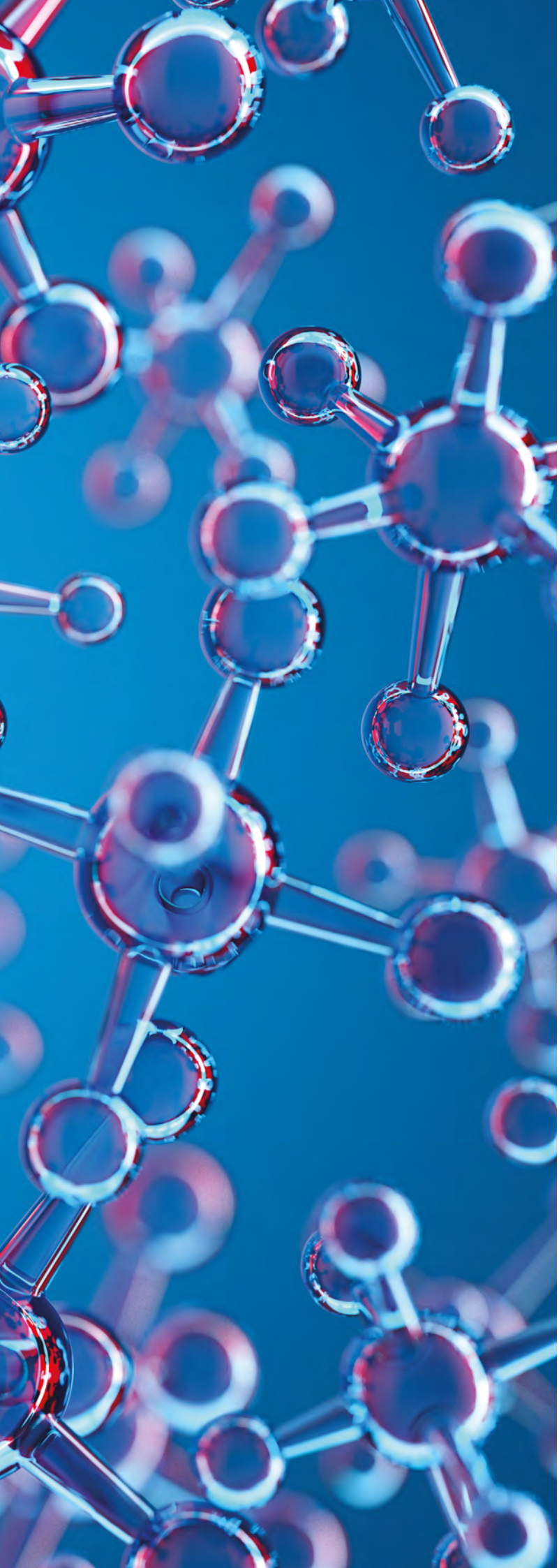
Biotech meets BioSec

Geopolitical Impacts on Biotech Supply Chains & Clinical Trials



Marwood

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Over the last few years, the biotech market has grappled with a global pandemic, numerous drug shortages, burdensome supply chain disruptions, escalating trade tensions, and a difficult funding environment. Underlying these broader issues is the threat to each nation's *biosecurity*.

Historically, the term has mostly referred to practices that prevent the spread of harmful pathogens, such as disinfection or quarantine. Today, nations have broadened the term to encompass practices that improve the health of their biotech industries. After all, fostering domestic biotech innovation with self-sustaining, high-quality supply chains inarguably does bolster a nation's biosecurity.

On the other hand, enabling a country's biotech startups to access foreign, low-cost supplies and services also fosters domestic innovation. Providing citizens with expedited access to breakthrough treatments approved in foreign countries also bolsters a nation's biosecurity.

China, as the world's fastest-growing hub for biotech development, manufacturing, and research services, is now causing western nations to grapple with this delicate balance; some through domestic stimulus and others through punitive restrictions. As the current market leader in biotech innovation, the US seems to favor the latter approach. >

The US BIOSECURE Act

On September 10, the US House of Representatives overwhelmingly passed the BIOSECURE Act on a suspension vote of 306-81, partially as a result of growing, bipartisan anti-China sentiment. In its current form, the BIOSECURE Act would prohibit executive agencies from providing loans, grants or subsidies or procuring or obtaining equipment or services from "Companies of Concern" (CoCs) [Table 1]. It would also prohibit executive agencies from entering into, extending, or renewing contracts that require the direct use of equipment or services from CoCs, such as contract research, development or manufacturing organizations, or entering into contracts with entities that use equipment or services from CoCs, such as biotech sponsors.

The most notable of these listed CoCs is WuXi Apptec and its subsidiary Wuxi Biologics, a leading global contract research, development, and manufacturing organization (CRDMO). WuXi is notorious for undercutting Western CRDMO competitors on price, thus enabling a global array of pre-market biotech sponsors to limit the costs of their R&D in a difficult funding environment.

Although BIOSECURE is still subject to amendment, would not affect existing contracts until 2032, and could potentially still allow US insurers to cover products developed using CoC products or services, its likely passage by year-end would have significant implications for the global biotech market that will be explored later in this piece.

In addition to BIOSECURE, the House has also focused on the use of China-based clinical trials for purposes of US FDA submissions. In August 2024, the Select Committee on the Chinese Communist Party (CCP) sent a letter to the FDA requesting information on research conducted in China. The lawmakers expressed national security concerns with U.S. drug manufacturers conducting clinical trials with Chinese military organizations. Without naming names, this letter called out Alzheimer's research being conducted with People's Liberation Army (PLA) hospitals and schools (Eli Lilly's TRAILBLAZER study), called out a cancer clinical trial conducted with a hospital owned by an entity on the Commerce Entity

> *"WuXi is notorious for undercutting Western CRDMO competitors on price, thus enabling a global array of premarket biotech sponsors to limit the costs of their R&D in a difficult funding environment"*

TABLE 1
"Companies of concern"

CHINESE "COMPANIES OF CONCERN"	DESCRIPTION	MARKET CAP	REVENUE
药明康德 WuXi AppTec	Leading Chinese provider of R&D & manufacturing services to pharma and biotech companies	$22.8B	$5.7B
WuXi Biologics Global Solution Provider	WuXi Apptec subsidiary CRDMO providing R&D and manufacturing solutions for biotech clients	$9.4B	$2.4B
BGI	Provides clinical molecular diagnostic solutions and high-throughput sequencing research services	$2.8B	$614M
MGI	Provides genomic sequencing services, instruments, and reagents for biotechnology R&D	$3.4B	$411M
Complete GENOMICS	MGI subsidiary offering a range of end-to-end next-generation sequencing for spatial transcriptomics	$108M	$19M

List (Pfizer's axitinib HCC study), and called out manufacturers who conduct research in the region surrounding the Uyghur genocide.

The Senate companion bill to the BIOSECURE Act, the Prohibiting Foreign Access to American Genetic Information Act, will likely be reconciled to directly mirror the House bill, pending further amendments.

The Proposed EU Critical Medicines Act

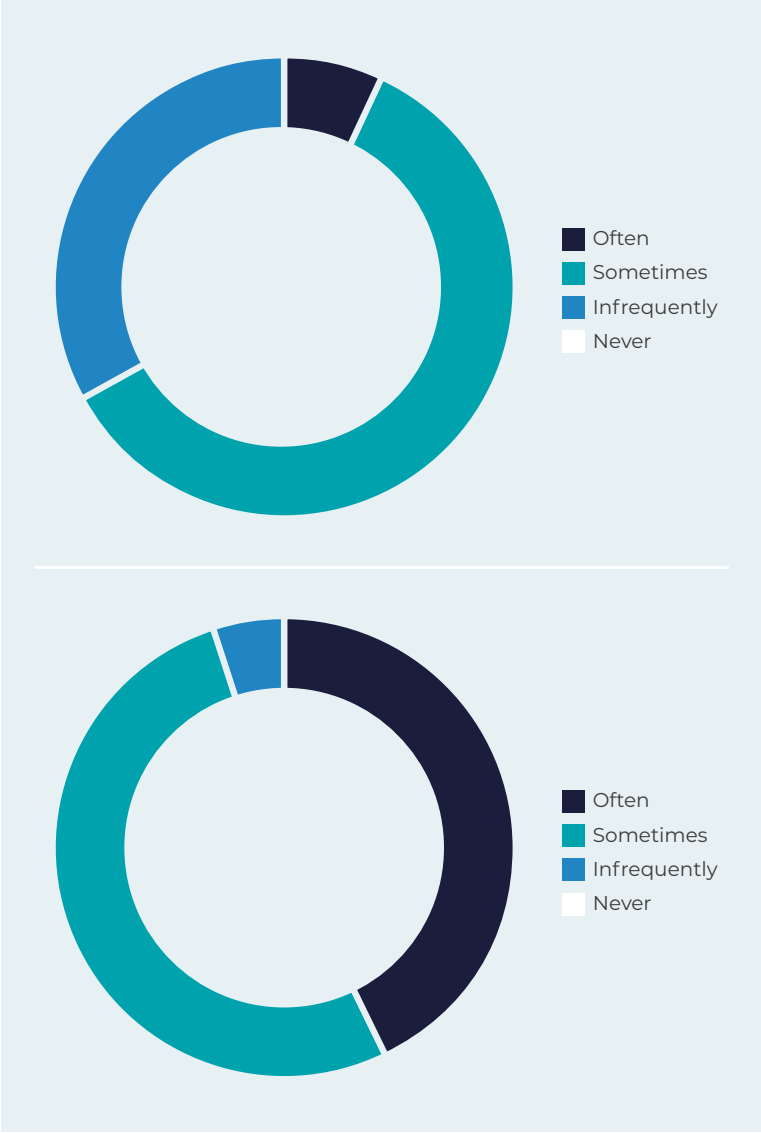
While the BIOSECURE Act is the main focus of sponsors trying to stay cost-conscious, there are also policy initiatives in the EU and UK that are similarly hoping to reduce reliance on foreign markets. However, unlike in the US, these initiatives focus more on the *carrot* than the *stick* – stimulus through investment and funding vehicles.

The European Economic and Social Committee (EESC), a body of the EU, adopted an opinion in December 2023 that proposes several mechanisms to ensure stability of medicine supply.

The EU's lead rapporteur for this opinion, Lech Pilawski, stated, "We are jeopardising our citizens' health by relying on external suppliers for essential pharmaceuticals. Europe cannot afford to gamble with the lives of its citizens. We must act now to ensure that Europeans have access to the medications they need."

The EESC proposes a Critical Medicines Act to address this issue. It includes the following measures to combat this issue and strengthen the domestic supply of biotech advanced pharmaceutical ingredients (APIs):

- **Enhanced EU Funding:** The Critical Medicines Act aims to establish a new EU mechanism to promote the development and production of APIs in Europe. This will be backed by enhanced EU funding for research and development of APIs, infrastructure development and operating costs
- **Investment in Innovative Production Technologies:** The proposed Act will promote investment in research and development for innovation in new manufacturing practices via encouragement of collaboration between academics, industry and other stakeholders to enhance adoption of cutting-edge production technologies
- **Adoption Of Fair Pricing Mechanisms:** Ensuring patients have equitable access to medicines and APIs and finished medicines remain affordable is a key priority. The Act will include provisions for ensuring this via competitive bidding processes, pricing controls in Member States and enhanced adoption of generic alternatives where feasible.



↑ **FIGURE 1 (TOP)** Frequency of BIOSECURE Supply Chain Discussions

FIGURE 2 Frequency of BIOSECURE Clinical Trial Discussions

The EESC postulates that relocation of biotech API production to Europe will have several tangible benefits for the EU, namely:

- Stimulation of economic activity and resulting growth
- Generation of new employment for EU nationals
- Increased competitiveness of the EU against non-EU peers especially the USA and China
- Potential reduction in pharmaceutical production costs
- Increased resilience of the EU medicines supply chain to external shocks
- Enhancement of EU status as an industrial leader >

"We are jeopardising our citizens' health by relying on external suppliers for essential pharmaceuticals. Europe cannot afford to gamble with the lives of its citizens. We must act now to ensure that Europeans have access to the medications they need"

↑ **FIGURE 3**
BIOSECURE Impact on CRDMO Relocation, by continent (N=37)

The United Kingdom can also be expected to mirror the EU Critical Medicines Act if it is passed – the country has not deviated significantly from EU policy despite Brexit.

On the clinical trial side, however, the European Medicines Agency (EMA) has been increasingly open to accepting data from foreign clinical trials, provided they meet specific ethical and scientific standards set by the EMA. The EU has also signed mutual recognition agreements (MRAs) with third-country authorities such as those in Australia, Canada, Israel, Japan, New Zealand.

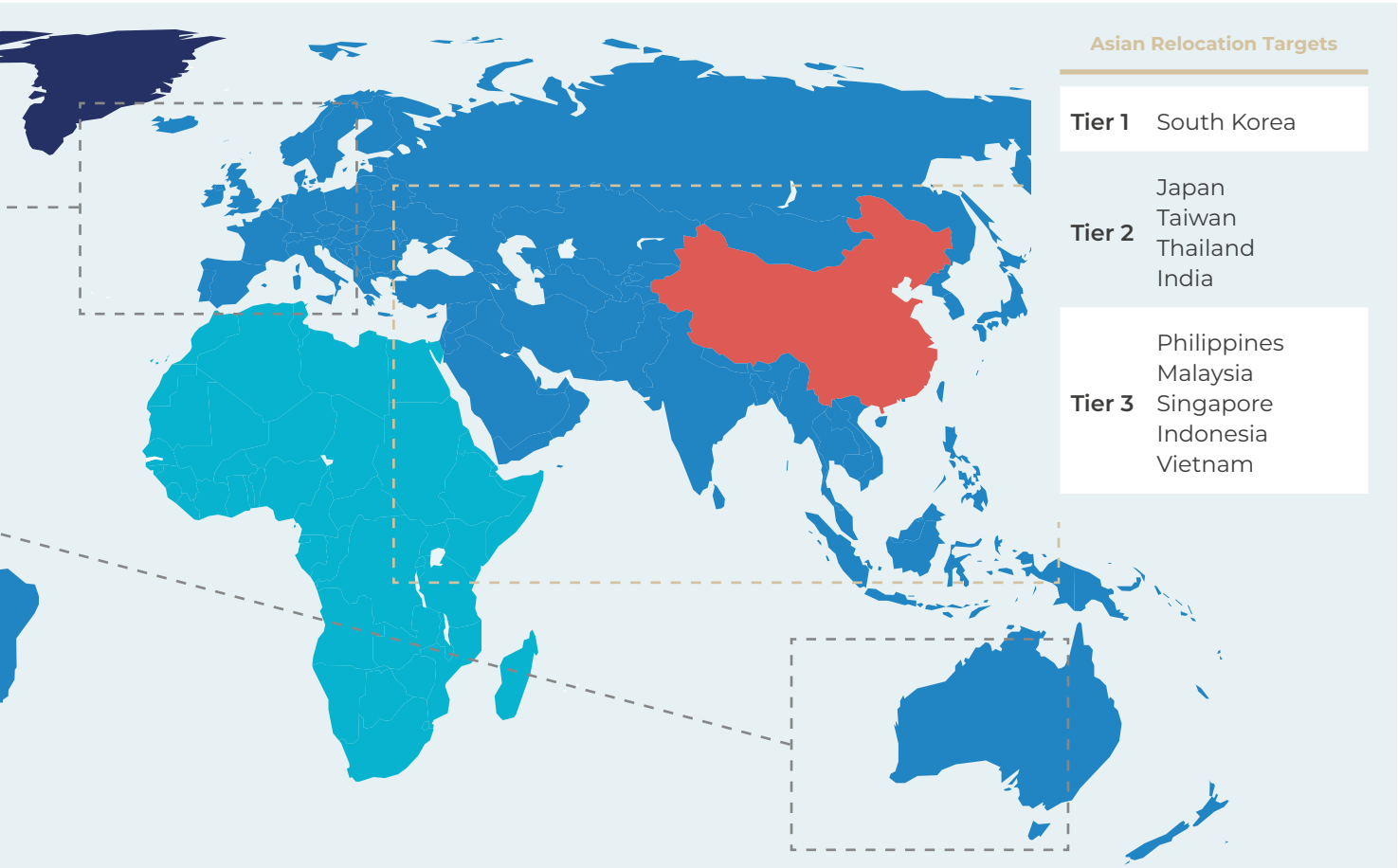
Similarly, the UK's Medicines and Healthcare products Regulatory Agency (MHRA) has been adapting its approach to acceptance of data from foreign clinical trials. In order to streamline the regulatory approval process, the MHRA has introduced the International Recognition Procedure (IRP) which allows the MHRA to leverage approvals from trusted regulatory partners in countries such as Australia, Canada, the European Union, Japan, Switzerland, Singapore, and the United States. However, China remains notably absent from the EMA and MHRA's cross-border streamlining of regulatory approvals.

The Biotech Sponsor's Perspective

Marwood sought to better understand how biotech sponsors are planning to respond to these geopolitical dynamics, if at all. Marwood gathered perspectives from supply chain, procurement, and clinical trial operators at biotech sponsors (N=37) to better understand how foreign contracting trends are being impacted.

First, Marwood confirmed what many in the industry have known for some time – Chinese CRDMOs offer significantly lower prices. Chinese CDMO services and supplies are considered to be 34% cheaper and CRO services are considered to be 31% cheaper than those of US or European counterparts. However, some noted WuXi's cheaper prices come at a greater risk, citing unreliability, spotty quality management, and lack of IP protection as the primary reasons why they would seek to contract more expensive ex-China alternatives.

For the time-being, sponsors' focus on BIOSECURE's impact seems to be more concerned with impact to biotech supply chains for both pre-market and in-market products. Supply chain operators noted



meeting on a more frequent basis to discuss the impacts of BIOSECURE relative to clinical trial operators [Figures 1 & 2]. Similarly, 56% of supply chain operators with Chinese suppliers noted that they would move their supplier contracts out of China within the next decade, while 61% of clinical trial operators said the opposite of their Chinese CRO contracts.

Across clinical trial and supply chain operators, the most common reasons cited for maintaining Chinese contracts are existing China-based subsidiaries, licensing agreements, cost-savings, and plans for Chinese market access given the size of the market. Those who anticipated replacing their Chinese contracts with ex-China CRDMOs noted a preference for expanding the scope of their existing ex-China contracts rather than contracting with new organizations, particularly for CRO services.

Marwood also sought more clarity regarding sponsor geographic preferences as they evaluated new CRDMO contracts. By continent, the majority of sponsors indicated an interest in North America (54%), followed by Europe and Asia (both 35%), followed by Australia and South America (both 16%). Only 11% of sponsors are interested in relocating contracts to Africa. Of ex-Asian countries, a majority indicated an interest in the US (76%). Of Asian countries outside of China, sponsors are most interested in South Korea (69%). See Figure 3 for a detailed breakdown.

Conclusion

While the international push towards national biosecurity evolves, it is important to keep abreast of not only this complex issue, but also how biotech sponsors plan and adapt to it. Although the BIOSECURE and Critical Medicines Acts are still in their early innings, the biotech sector rewards operators that think far into the future, from discovery to development to life cycle management. In response to these global policy, supply chain, and trade dynamics, Marwood has observed biotech operators do just that. As biotech funding begins to thaw, and the cost-conscious “virtual biotech” becomes the emerging standard, there is a clear opportunity for CRO and CDMO platform investments that can be as forward-looking as their biotech clients by remaining conscious of these broader global dynamics. ■

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