BIOSECURE ACT – 2024 DEBATE

Impact on US Life Science Companies with Chinese Suppliers

TENZING

A CALL TO ACTION

With growing bipartisan support and after debate in both the US House and Senate, Life Science companies recognize the BIOSECURE Act is likely to pass and be signed into law regardless of the November elections. If enacted, it will prohibit US Federal Agencies and companies receiving federal funding to work with select Chinese Life Science companies.

Although diplomacy is the preferred approach to managing foreign relationships, since its founding, the US has enacted trade laws to defend itself and manage its affairs. The BIOSECURE Act is targeted at select Chinese Life Science companies and is part of the response to the escalating trade war between the US and China. The BIOSECURE Act has yet to be enacted, but the potential passage will impose a significant supply risk for Life Science companies.

While the prohibited company list is currently short, this appears to be only the beginning as the legislation provides language for other Chinese Life Science companies to be labeled "companies of concern." As a result, clinical and CMC (chemistry, manufacturing and controls) sourcing teams will need to clarify the ownership and control structures for all suppliers to manage future compliance requirements.

Current Draft US Legislation and Scope

Both US House and Senate committees have debated and proposed similar bills to reduce the potential threat of the Chinese Communist Party (CCP) and Peoples Liberation Army (PLA) influence in drug studies and manufacturing. In general, legislative language between the two bills will prohibit the heads of US agencies from engaging with any listed entity to (1) use biotechnology equipment or services produced or provided by a company of concern or (2) if it believes the use of biotechnology equipment or services will be produced or provided by a company of concern.

There is comprehensive language to limit engagement with subsidiaries, affiliates and successors of the following targeted Chinese companies:

- WuXi Biologics
- WuXi Apptec
- MGI/Complete Genomics
- BGI Group

There is language in both bills directing the Office of Management and Budget ("OMB") to develop a broader list of "biotechnology companies of concern" who are subject to the jurisdiction, direction, control or operating on behalf of a "foreign adversary" (China, Iran, North Korea and Russia). While not definitive, this language suggests the possibility of adding additional Chinese suppliers. Further complicating matters on this "catch all" clause is the ongoing investment by Chinese companies in North America, India, Europe and other global regions. Ownership and operating situations vary from joint ventures to full ownership through various subsidiaries.

To address concerns about an immediate market disruption, in May 2024 the US House subcommittee amended the legislation to provide a 7-year timeline for existing contracts ("grandfathered") to comply with a deadline of January 31, 2032. Unfortunately, this updated language only provides short-term relief as the re-sourcing process to find and secure new suppliers often takes several years.

Re-sourcing Framework

While the re-sourcing process requires significant costs and resources to address complex issues (business requirements, quality, regulatory, qualifications, capacity, etc.), generally it involves these activities:

1. End-to-End supplier ownership documentation
2. Category Management and Strategic Sourcing
3. Compliance management

As taxing as this may be for clinical and CMC teams to find and qualify new suppliers, it is important to engage the entire company in this process. Teams from business development, legal, finance, regulatory and others will need to address development assets in discovery and preclinical stages where supplier relationships are initially formed.

End-to-End Supplier Ownership Documentation

Developing a central repository documenting all suppliers in the drug development and manufacturing process and their ownership structure is an important first step. Depending on the size of the supply base and the supplier structure, this process may require significant effort. For example, a supplier may be registered outside of China and not have operations in China. However, the ownership structure may be unclear if there is a Chinese company or individual(s) who have significant ownership influencing the governance.

While ERP and procurement systems like NetSuite, SAP, Coupa, GEP, Ariba and others can help streamline the process, using them with third-party databases (e.g. Moody's, Thomson-Reuters) is just a first step. It is likely going to take further due diligence and direct supplier interaction to validate ownership and governance.

Although the initial focus is on the named Chinese entities, the draft language allows the naming of other Chinese entities in the future. As an illustration of the ongoing vetting of Chinese owned companies, on May 30, 2024, bi-partisan members of the U.S. House Select Committee on the Chinese Communist Party sent a letter to the director of National Intelligence and the FBI regarding the ownership and control of GenScript Biotechnology Co., Ltd. This letter explains the perceived ownership and control of the company and requests a briefing on their ties to the CCP. While GenScript may not be added to the list of prohibited Chinese companies, others are likely to be added in the future. This will require Life Science companies to develop a more comprehensive and efficient supplier vetting process.

Category Management and Strategic Sourcing

Once a comprehensive supplier list is developed, it is important to ensure the following steps are included within the Category Management process:

1. Broad engagement with company subject matter experts and executives
2. List of new suppliers involved in the drug development discussions (discovery, preclinical, business development)
3. CDMO global market analysis of supplier capability (molecule size, manufacturing phase, manufacture product, omic data needs, etc.) and capacity (current and planned)
4. Detailed category strategy addressing the market to include strategic sourcing program, objectives and detailed timelines
5. Make vs. buy framework to facilitate sourcing options across the drug development and manufacturing process

Developing sourcing options is an iterative process requiring discussions with team subject matter experts across clinical operations, analytical science, manufacturing controls, supply chain planning, etc. While there will be significant emotions and challenges in this phase, a Category Management process provides the company with important supply market insights captured from Requests for Information to specific Requests for Proposals.

Using baseline information developed in the Category Management process, a sourcing team can explore options in a growing and fragmented global market to replace existing Chinese suppliers. While the global CDMO market growth is expected to grow at a 13% compound annual growth rate, regional growth will vary. While the initial concern and focus is on China, it is important to note that over 60% of the CDMO market is North America and European based. CDMO capacity continues to grow in India, South Korea and Japan are taking place as those countries investing in drug development and CDMO capacity. Further CDMO capacity is also growing in Brazil and Argentina, representing 7-9% of the global market.

In addition to looking to move entire production to a non-Chinese based company, sourcing teams should also consider bringing certain portions of their production process inhouse. This can include steps like API (Active Pharmaceutical Ingredient) extraction, synthesis, fermentation and/or drug formulation. Through a combination of inhouse and outsourced process steps, a solution may develop that addresses supply risk, cost, compliance/quality and capacity needs.

Although trade legislation like the BIOSECURE Act is concerning and disruptive, the role of Procurement and Supply Chain teams is to anticipate these issues and provide the organization with support and leadership. Employing a Category Management approach with a frequent refresh is a prudent way to facilitate discussions with executives and board briefings and ensure all costs and risks are considered.

Compliance Management

While identifying, evaluating, contracting and transitioning to new suppliers is a crucial first step, demonstrating compliance is also needed. Formal audits and Requests for Information from government agencies to produce required documentation are often complicated because companies have disconnected ERP, contracting and procurement platforms. Often employees find they must search e-mails, financial and contracting systems, SharePoint folders and other sources.

Depending on a company's process and system maturity, it may take time to implement an efficient supplier compliance process. Yet, by starting with a vision that systems should support the team and process, companies can start collecting essential supplier information using SharePoint or other software intake tools. As planning and budgets evolve, companies can evaluate and implement comprehensive supplier management platforms to efficiently evaluate the supply market and respond to audit requests.

In Conclusion

While the US-China trade rhetoric and legislation may change with a new administration, it would be risky to think the debate on the BIOSECURE Act will come to an end. Supply risk management requires ongoing incorporation of geopolitical risk into Category Strategies, sourcing plans, and systems considerations. Maintaining vigilance at a senior level on these supply risk issues is imperative to a company's ongoing drug development and commitment to patient care.

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