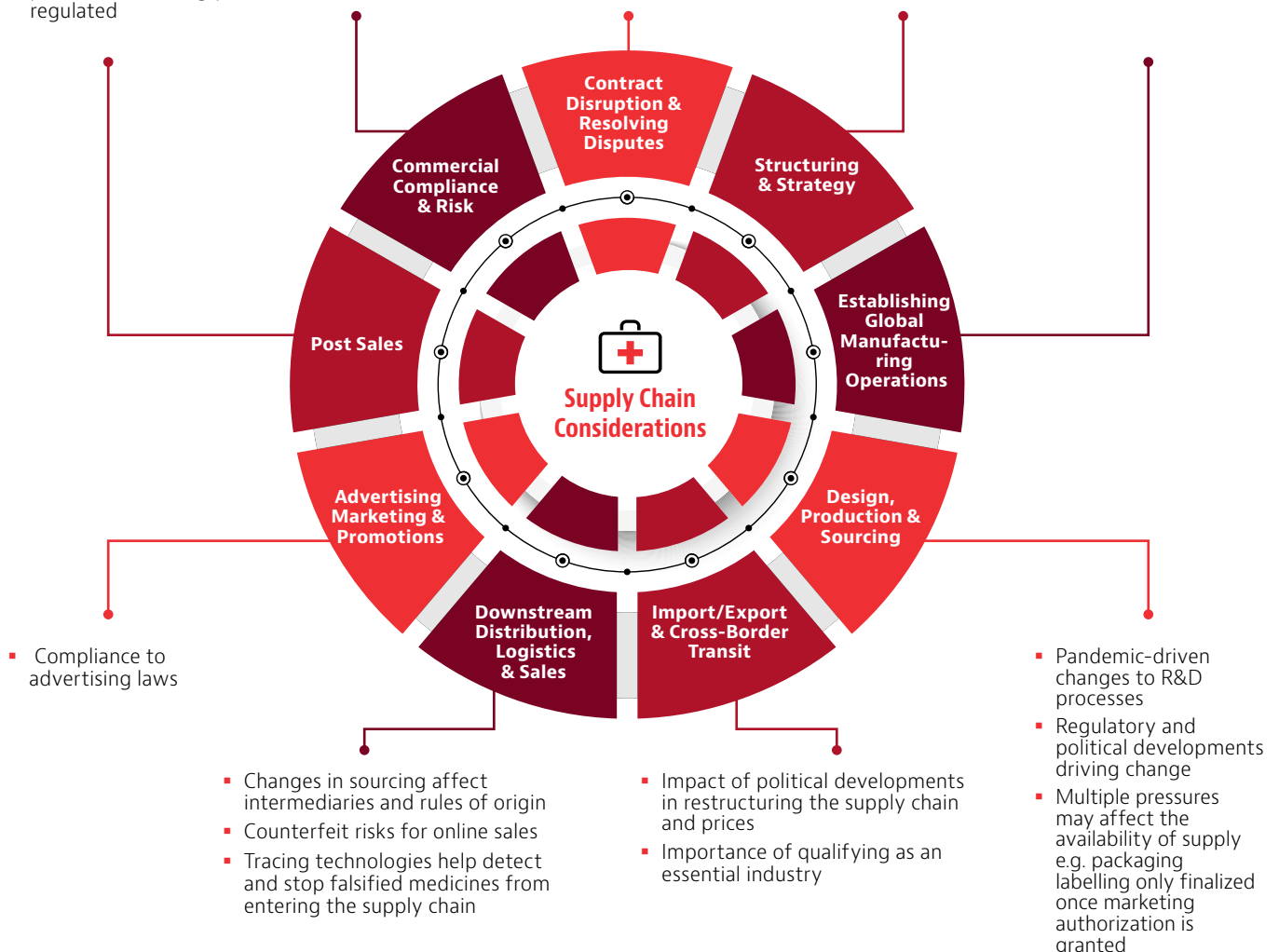


## Managing the Healthcare & Life Sciences Supply Chain

The healthcare and life sciences supply chain is global and complex, with a multitude of moving parts occurring simultaneously. More than ever before, each stage of the supply chain life cycle has grown more connected and interdependent.

- Quality and safety controls complicated by use of distributors
- Tracing technologies facilitate effective product recall
- Exporting of waste products increasingly regulated
- Robust contract protection against third party risks (termination provisions)
- Observing industry codes for dealing with HCPs
- Defining a force majeure event
- Flexible contingency planning for contracts
- Fit for purpose dispute resolution and arbitration clauses
- Early engagement with authorities
- Supplier selection criteria and expectations
- Digitization and technical demands influencing collaborations
- Significant variation of FDI regimes across jurisdictions



**Companies in the sector are embarking on transformative deals to reinvigorate their supply chains.**

Almost half of the respondents\* have embarked on a supply chain transformation deal in the last 12 months and 30% plan to do so in the next 12 months.

\*Based on survey responses from Baker McKenzie's Healthcare & Life Sciences Supply Chain Webinar Series

**Image 1.** A holistic view of the healthcare & life sciences supply chain life cycle and important factors to consider at each stage.

# What are the key considerations when optimizing your supply chain?

## M&A

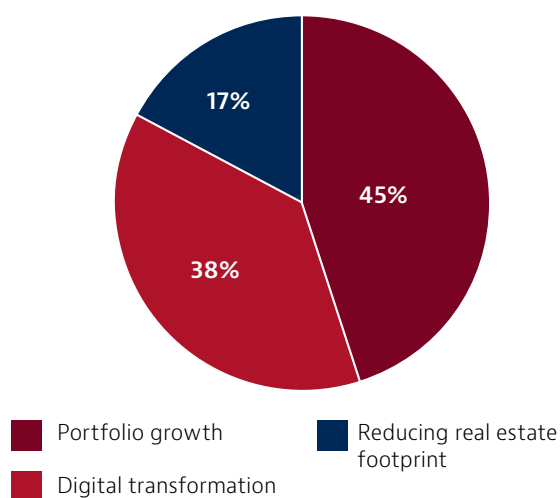
**Conducting due diligence.** Acquiring younger companies or start-ups with limited financial information affects the ability of purchasers to place a value on the business and for both parties to agree on a value. Tread carefully if the business is involved in any clinical trials or R&D because of potential data consent issues.

**Joint ventures and collaborations.** These are popular mechanisms that allow companies to tackle supply chain risks together, saving on drug discovery costs and utilizing new technologies such as blockchain to trawl competitors' data with full traceability but crucially, without revealing commercial secrets to rivals.

**Closing readiness.** If you are a buyer, ensure that you come to the table prepared to discuss your plan from signing to closing and that the right people from the seller are included in the discussions (e.g. plant operations, regulatory). Consider employee communications early on and arrange pension plans in advance. Ensure that you address EHS issues when separating and selling parts of manufacturing sites.

**Transition and integration.** Be aware of the target business' asset readiness and scope of transition service. Changing IT systems on a manufacturing site can take a long time so it is important to understand the overall value proposition in generating efficiencies. Understand which licenses are applicable, including from a manufacturing and import perspective.

### What is your top deal making priority right now?



\*Based on survey responses from Baker McKenzie's Healthcare & Life Sciences Supply Chain Webinar Series

## Tax

**Tax reform on a global scale.** At a domestic level, many countries and jurisdictions around the world are undertaking significant tax reforms in response to the changing global business environment. At the international level, in a coordinated effort to combat perceived tax avoidance, the OECD has gained significant support for its two pillar plan to reform international taxation rules. Many of the international efforts directly implicate supply chains and how taxable income is allocated among the various jurisdictions in those structures via transfer pricing. With the prospect of significant tax and other policy changes, and the potential for increased tax rates, this is now an opportune time to consider what the impact may be across supply chains and structures.

**Tax controversies at every stage of the supply chain.** Tensions often arise between and among the jurisdictions where R&D is performed, those with manufacturing operations, and market jurisdictions regarding how much value (and therefore taxable income) is being assigned to each. Market jurisdictions where the consumers are located increasingly clamor for a greater share of profits.

**Characterization of collaboration agreements.** When collaborations are characterized as partnerships in jurisdictions where tax authorities are increasing resources to audit such agreements, adverse impacts can arise, resulting in potential income tax and eroding patent box regimes. Healthcare and life sciences companies are now evaluating workarounds such as reviewing provisions which could impact partnership characterization, or considering structural alternatives such as moving commercialization activities into a separate entity.

 **Companies continue to struggle in understanding the impact of increasingly sophisticated transfer pricing controversies.**

**55%** have no idea about their company's transfer pricing controversies around the world

\*Based on survey responses from Baker McKenzie's Healthcare & Life Sciences Supply Chain Webinar Series

# What are the key considerations when optimizing your supply chain?



## Compliance

**Evolution in the use of third parties.** There has been an evolution in the use of third parties and this has led to new risks. While use of third parties introduces much needed flexibility and cost savings, it increases compliance and supply chain risks. As a result, there is a need for careful third party due diligence.

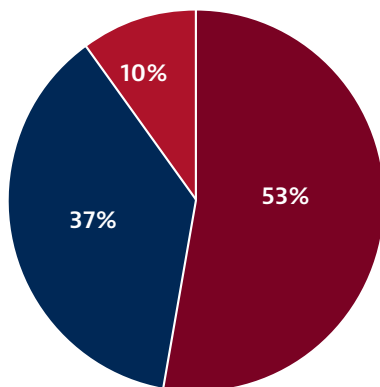
**New risks emerging.** In addition to the familiar risks for the healthcare and life sciences industry, we see new risks emerging that can only be mitigated through compliance measures, such as risks arising out of trade restrictions and prohibitions.

**Customization of risk management models to digitization and new policies.** Companies should consider developing a customized risk management model for the digitization of the supply chain. Adopting policies for the protection of new types of intangible assets will help enhance the value of personal and non-personal data.

**Digital transformation can drive collaboration and efficiency.** Digital transformation can be an opportunity to drive collaboration between the industry and regulators (including regulatory harmonization) and to improve the efficiency of supply chain compliance.

**New business opportunities.** Attention to compliance can help identify new business opportunities (thanks to better use of data and resources). It can also lead to positive effects such as cost-effectiveness and the ability to anticipate risks and overcome problems more rapidly.

**Apart from COVID-19, which development is most impacting your supply chain?**



- Import & export trade restrictions
- Increasing nationalization and regionalization of supply chains
- US-China trade war

\*Based on survey responses from Baker McKenzie's Healthcare & Life Sciences Supply Chain Webinar Series



## Trade Secrets

### WTO IP waiver and local requisition measures.

The potential WTO waiver of IP rights (including know-how and trade secrets) for COVID-19 would temporarily suspend IP rights, requiring member countries to either enact new local laws or temporarily suspend existing laws to implement the decision. The wording of this proposal is currently under debate - the local requisition measures and the WTO IP waiver may provide a precedent for future pandemics or other emergencies, yet unknown. Even if you are not in the COVID-19 business today, it could potentially impact your business in the future.

### Recommended measures for companies in light of the requisition measures and the WTO waiver

- Companies should conduct an audit of their trade secrets and other undisclosed sources of information to assess the information most at risk and identify potentially affected products.
- Companies should identify countries that present the greatest risk profile for their companies.
- Where possible, they should engage with industry bodies or directly with governments to potentially influence the position a government may take before the WTO or subsequently to assist locally in framing any potential measures that could minimize exposure.
- Companies should consider whether other IP protective measures or strategies exist to add additional layers of protection for sensitive or proprietary information.

### Restriction on the use and disclosure of trade secrets and knowhow.

As trade secrets and knowhow information relevant to COVID-19 products may also be valuable to the business' non-COVID products, it is critical for businesses to restrict third party use of such information and to limit third party publication or disclosure of such information. Attention should also be given to existing contractual provisions in manufacturing and other similar agreements to assess the level of protection against disclosure.



**Trade secret protection is becoming progressively challenging, given the rapid pace of scientific innovation.**

**80%** do not or are not sure if their company keeps an inventory of its trade secrets

\*Based on survey responses from Baker McKenzie's Healthcare & Life Sciences Supply Chain Webinar Series

# What are the key considerations when optimizing your supply chain?



## Digital Transformation

**Data emerging as the new battleground.** Embracing digital solutions leads to legal and regulatory challenges, such as the regulation around the use and protection of patient data. At the same time, digital solutions increase the risk of a cybersecurity incident, amid increased interest in accessing and protecting sensitive health and patient information.

**Investing in digital transformation is worthwhile.**

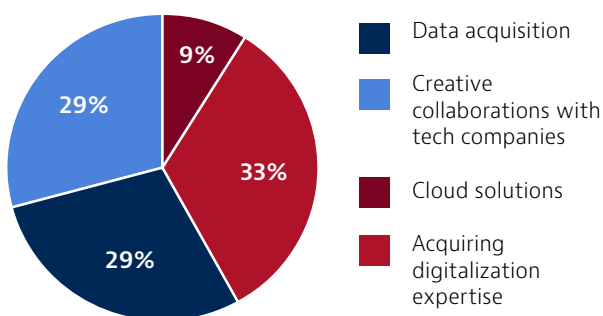
Digitalization also leads to tremendous opportunities: enhanced value of data, greater cost-effectiveness, faster response to supply chain disruptions, improved accuracy and opportunities.

**Rise of frontier technologies.** Quantum computing is emerging as a game changer for healthcare and life sciences. New approaches to product distribution is also emerging, including predictive analytics to precisely forecast patient demand and anticipate potential shipping delays.

**Adoption of next generation traceability tools.**

New performance management systems enable end-to-end transparency throughout the healthcare and life sciences supply chain. The integration of supplier data and service providers in a “supply chain cloud” ensures that all stakeholders steer and decide on the same facts.

**What aspect of a digital transformation deal do you find most attractive?**



\*Based on survey responses from Baker McKenzie's Healthcare & Life Sciences Supply Chain Webinar Series



**USD 22 billion:** The amount of funding that investors plan to direct into digital health innovation

\*Based on our thought leadership report, [“Hyper-Hybridity: Defining a New Era of Digital Health Innovation in Asia Pacific”](#)



## ESG and Sustainability

**Mounting interest in renewable energy.**

The industry is increasingly looking at renewable energy to power their operations, save on electricity costs and deliver on decarbonization goals. Some of the mechanisms include long-term corporate purchase power agreements (PPAs) or using renewable energy contracting structures such as virtual (synthetic) PPAs to offset emissions via renewable energy certificates.

**Promoting inclusive and diverse supply chains.**

Diversity is growing in importance as a key risk mitigation strategy in managing supply chains, ensuring business continuity and gaining access to new demographics while building your corporate socio-economic value.

**Emerging enforcement risks for climate risk disclosures.**

Governments around the world are starting to focus on climate change and clean energy, including reviewing corporate climate risk disclosures, with noncompliance possibly leading to lawsuits or other enforcement actions. Risks increase significantly for companies who have not developed a solid risk-based response or a robust ESG program.

**Increasing importance of ESG considerations in boardroom decisions.**

In order to do ESG well, companies need to get their governance right. Along with WBCSD, we are challenging directors to assess whether they are taking all relevant steps in the boardroom to ensure the company not only properly assesses and mitigates sustainability risks but also understands the opportunities that sustainability considerations can bring.

**62%** believe that their supply chain due diligence program meets established compliance risks and emerging ESG challenges only to some extent

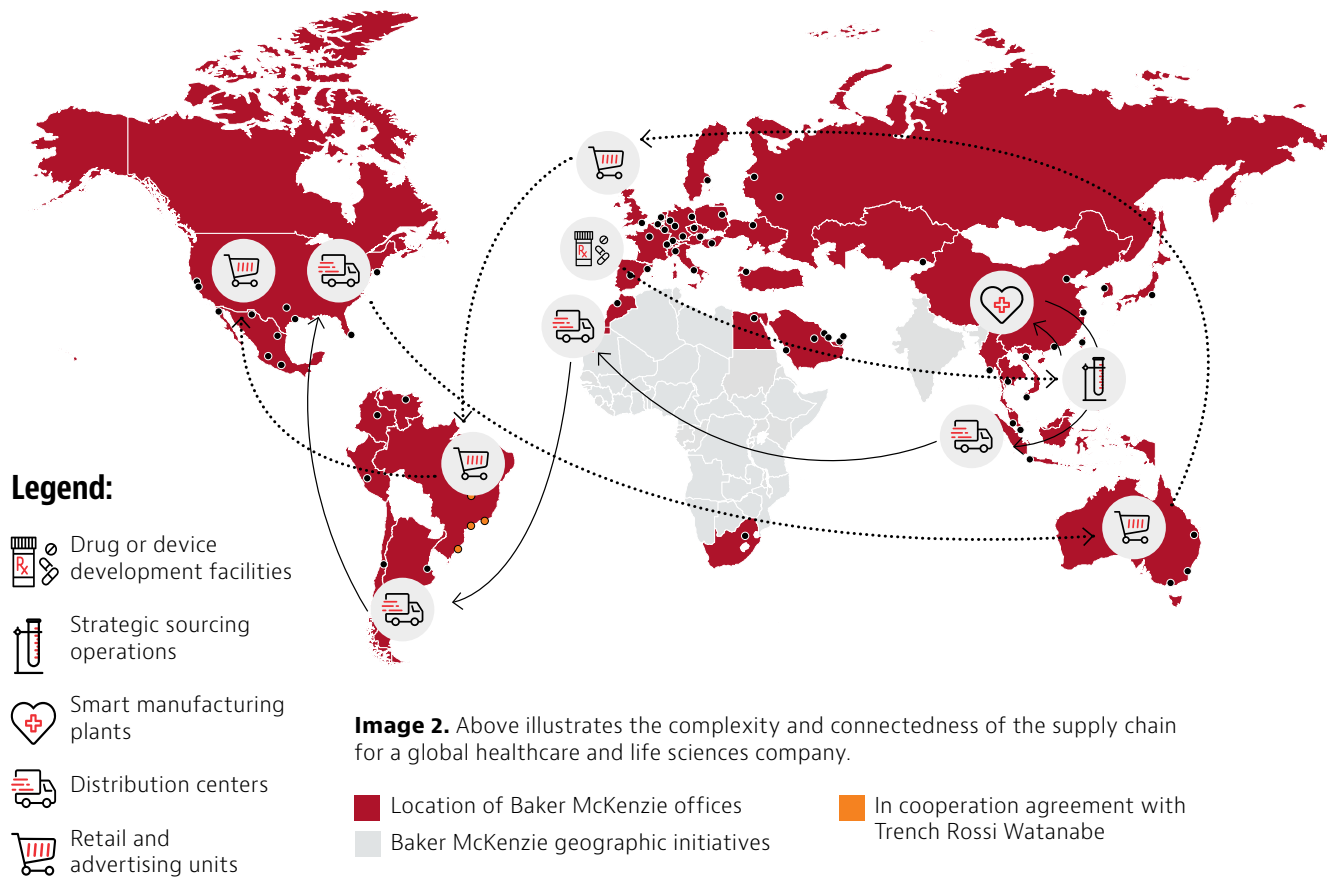
\*Based on survey responses from Baker McKenzie's Healthcare & Life Sciences Supply Chain Webinar Series



**73%** of compliance leaders say they have seen an increase in the focus on D&I from critical stakeholders in the past year

\*Based on our series examining corporate D&I, [“Mind the Gap”](#)

# The Interdependence of the Supply Chain: A healthcare and life sciences view



## Firm facts:

**76**

Offices

**46**

Countries

**800+**

Healthcare & life sciences lawyers

**100+**

Regulatory lawyers focused on the industry

**6,000+**

Total lawyers and other fee earners globally

## Our top 50 Healthcare & Life Sciences clients comprise of:

- 9 of the 10 pharmaceutical companies listed in the 2021 Global Fortune 500
- 7 of the 10 largest medical devices companies ranked in the 2021 Global Fortune 500
- 13 of the top 20 biopharma revenue generators globally



Baker McKenzie's expansive global network is well equipped to advise on complex matters relating to the life sciences space. With highly rated and dedicated life sciences groups across Asia, Europe and Latin America, the firm performs highly on international mandates. Its main areas of focus are:

- Cross-border corporate transactions
- Regulatory and IP mandates
- Product licensing
- Market authorizations and clinical trials

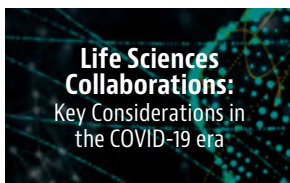
**Chambers Global, Life Sciences 2021**  
**Ranked in the top 10 law firms in the world for life sciences**

# Resources to Optimize Your Supply Chain

Ensuring and maintaining a resilient supply chain is both a key survival and growth tactic in today's evolving business and legal landscape.



Click on the thumbnail to sign up for upcoming sessions and access recordings of our **Supply Chain Webinar Series**, which focuses on the trends, issues and opportunities across each stage of the supply chain life cycle for healthcare and life sciences companies.



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