IP, or ill-defined contractual and governance provisions, rather than malicious intent. But the commercial risk remains, and issues can quickly become critical in circumstances of IP leakage and where potentially unsafe counterfeit products enter the market.

How can pharmaceutical and medical device companies get ahead of IP risk?

- **Build an IP strategy for outsourcing.** Contract manufacturing and outsourcing is core to the strategy of many healthcare companies and building specific IP strategies to cover vetting, contractual protections, non-disclosure, IP exploitation governance protocols in a systematic way is key.
- **Choose the right partner.** Your choice of outsourcing partner is critical. Look for a reliable contractor with a reputation for respecting IP rights and conduct a security audit to help identify potential vulnerabilities that could lead to IP breaches.
- **Draft comprehensive contracts.** One tool to mitigate the risk of IP theft is by carefully crafting contracts from the outset. Consider non-disclosure, IP ownership clauses, data access limitation, audit rights, indemnity clauses and warranties.
- **Understand jurisdictional approaches to IP enforcement.** In Asia Pacific there is significant variation in approaches to IP enforcement and the resources different authorities are able to dedicate to investigations and litigation. Account for this risk in your IP protection strategy – considering the local IP landscape, recent statements from authorities and outcomes in similar cases.

Elisabeth White
Partner, Australia

2. Understand what good manufacturing practice looks like

Companies producing healthcare and life sciences products must adhere to Good Manufacturing Practice (GMP) guidelines in order to receive licenses and operate safely. These standards are designed to maintain strict quality control throughout manufacturing processes, helping to demonstrate a track record of compliance and assurance on product safety and efficacy. This is especially important to global pharmaceutical companies outsourcing development and production via CDMOs.

How pharmaceutical companies can mitigate compliance risk in manufacturing production

- **Prepare for inspection.** Regulatory authorities in Asia Pacific regularly conduct inspections of manufacturing facilities to ensure compliance with GMP standards. These inspections may be scheduled or unannounced, and they evaluate the organization's adherence to quality management systems, production processes and control measures.
- **Look for evidence of robust Quality Management Systems (QMS).** Manufacturers are required to implement a QMS that ensures consistency in production and control activities. This involves having standard operating procedures in place, conducting regular internal audits and implementing corrective and preventive actions when necessary.
- **Insist on proper documentation and record keeping.** Proper documentation and record keeping is an essential part of GMP enforcement. CDMOs must maintain accurate and detailed records of all manufacturing processes, quality control tests, and any deviations or issues that occur, along with the corrective actions taken.
- **Know your quality oversight obligations.** Companies that use CDMOs for their manufacturing needs are ultimately responsible for the quality, safety, efficacy, and GMP compliance of their products. Conducting your own audits and inspections of CDMOs is important for ensuring adherence to GMPs.

3. Think strategically about customs and trade

Trade compliance is a critical area of operational resilience, particularly in healthcare and life sciences, where products are handled by multiple suppliers across several borders on the journey from raw material to finished article.

Scrutiny of tariff classification, customs valuations, and product origin, as well as enforcement actions under the various duty exemption programs and free trade agreements, are growing in Asia Pacific. As governments focus on revenue collection and set targets for enforcement, global companies with supply chain partners in the region can expect greater contact with authorities. A proactive approach to customs audits and investigations will keep supply chains moving.

In addition, as a result of supply chain restructuring due to geopolitical risk considerations, companies have been continuing diversifying their supply chains and footprints in the Asia Pacific region. This diversification allows companies to reevaluate their options and maximize supply chain efficiency, but at the same time, exposes companies to new trade and regulatory requirements in the new jurisdictions. The considerations in this regard include not only the customs challenges outlined above, but also export controls, sanctions, countermeasures, trade remedies (antidumping and anti-subsidy investigations) and geopolitical outlook and future trend.

How global companies can manage the rise in trade compliance audits

What's driving trade compliance audits

- Tariff classification. Global companies sometimes assume that the HS codes they use, for example, in the US will be the same as in other markets. In reality, only the first six digits are harmonized globally. As a result, we are seeing active challenges on HS codes which attract 0 per cent duty. Non compliance can impact on import licenses, your ability to apply tax incentives or to secure certificates of origin.

- Customs valuation and transfer pricing. The relationship and tension between customs valuation and transfer pricing is an important issue that is gaining prominence with regulators. Complexity arises in demonstrating how the customs value is determined by: 1) the transfer price between two related companies; 2) identifying and capturing additions to value (e.g. assists to imported goods, royalties and licensing fees); and 3) managing transactions that are not subject to a sale (e.g. transferring inventory). There are few clear policy guidelines on these issues in Asia Pacific yet. But we are seeing authorities in the region make a consistent effort to build capability here. Regulators in Asia Pacific's mature jurisdictions are looking at profit margins and transfer pricing documents upfront and reviewing them against customs value to ensure these are acceptable. Elsewhere, they are more likely to target post-importation adjustments.

- Bonded warehouses and free trade zones. In the global supply chain, Asia Pacific is often the destination for large volumes of imported goods, which are then produced or manufactured locally and distributed in the region. As a result, we are seeing a rise in compliance audits related to bonded warehouses, free trade zones and suspended import duties. These facilities are designed to attract foreign investment but they often come with stringent restrictions that raise the risk of non compliance. For example, rules may stipulate that a certain amount of goods produced must be exported, impose use restrictions or specific reporting requirements. In the cases of non-compliance, regulators may seek to claw back duties later.

- Product origin verification. Product origin verification is intended to avoid exporters rerouting products via different countries to circumvent trade remedies. Several jurisdictions in Asia Pacific are already subject to trade remedy investigations by the World Trade Organization, and an increase in self-declaration as part of new free trade agreements (FTAs) is sure to attract further regulatory investigations and audits.

- Export controls and trade sanctions. Export controls and sanctions regimes are rapidly evolving in Asia Pacific, driven by the geopolitical tensions, and have increasingly become new focus of enforcement in mature jurisdictions, like China, Japan, Singapore and Australia. The Chinese countermeasures and blocking rules against Western sanctions targeting Chinese companies have further complicated the enforcement landscape and companies' compliance strategies in this area.

How to strengthen trade compliance

- Be prepared. Authorities in Asia Pacific are increasingly operating a post-importation customs framework, as well as the point of import/export. This means being prepared for more regular audits and retaining documentation related to historic trade.
- Be consistent. Collaboration between authorities is growing. For example, documents are frequently shared by tax authorities in relation to customs valuation, which can lead to adjustments later. Ensure you are sharing the right information with all parties.
- Weigh up disclosures. Mistakes happen. Generally disclosure of compliance failures is viewed favorably by authorities, even where benefits such as penalty reduction aren't guaranteed. But there is no consistent approach with respect to disclosures in Asia Pacific. If you have identified a compliance gap, carefully weigh the decision to disclose, considering: 1) how long it has been since the violation; 2) the nature of non-compliance; 3) the amount of duty or tax underpaid; and 4) whether the company is ready to proceed with disclosure. Do you have the right documentation and can you demonstrate corrective steps have been taken?
- Adopt a localized approach. Corresponding in local language and adhering to social etiquette goes a long way to building productive relationships with authorities in Asia Pacific. This has a number of upsides for global companies, including better access to information to clarify the shape of compliance obligations and cushioned impact where compliance issues occur. A balanced approach that holistically considers the local rules and sensitivities, in addition to the relevant trade laws with extraterritorial reaches, is critical for addressing potential conflicts of laws, which are becoming more common in the trade compliance space.

Market opportunity #3: Driving long-term resilience through ESG

ESG is a proven driver of resilient performance – opening up investment opportunities, building corporate brand and promoting long-term growth. From net zero commitments and responsible sourcing to ethical supply chains and diversity, healthcare and life sciences companies are increasingly focused on sustainability.

What you need to know about the investment landscape

If the global healthcare industry were a country, it would rank as the fifth-largest greenhouse gas emitter in the world, responsible for approximately 4.4 per cent of global emissions of which around 71 per cent are driven by production, transportation and disposal processes.[15] Part of protecting the bottom line through driving operational resilience means supporting ESG commitments and obligations.

When it comes to ESG scores, pharmaceuticals in the region currently underperform compared to peers in the US and Europe.[16] As a result, ESG considerations are gaining strategic importance, particularly as they become interlinked with wider commercial opportunities. For example, the Japanese government announced in May 2023 that only companies that carry out human rights due diligence will be eligible to bid for public projects.

Opportunities for key players to drive growth

- **Global pharmaceuticals and medical devices.** ESG matters to the resilience and reputation of large industry players. Adopting international best practice standards among regional subsidiaries and supply chain partners is a top priority, as 62 per cent of companies believe that their supply chain due diligence program meets established compliance risks and emerging ESG challenges only to some extent.[17] Several big pharmaceuticals companies have also linked ESG commitments to capital raising, including sustainability bonds and notes, capitalizing on the power of ESG to unlock investment and accelerate progress.

- **Manufacturers and distributors.** Local manufacturing and distribution partners have a significant opportunity to seize competitive advantage through ESG. As global organizations meet more stringent disclosure requirements, adopting more transparent, robust and responsible approaches to sustainability, social issues and governance will be game-changing.

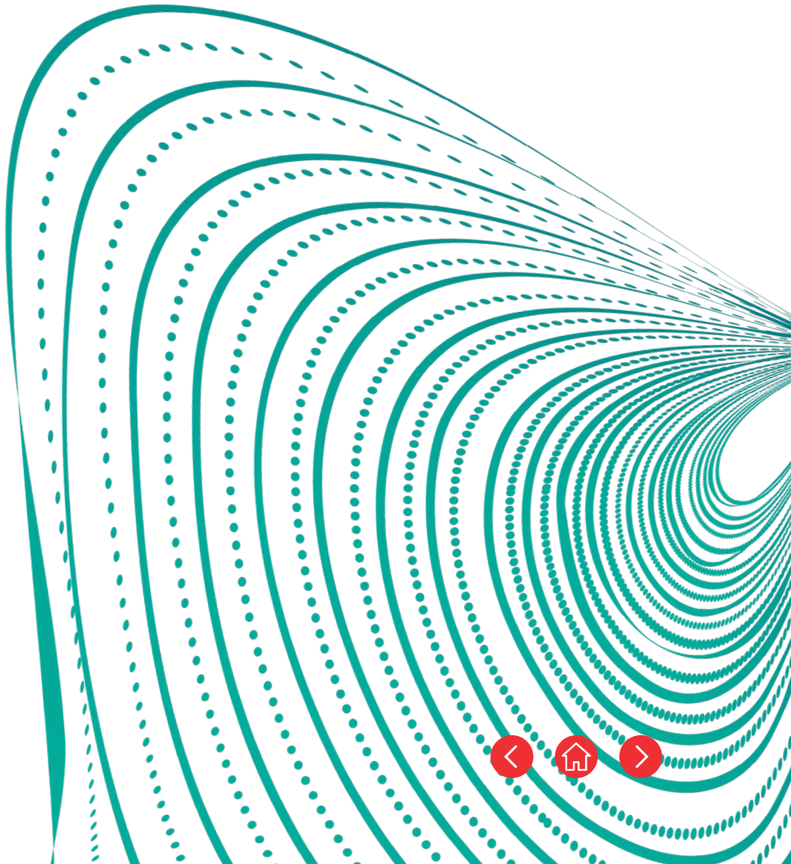
15 Bain & Co and APACMed, https://www.bain.com/insights/why-esg-matters-for-medtech-in-the-asia-pacific-region/

16 Natwest, https://www.natwest.com/corporates/insights/sustainability/how-pharma-firms-are-refilling-their-esg-prescriptions.html

17 Baker McKenzie, https://www.bakermckenzie.com/-/media/restricted/healthcare-life-sciences/hls-supply-chain-brochure.pdf

- **Third-party digital companies.** Supply chain digitalization is a critical component of operational resilience for domestic and global players in the industry, and technological innovation in this area has been remarkable. From IoT tracking solutions that can transmit freight conditions in real time to robotic process automation to digital collaboration tools, niche tech providers are powering the new supply chain. Global VC funding for these companies between 2018 and 2022 reached USD 50 billion. But in 2023 digital providers experienced a capital squeeze, with global financing deals plummeting to USD 2.1 billion,[18] which could see transformation stall.

- **Investors and financial institutio**ns. ESG and finance are increasingly connected. The growing popularity of sustainability-linked supply chain finance, which applies a pricing benefit to suppliers who meet predefined sustainability criteria, is helping organizations to incentivize supplier transition to greener practices. Investing in pharmaceuticals green bond chain startups will also realize new ESG-related life sciences initiatives and promote transparency.



18 Crunchbase, https://news.crunchbase.com/transportation/supply-chain-funding-falls-2023/

Regional spotlight: Regulatory approaches to ESG

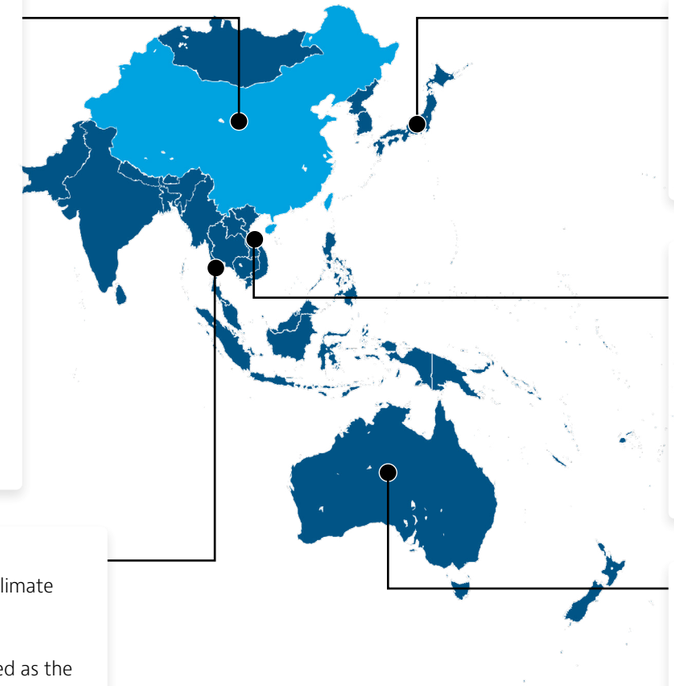
Mainland China

- China's government has implemented ESG commitments through its 14th Five-Year Plan, which includes promoting green and low-carbon circular economic development.
- In healthcare, China has emphasized improving public health services and boosting the biopharmaceutical industry to meet ESG goals.
- Mandatory ESG disclosure requirements for companies in China are evolving. Currently, some ESG disclosure requirements are mandatory for companies publicly listed in China. This is arguably part of Chinese regulatory efforts to are to make ESG disclosures mandatory for all firms listed on domestic markets to address a lack of standardization.[19]

19 ESG Investor, https://www.esginvestor.net/live/china-considers-mandatory-esg-disclosures-framework/

Thailand

- The Thai government has stepped up efforts to address climate risks and drive sustainable growth, aiming for a balanced development of economy, society, and environment.
- The Bio-Circular-Green Economy (BCG model) was adopted as the Government's key policy in 2021, focusing on applying science, technology and innovation to turn Thailand's strengths in biological and cultural diversity into competitive advantage. It focuses on four industries, one of which is medical and wellness.
- In the healthcare sector, Thailand is focusing on enhancing public health infrastructure and medical innovation. Digital health, including telemedicine, remains one of the key focus areas of the new government's healthcare policies.



Japan

- Reducing health disparities has been a goal of Japan's national health promotion strategy since 2012. The strategy is designed to close the gap in healthy life expectancies between population groups and encourage local governments to reduce health disparities.
- ESG disclosure is mandatory for public companies in Japan.

Vietnam

- ESG impact reporting has been a mandatory requirement for listed companies in Vietnam since 2016. Disclosures are voluntary for non-listed organizations.
- At the UN's Climate Change Summit in 2021 (COP26), Vietnam made commitments to stop deforestation by 2030, reduce greenhouse gas (GHG) emissions by 9 percent with domestic resources and 27 percent with international support by 2030, and to phase out coal-fueled power generation by 2040.

Australia

- The Australian government has prioritized ESG factors in its National Health and Medical Industry Growth Plan, with a particular focus on medical research and advanced manufacturing. This includes initiatives to reduce environmental impact and improve social outcomes in the healthcare sector.
- In June 2023, the Australian government initiated steps to make ESG reporting mandatory for major companies and financial institutions. This move is largely based on the International Sustainability Standards Board (ISSB)'s guidelines, which aim to ensure greater transparency on ESG disclosure.

Key legal considerations for ESG

As operational resilience and ESG become increasingly connected, what are the legal considerations for global and local organizations?

1. Ensuring ESG visibility in the supply chain

Complex, cross-border supply chains are a feature of the healthcare and life sciences industry, and oversight of partner activities can be more challenging to establish compared to peers in other industries. As mandatory requirements come into force in Asia Pacific and scrutiny on international compliance grows, ESG due diligence is in the hot seat.

In this context, supply chain partners in Asia Pacific have an opportunity to win market share on the basis of strong ESG practices.

Several jurisdictions in Asia Pacific have introduced related governance and reporting obligations in recent months. Japan is leading the region on human rights due diligence, with new guidelines issued in 2023 that mandate businesses to monitor forced and child labor risk, religious and gender-based discrimination and unfair labor practices among suppliers and partners. Further, in September 2023, South Korea introduced a bill to legislate corporate responsibility on human rights and the environment, and to confirm a corporate duty to conduct human rights and environmental due diligence. The Australian government also intends to reform its Modern Slavery Act 2018, with enhanced human rights due diligence requirements, supply chain transparency and penalties to support corporate accountability.

What does robust supply chain due diligence look like?

- **Gather data.** Information on environmental performance, employment and working conditions in supply chains can be difficult to uncover, but it is critical to overall transparency. Use digital tools to access the best possible data on key aspects of ESG and create a platform to aggregate and organize material for ease of reference.
- **Map supply chain risk.** Use data to build a picture of actual and potential risks across your supply chain, including environmental issues such as medical waste and pollution arising from processing APIs, and social considerations like healthcare equity and access to affordable health. Identify hotspots and mission critical issues that could disrupt supply or lead to reputational issues and disputes. For example, 60 per cent of pharmaceuticals APIs are manufactured in China and India, which carry a high modern slavery risk.[20]
- **Assess processes and controls.** Pinpoint gaps in your systems and suppliers' processes that could exacerbate underlying supply chain risk (e.g. procurement compliance protocols, outdated technology). Develop action plans to address these issues.
- **Digitize what you can.** Managing supply chains in digital environments offers big commercial advantages, including a greater ability to respond to supply shocks, reduced operating expenses and working capital requirements, fewer delays and better trade compliance. Consider where digitalization can support transparency and resilience. For example, blockchain and cloud databases that can link purchase order data, transport data, warehouse tracking systems and in-transit telematics.
- **Track progress.** Measure impact and communicate progress to build accountability. Integrate supply chain ESG performance into global reports.

Anne Petterd
Partner and Asia Pacific Head of International Commercial & Trade, Australia

20 RightsDD, https://www.rightsdd.com/guide-to-modern-slavery-risk-in-pharmaceutical-supply-chains

2. Protecting against greenwashing litigation

Consumers, shareholders and investors are demanding greater action and accountability on ESG, and are paying close attention to the green claims made by healthcare and life sciences organizations. In addition to mandatory disclosures, many companies are setting ambitious diversity and climate targets on a voluntary basis. This has opened up a potential disconnect between promises and reality, prompting a rise in contractual disputes, false advertising suits and class actions. 46 per cent of global organizations report that environmental litigation is their greatest source of contentious risk.[21]

Operational ESG claims are likely to be a larger concern for pharmaceutical companies compared to product-related ones (e.g. reducing water consumption, carbon emissions and hazardous waste). However, miscommunication and misunderstanding around "natural" versus "chemical" compounds is emerging as an area of greenwashing risk.

Key steps to strengthen ESG litigation preparedness

- **Address contractual risk.** Companies must look very carefully at the commitments and representations they are making around ESG in contracts. If the contract stipulates compliance with certain standards, violation of duty can trigger a damages claim for breach of contract. The best approach for avoiding action is to confirm in advance that a company can live up to specific duties and obligations before agreeing to them. It is also advisable to agree on limitations of liability in order to make the remaining risk manageable. This is particularly pertinent in Asia Pacific. As the production center of the world, many supply chains originate in the region, but these markets are not always the best venues for resolving high value commercial disputes. Examine commercial agreements through this lens – determining dispute resolution processes and preferred jurisdictions in advance.
- **Assess marketing authorization limitations.** Under new proposals, EU authorities will be able to refuse marketing authorization applications for pharmaceuticals products on environmental grounds, and suspend, revoke or vary marketing authorizations based on environmental risk. This is a trend to watch for global pharmaceutical companies and domestic players in Asia Pacific, where legislation often follows Europe's lead.
- **Verify claims.** Adopt a clear set of rules for the verification of green claims, including audits of any companies that provide certification. Keep records of claim verification.
- **Engage leaders.** Poorly managed litigation can have a serious and lasting impact on company brand and stakeholder trust. Therefore, litigation readiness is not just an issue for in-house counsel – it is also relevant for C-Suite and Boards. Share points of opportunity and concern, and include leaders in high-level plans.
- **Coordinate effectively.** Establish a trained litigation team to coordinate colleagues across departments and consider centralizing and codifying your approach to litigation in the form of company-wide policies. But be aware that an effective litigation response often requires multi-jurisdictional consideration of regulation and the legal mechanisms for resolution. Track local litigation trends relevant to your company and create scenario plans to anticipate change.
- **Revisit strategies over time.** Create a virtuous circle of understanding and action. Learn from past litigation handling, address failures in response, revisit employee training and update protocols based on new intelligence.

21 Baker McKenzie, https://www.bakermckenzie.com/en/-/media/files/insight/topics/litigation-intelligence/litigation_intelligence_ready_for_anything.pdf

On ESG Governance, Reporting and Regulatory Compliance

Companies must address contractual risks. Mitigation of such risks involves ensuring that a company can in fact comply with the specific terms and obligations before agreeing to them. It is also advisable to seek to include limitation of liability provisions to manage risks of breach.

Effective communications – internal and external – is critical. Poor management of communications in the event of enforcement or litigation can have a serious and lasting impact on company brand and stakeholder trust.

Create a virtuous cycle of review, audit and action. Proactively review and audit processes, learn from any past incidents, consider improvements and remedial actions, update procedures and protocol, and train and communicate.

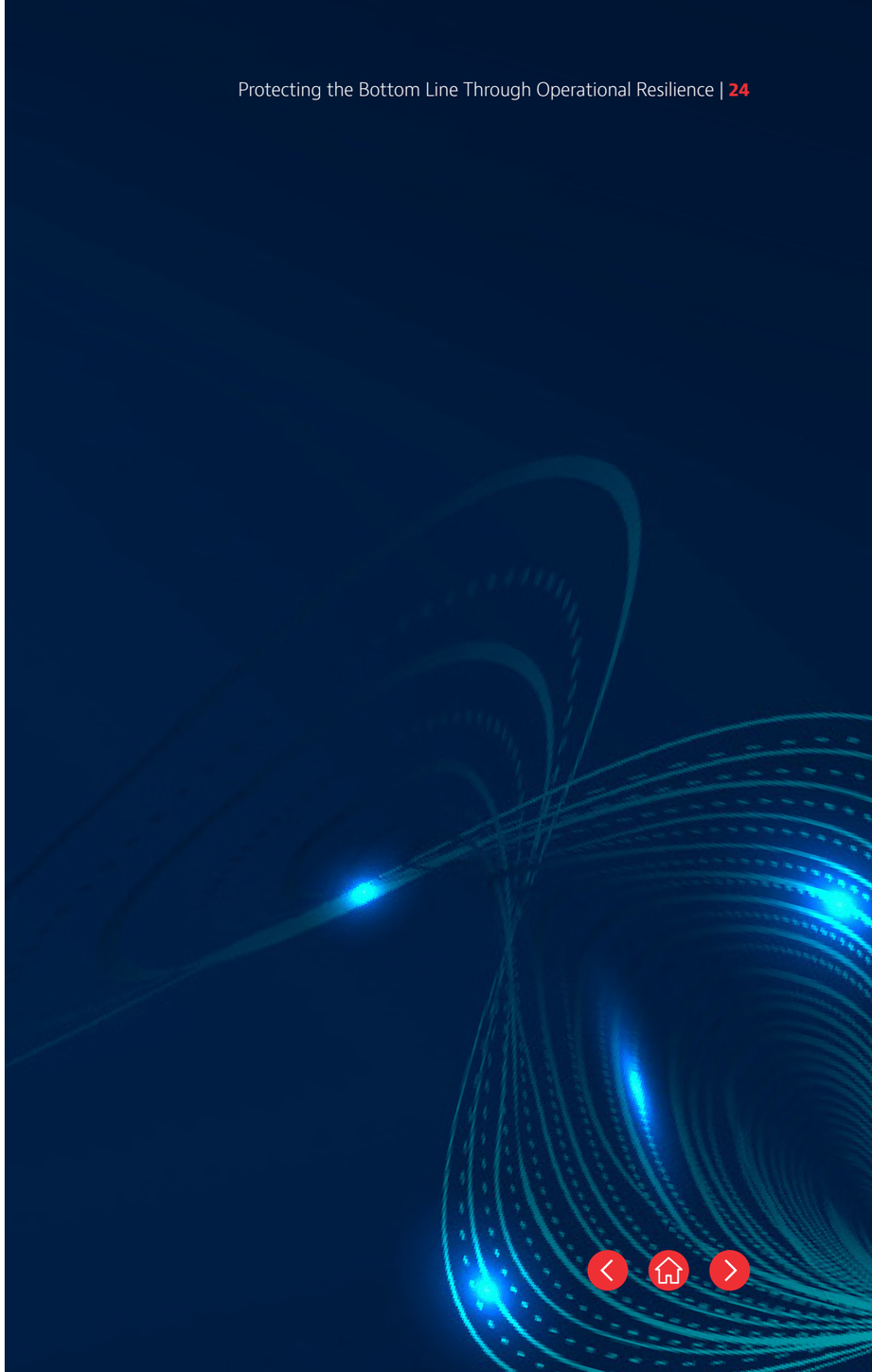
Celeste Ang
Principal, Singapore

05 Key takeaways

Asia Pacific is the home of smart growth. Robust local demand and highly specialized, economical production capabilities combine to create a unique destination to build resilience.

Whether you're an investor who wants to acquire carved-out assets, a pharmaceutical company looking to divest and outsource, or a medical device player transforming your supply chain, 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 building resilience in Asia Pacific

- **Optimize divestitures.** Carve-outs, spin-offs and take-private deals are increasingly important features of the market, as corporates address balance sheet vulnerabilities and redeploy capital for growth. Minimizing disruptions by having rigorous planning vis-à-vis IP protection, data security strategies, governance frameworks and regulatory obligations will be key.
- **Tackle third party risk.** Asia Pacific is a global production powerhouse, and outsourced manufacturing and distribution is of huge strategic importance to global healthcare and life sciences companies in the region. Understanding contractual terms and liabilities, particularly in relation to ESG, managing IP risk is key to maintaining resilience in third party agreements.
- **Prioritize trade compliance.** Trade compliance is one of the most complex and high stakes legal consideration for global players in Asia Pacific. Particularly as scrutiny of tariff classification, customs valuations, duties and product origin verification rises, getting up to speed on what is driving audit activity and taking a proactive, localized approach will promote operational resilience. Additionally, sanctions, export control and relevant conflicts of laws should also be taken into consideration.
- **Prepare for transparency.** Transparency and accountability are key trends for corporates globally. Having a clear view of ESG obligations and performance, operational risks and litigation hotspots will help ensure disclosures are made appropriately. Additionally, leadership commitment, corporate governance anda robust ESG compliance program are crucial to success.

If you missed the previous series

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

Expect insights on innovative cross-border deal structures, anti-trust and competition, data compliance, AI governance 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

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Private equity
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