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
- Robust contract protection against third party risks (termination provisions)
- Exporting of waste products increasingly regulated
- Tracing technologies facilitate effective product recall
- Quality and safety controls complicated by use of distributors
- Defining a force majeure event
- Flexible contingency planning for contracts
- Observing industry codes for dealing with HCPs
- Early engagement with authorities
- Supplier selection criteria and expectations
- Digitization and technical demands influencing collaborations
- Significant variation of FDI regimes across jurisdictions
- Compliance to advertising laws
- Changes in sourcing affect intermediaries and rules of origin
- Counterfeit risks for online sales
- Tracing technologies help detect and stop falsified medicines from entering the supply chain
- Impact of political developments in restructuring the supply chain and prices
- Importance of qualifying as an essential industry
- Pandemic-driven changes to R&D processes
- Regulatory and political developments driving change
- Multiple pressures may affect the availability of supply e.g. packaging
- Labelling only finalized once marketing authorization is granted

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
What are the key considerations when optimizing your supply chain?

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?

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

<table>
<thead>
<tr>
<th>Priority</th>
<th>Percentage</th>
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<tbody>
<tr>
<td>Portfolio growth</td>
<td>17%</td>
</tr>
<tr>
<td>Reducing real estate footprint</td>
<td>45%</td>
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<tr>
<td>Digital transformation</td>
<td>38%</td>
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55% have no idea about their company’s transfer pricing controversies around the world.

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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?

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

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**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.

**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.

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

- Data acquisition: 9%
- Creative collaborations with tech companies: 33%
- Cloud solutions: 29%
- Acquiring digitalization expertise: 29%

*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-Hybrity: Defining a New Era of Digital Health Innovation in Asia Pacific"

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

*Based on our series examining corporate D&I, “Mind the Gap”

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 survey responses from Baker McKenzie’s Healthcare & Life Sciences Supply Chain Webinar Series
The Interdependence of the Supply Chain:
A healthcare and life sciences view

Image 2. Above illustrates the complexity and connectedness of the supply chain for a global healthcare and life sciences company.

Legend:
- Drug or device development facilities
- Strategic sourcing operations
- Smart manufacturing plants
- Distribution centers
- Retail and advertising units

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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