Risks and resiliency in the drug supply chain
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COVID-19 accelerating risks

The pharmaceutical value chain is made up of many connected components that have been significantly decentralized and optimized to reduce the cost of production and distribution. The COVID-19 pandemic has further exposed the potential for disruption to the supply chain on which this model relies. While it is too early to tell whether there will be even further shortages of medications, supplies and equipment needed to treat the growing demand due to the pandemic, it is essential for pharma executives to understand where potential points of failure are and what dependencies exist in the value chain beyond manufacturing. It is also critical for pharmaceutical companies to revisit the design of their value chain, evaluating each step to see where there is potential for failure and to determine where more flexibility needs to be built in.

The following considerations prioritize the most critical areas that should be reviewed (by industry, regulators and other key stakeholders) for a resilient and reliable drug value chain that is facing unprecedented pressures and disruptions.
Supply risks

There are several key components involved in manufacturing and packaging any drug. Companies should review the areas where supplies of these components are subject to disruption.

Active pharmaceutical ingredients (APIs):
Raw materials, including chemical building blocks, regulatory starting materials and chemical intermediates are critical components needed for manufacturing APIs. All drug manufacturers rely on access to safe APIs to manufacture their product. APIs are largely synthesized, fermented, extracted or isolated in countries outside the US before they are packaged and exported.

Formulated drug products:
APIs and excipients (which are inactive substances serving as the vehicle or medium for a drug) are formulated into bulk capsules, tablets and other semifinished product forms. They are typically manufactured in a geographic region nearer to their ultimate end market. Still, it is not uncommon for bulk products and even some fully finished and packaged products to be manufactured in other countries and exported to the US.

Packaging and labeling:
Beyond the active ingredients and excipients that are necessary for the production and distribution of drugs is packaging, often made outside the US. Packaging and labels rely on components like resin-based bottles and films, paper cartons and labels, stainless steel needles and other materials required to safely contain, transport and administer medication. National lockdowns in key export countries may occur sporadically and intermittently and are likely to contribute to risks of inconsistently reliable supply.

Pharmaceutical supply chain: areas of potential disruption and interruption

- Disruption of any of the connected components in the pharmaceutical supply chain can lead to potential drug delays.
- Manufacturer reliance on sporadic raw material supplies for drug APIs, excipients and formulation, as well as packaging and labeling, can cause production and supply bottlenecks.
Short-term drug supply constraints

Even after the various components are combined to create the finished drugs, there can still be disruptions to the distribution of those drugs. Several indicators point to a potential short-term shortage of certain drugs because of temporary lockdowns of manufacturing plants and delays or suspension of international shipments. Further contributing to disruptions are border restrictions and suspensions on air cargo carriers. The sporadic and continued flare-ups of infections, increasing numbers of patients on ventilators and the high demand for ventilator-related drugs are contributing to short-term supply shortages. Drug shortages seen so far are mostly for products used for COVID-19 patients in ICUs or on ventilators. Some of the shortages are artificial and a result of stockpiling, protectionist trade restrictions or lack of enough inventory.

Operations risks

Risks and delays may occur due to critical-employee absenteeism, plant capacity constraints, production limits, distribution and transportation (domestic and cross-border) issues, shipping capacity (inbound container and maritime shipping volumes) and increased inspections or quarantines. Changes in personnel work shifts to reduce the number of people in the facility at any given time may translate to reduced output. There is also evidence that capacity within parts of certain supply chains, such as cold chain storage, is becoming constrained as more companies try to increase inventory to offset the unprecedented fluctuations in the demand signals for products. Over the longer term, capital projects that were aimed at increasing capacity or are necessary for new product introductions may be halted, delayed or only slowly implemented.
Regulatory risks

Facility inspection delays for new products, generics and biosimilar applications could lead to longer approval timelines, extending the time it takes for critical new therapies and lower-cost alternatives to reach consumers. Additionally, intensified inspection efforts following importation could further delay drugs reaching patients in need. Assessing the full breadth of regulatory impacts on facilities across the drug portfolio will inform what strategic planning is necessary for the post-pandemic environment.

ANDA approval process

An abbreviated new drug application (ANDA) is an application for a US generic drug approval for an existing licensed medication or approved drug. The ANDA is submitted to the Food and Drug Administration, which provides for the review and ultimate approval of a generic drug product.

12–18 months

- Facility inspection delays for new products, generics and biosimilar applications could lead to longer approval timelines, extending the time it takes for critical new therapies and lower-cost alternatives to reach consumers.
- Intensified inspection efforts following importation could further delay drugs from reaching patients in need.

Assessing the breadth of regulatory impacts on facilities across drug portfolio will inform what strategic planning is needed for post-pandemic environment.
Geopolitical risks

Even if organizations can work around structural vulnerabilities, the influence of geopolitical factors is complex and very difficult to predict. For instance, COVID-19 has exacerbated US-China tensions, eclipsing the positive messages and economic benefits from the “Phase 1” trade deal that was agreed to in January. This has further added another thread to the expanding narrative of superpower rivalry, increasing the level of geopolitical risk faced by companies that have operations in both countries.

A key geopolitical risk for pharmaceutical companies in the COVID-19 era is shifting trade policies. Governments have quickly closed borders in a rush to reinforce notions of national security. COVID-19 could escalate nationalist and populist sentiments, as people embrace “buy national” attitudes. Post-COVID-19, these sentiments may propel some governments to impose new restrictions on the movement of people, goods and technologies. They may also mandate onshore R&D, manufacturing and stockpiling of pharmaceuticals, medical gear such as ventilators and test systems, and personal protective equipment.

Policy responses to the pandemic are therefore highlighting supply chain risks – especially if a firm is dependent on a single supplier or country. Supply bottlenecks and, in some cases, export restrictions have exacerbated supply chain pressures, which in turn will cause firms to re-examine long and vulnerable supply chains. COVID-19 is therefore likely to ramp up “China-plus-one” strategies, which allow companies in China to diversify their operations by adding another location in Asia, as well as other supply chain diversification efforts. Developing more resilient supply chains will be a business imperative and, for pharmaceuticals, likely will be mandated by governments.
Implications for pharma

In the short term, there may be an increased risk to the generic drug supply chain. Generic drug companies have greater sensitivity to supply chain risk, as their profit margins are generally lower than those of branded companies; generic companies also depend more on India and China for their supply chain and often maintain less safety stock than their peers that primarily manufacture branded drugs. Additionally, API costs represent a larger portion of revenues for generic companies, so cost increases due to shortages would hit them harder.

There is less risk for pharma companies making branded products, as they have at least several months of safety stock in APIs, finished products and products in the distribution channel. Additionally, given the economic model of branded pharma products, even an unexpected increase in the price of APIs would not likely have a material impact on the business.

Though many pharmaceutical companies have sophisticated models in place for their manufacturing and supply chains, the pandemic should be used as an opportunity to consider the following questions:

1. Do we need redundancy to pivot to a secondary supplier in a different location?

2. What if significant events like a pandemic are not a “less than zero” probability?

3. What should the new model look like? Do we need to turn it on its head or just refine it to bolt on additional measures of security to reduce the short-term impact and address future risk?

Implications of COVID-19 on pharma

Companies need to rethink whether current models can manage risks associated with low-probability and high-impact events.

Generic drug manufacturers face more risks from pandemics such as COVID-19 owing to lower profit margins, higher dependence on other countries for supply chain and higher impact of API shortages.
Taking action

While each product has a unique supply chain, the following is a list of things to consider in value chain modeling during and after the pandemic:

1. Evaluate each step of the current value and supply chain to identify potential weak links, risks and failure points; include an objective assessment of the reliability and health of dependent organizations and process dependencies.

2. Establish inventory adjustments, based on fluctuating demand scenarios.

3. Determine access to raw materials being held with suppliers (and their suppliers).

4. Assess existing relationships and reliance on external partners or suppliers.

5. Determine whether opportunity exists to diversify or create capacity redundancy in the event of business interruption.

6. Develop dynamic financial models to enable more iterations for financial models, projections and forecasts; assess lost revenue vs. cost of capital/holding inventory.

7. Redesign the model to include redundancies, backup plans and new contracted partnerships (public/private) that can be activated immediately.

8. Include past and potential geopolitical actions in the risk assessment and assign a score both to the probability and impact to the business.

9. Diversify reliance on global sources and revisit service-level and performance guarantees to include requirements for backup and business continuity plans.

10. Evaluate the potential for long-term partnerships, leveraging current collaboration opportunities.
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