



PLANNING FOR THE UNPREDICTABLE IN HEALTH CARE SUPPLY CHAINS

By Megan DeFauw, Shana Topp, Bryan Head, Ben Aylor, and Aaron Snyder

AS THE COVID-19 PANDEMIC has made all too clear, today's biopharmaceutical and medical technology supply chains are extremely susceptible to economic shocks. The pandemic's impacts have made it difficult for many companies—both manufacturers of COVID-19 medicines or personal protective equipment (PPE) and producers of other essential medical products—to maintain an adequate supply. Compounding these challenges, some governments are thinking about taking steps to shore up their supply of critical products for their own populations.

To safeguard their supply networks, companies need to adopt new ways of thinking about supply chain resilience and incorporate them into their network strategy. It will be especially important to set and measure resilience targets, determine what changes are needed to meet them, and weigh the tradeoffs.

How COVID-19 Is Changing the Context for Network Decisions

Today's biopharma and medtech supply chains took shape during an unprecedented era of globalization. As a result of tax policies, pricing pressures, the maturation of contract manufacturing organizations (CMOs), and the increasing availability of skilled talent in emerging economies, companies developed highly complex supply networks with a high volume of cross-regional trade. (See Exhibit 1).

Today, these supply chains rely far more heavily on suppliers in emerging economies than in the past. However, as they have become largely optimized for cost, invested Capex, and product quality, they have also become increasingly vulnerable to disruptions.

Supply Chain Vulnerability. When COVID-19 hit, manufacturers and their suppliers were immediately affected. The first biopharma product shortage attributable to the pandemic was reported to the FDA in late February 2020, at about the

same time as the first non-travel US case was confirmed.

As the crisis escalated over the next few months and demand for certain medicines and medtech products—particularly PPE and ventilators—rose, stockouts became an issue. Some companies relied on careful allocation and daily sales and operations execution reviews to get products to the patients and health care workers who needed them. Others were forced to dip heavily into inventories because key suppliers, especially those from China, were unable to produce or ship for many weeks.

Protectionist Policies. Complicating network decisions further, many governments are now considering enacting policies to ensure that a sufficient supply of critical medicines and medical products is available locally. So far, no government has enacted blanket policies in response to COVID-19 that would require health care companies to drastically rework their manufacturing networks—and such moves remain highly unlikely. But policies that encourage the local production of specific medicines or medical products are already

in the works. This could alter the optimal supply chain configurations for some companies, particularly those that manufacture essential products.

The US government, for example, has provided loans and subsidies for the domestic manufacture of essential medicines; in addition, the recent “Buy American” executive order has the potential to significantly increase inshoring and investments in US manufacturing. The European Commission is also reviewing potential legal changes with an eye toward improving supply chain resilience. (See Exhibit 2.)

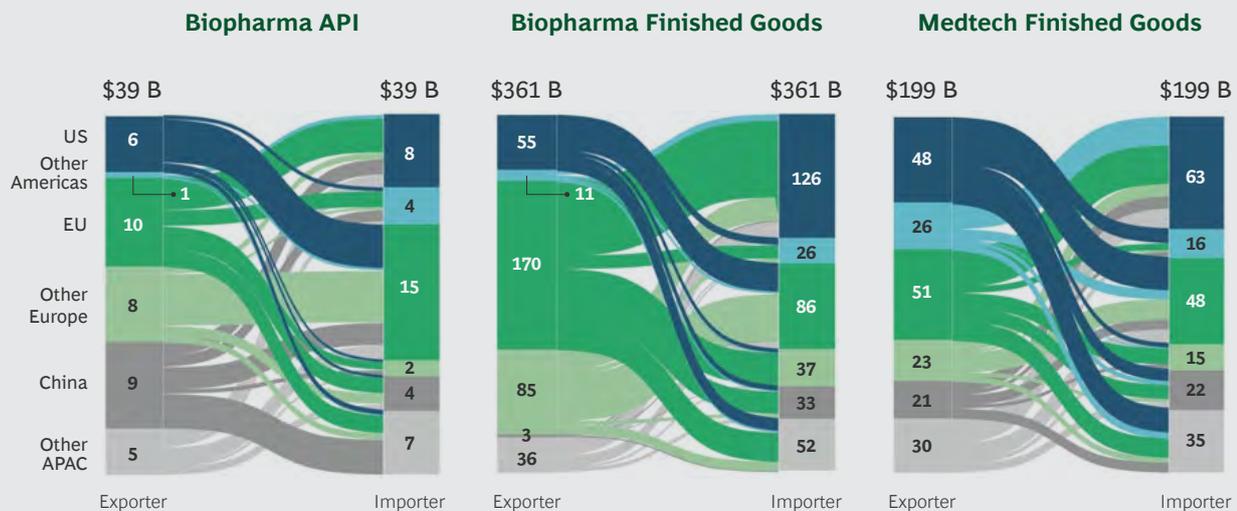
How Biopharma and Medtech Companies Should Respond

In the face of these unknowns, biopharma and medtech companies need to revisit their network strategies—not just their typical periodic refreshing, but a reassessment that focuses on building resilience. We recommend incorporating the following practices.

Determine resilience targets. Companies should first determine which key perfor-

EXHIBIT 1 | Biopharma and Medtech Supply Chains Are Highly Globalized

Trade import/export selected trade routes¹, 2019

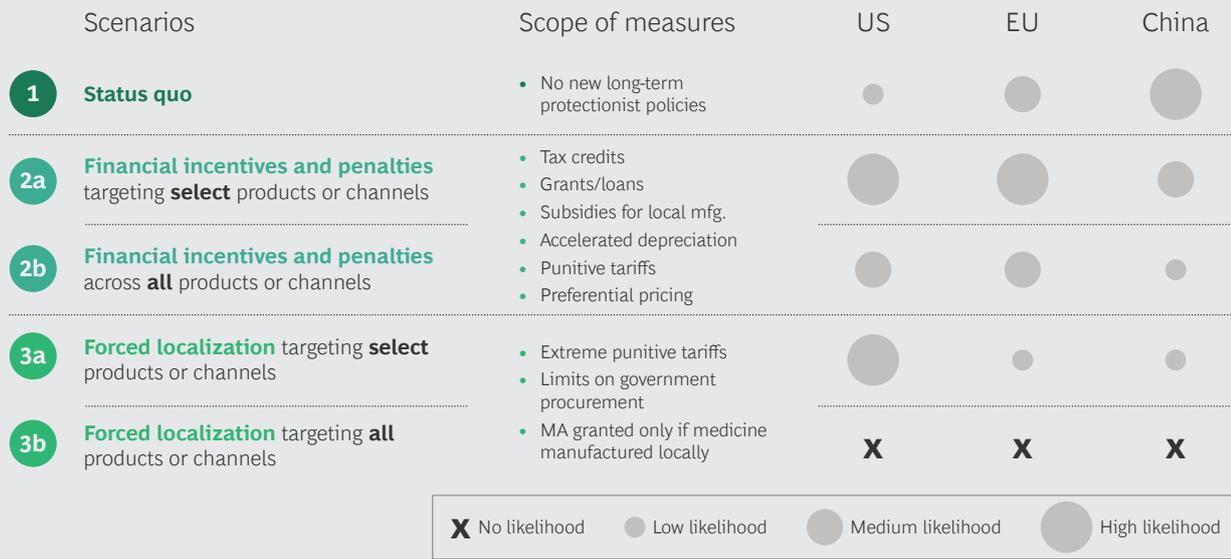


Sources: IHS Markit / Global Trade Atlas for 2009–2019; API IHS codes; select HS6 codes; BCG analysis.

Note: Figures are rounded.

¹Figures represent trade volumes between selected geographies only, calculated on reported imports for countries. Figures exclude intra-region trade.

EXHIBIT 2 | Significant Protectionist Policies Are Less likely Than Small, Targeted Measures



Source: BCG analysis.

Notes: Status quo in China means continuation of reforms. Extreme = >100% of declared value.

mance indicators are most relevant in measuring resilience and then evaluate each product in their portfolio accordingly. Days of inventory on hand and the availability of backup supply might be the metrics of choice for a biopharma company that produces oncology medications, while the mix of insourcing and outsourcing might be important for a medtech company that manufactures test kits.

Evaluate performance and assess risks.

Once these resilience objectives are clear, firms should evaluate each product or product segment to determine if it currently meets the established targets. Any products or segments that fall short need to be assessed in detail, taking two factors into account. The first is impetus to change—the company’s incentive to adapt, driven by the likelihood and magnitude of risk that network disruptions pose to supply. The second factor is the ease of adjustment, a measure of difficulty in reshaping supply chains that is based on cost, lead time, or other barriers.

- **Impetus to Change.** Companies can use a variety of measures to evaluate

the impetus to change, including how critical the product is for world health and whether its relative contribution to company revenue is significant. Given the criticality of their products, the risk of protectionist measures, and the complexity of their supply chains, biopharma and medtech companies overall have a higher impetus to change than companies in other industries. Yet there is substantial variation within the two sectors. For instance, impetus to change is generally higher for small-molecule drugs than it is for biologics. The former are commonly sourced from China and India, and supply shortages may lead directly to loss of market share. In contrast, biologics are typically sourced from many regions and are less at risk for market share loss because of their patent protection.

- **Ease of Adjustment.** This factor includes the financial capital needed to adjust the manufacturing footprint; the additional production capabilities that must be developed; and the size of the regulatory workload and the regulatory

and supply risk associated with shifting a supply source. Adjusting the supply chain for implantable devices, for example, would be far more difficult than for consumable products such as gloves or syringes because the regulatory workload and risk would be much greater for implantables.

Taken together, the impetus to change and ease of adjustment provide a good sense of the types of adjustments companies should make to improve the resilience of any given supply chain.

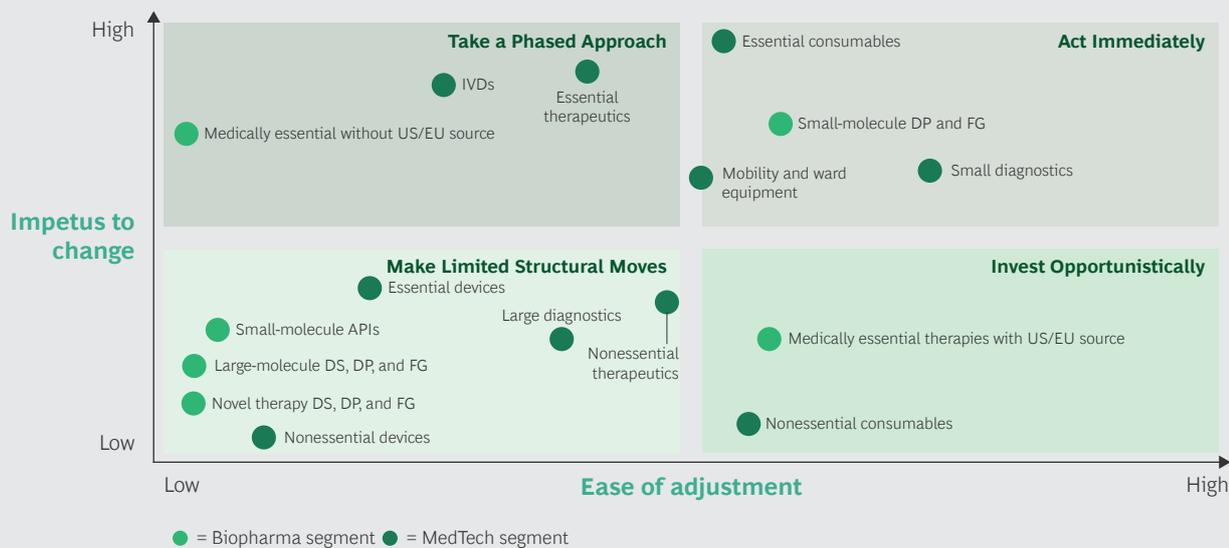
The supply chains of different product segments fall into four basic “response” categories based on the amount of risk and effort involved. (See Exhibit 3.) Companies should focus their attention on the segments where the risk is high.

- **High Impetus to Change and Ease of Adjustment.** Supply chains in this quadrant should be addressed immediately because they are more vulnerable to substantive supply disruption and are inexpensive to fix. Once such an area is identified, companies should make the required adjustments at once.

Take, for example, medtech companies that produce essential consumables like gloves and syringes. At present, these firms rely significantly on global supply chains. Since production is highly automated, it is relatively easy to stockpile products in preparation for future events. At the same time, regulatory barriers for these products are fairly low in most parts of the world and manufacturing is relatively un-specialized. Firms can take steps to distribute production across different suppliers and regions with an eye to building resilience in the medium and long term.

- **High Impetus to Change and Low Ease of Adjustment.** The manufacture of products in this quadrant may rely on a single source of materials or contend with other disruption risks, while also being expensive or otherwise very difficult to relocate. For these reasons, companies should take a phased approach—immediately taking whatever actions are easy to implement while putting the pieces in place that will build long-term resilience. For example, biopharma manufacturers

EXHIBIT 3 | The Response Options Vary for Each Biopharma and Medtech Segment



Source: BCG analysis.

Notes: Within segments, ease of adjustment will depend on the complexity of the technology. API = active pharmaceutical ingredients; DS = drug substances; DP = drug products; FG = finished goods.

of medically essential products that depend on active pharmaceutical ingredient (API) suppliers based outside the US or Western Europe should consider stockpiling inventory at each production step in the near term. They should also make sure that robust crisis response plans are in place at their key facilities. At the same time, these companies should evaluate options for resilience that are consistent with other network strategy goals for the long term, such as qualified alternative production sites or backup suppliers.

It's important to note that while generalizations can be made based on product type, companies should use the specifics of their own product portfolio and supply chains to develop a custom version of this matrix. They should then focus on addressing the two high-impetus categories. While the actions required will likely vary from firm to firm, they may vary even within a given firm. That's because the inherent risk and risk tolerance could differ from supply chain to supply chain.

Evaluate supply chain design options. To evaluate the potential options they've uncovered, companies need to model their networks in both the current and potential new configurations to see how they perform under different conditions.

Both day-to-day operations and several stress-inducing events, including ones with potentially extreme impacts, should be considered. Many different types of stresses should be modeled—from legislation that incentivizes local production of a particular product to a key contract manufacturer going out of business. Digital network optimization tools (such as digital twins) can be used to simplify this step and simultaneously evaluate performance on additional metrics such as cost, supply, and resilience.

Build a resilience roadmap. Understanding multiple risk-based scenarios can help companies determine the most appropriate levers for both mitigating supply chain risks and responding to disruptions when

they occur. The option set should include revising inventory and distribution strategies, diversifying the supplier base, moving production steps across internal sites, and leveraging CMOs with sophisticated manufacturing processes.

Companies should aim to assess each action on its potential value relative to its cost. Each decision should be made not in a silo but as part of an optimized portfolio of actions, with the particular product type, characteristics of the existing supply network, and level of risk tolerance taken into account. (See the sidebar, "One Biopharma Company's Resilience Strategy.")

The degree of change required will vary based on a firm's starting point. For example, companies that already have strategically qualified suppliers in different geographic regions may be better positioned to quickly respond to supply disruptions, while companies with a supplier base concentrated in one region may face a longer road to resiliency.

How to Augment Resilience Efforts

Regardless of the changes that companies decide to make to their structural network, building capabilities in three related areas can supplement these efforts.

Create E2E supply chain transparency. Real-time visibility across the full supply chain at an adequate level of granularity is critical for a robust view of supply risk. Today, many companies do not provide the level of visibility needed by decision makers and many are lagging in developing control tower capabilities. Creating supply dashboards will provide a real-time view of the physical flows from tier 1, 2, and 3 suppliers and across internal networks. Optimally, it's also possible to get information on supplier inventories and manufacturing performance. Original equipment manufacturers can use this level of detail to proactively change where they source materials and potentially shift between internal and external manufacturing sites where feasible.

ONE BIOPHARMA COMPANY'S RESILIENCE STRATEGY

Supply chain executives at a branded biopharma company with a broad portfolio of patented drugs evaluated the manufacturing network to identify where there was risk of disruption. They identified one plant where the risk and the potential impacts were too high to be managed with strategic inventory reserves alone. Given that the supply of several high-value biologic products was at stake, it was critical to address the issue.

The company developed a three-pronged risk-mitigation strategy.

- **A crisis response plan** was put in place for the at-risk facility to minimize overall downtime in the event of a disruption.
- **Flexible manufacturing capacity** was reserved at another internal site. That backup plant was to be kept “warm” so that it could provide

additional capacity in the event of a supply outage. This agreement was supplemented with cross-jurisdictional agreements that would allow the facility to borrow staff from other facilities in the event of an emergency.

- **Strategic partnerships** were made with various contract manufacturers so that the company could rapidly ramp up external manufacturing when needed.

The value of the new resilience strategy soon became clear. When a natural disaster reduced the at-risk plant's capacity, the facility was able to maintain supply by relying on its strategic inventory reserves. The crisis response plan brought the facility back online faster than plants belonging to other companies in the same geography—and the backup facility was not ultimately needed.

Boost regulatory insights and involvement. Biopharma and medtech companies operate in a highly regulated environment where the impact of new legislation may have long-term consequences. As a starting point, companies should incorporate current and potential regulatory changes into scenario planning. Going a step further, they can proactively participate in, and potentially influence, regulatory discussions that could affect their supply chains. For example, companies can respond to “public notice and comment” periods and provide data-based perspectives on the feasibility of proposed regulatory changes and their potential impact on the industry and patients. Such actions can go a long way toward building understanding of the enormous complexity of health care supply chains.

Upskill the workforce. Key supply chain personnel—including demand and supply planners, manufacturing line schedulers, long-term network capacity planning, and procurement managers—need to understand the potential impacts of different types of supply shocks so they can develop agile response plans when a crisis occurs.

THE COVID-19 PANDEMIC has highlighted the supply chain vulnerabilities that biopharma and medtech companies face today. But it's unlikely to be the last event to cause disruptions of this magnitude. To be prepared for such crises, operations leaders need to proactively develop scenario-based resilience plans. Traditional approaches to supply chain management will no longer suffice.

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