

A Complex Global Network: Safely Managing the Supply Chain

► From logistics to storage to tracking and more, the pharmaceutical supply chain is one of the most complex distribution systems of any industry.

Most companies lack the efficiencies and equipment needed to deal with the diversity of products in the complex pharmaceutical supply chain. According to a PwC report, pharmaceutical companies will need to rethink their supply chain approach to address a variety of issues. They must deal with products that often have short product lifecycles, such as bioengineered vaccines and biologics. They must find ways to address the needs of emerging markets. They must deal with more regulatory and public scrutiny. And they must find new ways to assess and monitor their medicines in a tough global environment, including dealing with problems around counterfeiting and product fraud.

Protecting the supply chain against counterfeiting, remaining in regulatory compliance, and ensuring timely delivery requires strong coordination.

Dealing with Counterfeits

Perhaps one of the most onerous issues for the industry is dealing with drug counterfeiting. The Pharmaceutical Security Institute has collected information on counterfeiting, diversion, and theft of medicines for 17 years. The PSI recorded 4,405 pharmaceutical crime incidents in 2018, an increase of 25% from 2017.

To deal with this problem, the FDA created the Drug Supply Chain Security Act to protect consumers from counterfeit drugs. In Europe, the Falsified Medicines Directive became law in February 2019, requiring manufacturers to include unique identifiers and an anti-tampering device on all their products and report any suspected falsification. Internationally, the Global Traceability Standard for Healthcare (GTSH) sets out the minimum requirements for all stakeholders involved in the healthcare supply chain internationally.

To address these serious problems, pharma companies need clear and up-to-date oversight of their suppliers and highly efficient processes. These include data about their suppliers — are they stable, financially solvent, and compliant and registered with the authorities. It's also important that manufacturers work

with regulators, industry bodies, and global agencies such as WHO and Interpol to address fraudulent activity.

Technology such as bar coding and RFID can help to identify the authenticity of a product. Another layer of security is having verification checks at various points in the supply chain — from raw materials, once products are blended, when doses are filled, during packaging, when they arrive at distribution centers, as well as at the customs port of entry.

A Changing Environment

According to PwC, there are four options for pharma companies in managing the supply chain. For developers of specialist medicines, the option is to either use contractors to manage their manufacturing and distribution or

build their own service-oriented supply chains. For makers of mass-market products, the way forward is to become a low-cost provider or build supply chains to service internal needs and external customers, the report states.

The changing marketplace will affect the supply chain, experts note. For example, personalized medicines create more complex manufacturing and distribution processes. Personalization also affects the delivery of care with a shift away from health being managed in hospitals and clinics to increased use of community carers. This means the supply chain will have to take into account wider distribution networks to ensure medicines are delivered without incurring higher costs.

In addition, as the regulators move more and more toward granting conditional licenses, requiring ongoing testing of various populations to determine safety and efficacy,

The 7 Pressures Forcing Industry to Reinvent the Supply Chain

1) New product types

- a. More complex manufacturing and distribution processes
- b. Different supply chains for different product types
- c. Shorter product lifecycles

2) Live licensing

- a. Incremental launch of new medicines
- b. Ability to scale up and down very rapidly
- c. Step changes in the revenue curve

3) Emphasis on outcomes

- a. Expansion into health management service
- b. Leaner and more adaptable cost structure that preserves gross margins at every stage of the product lifecycle

4) New modes of healthcare delivery

- a. The blurring boundaries between primary and acute care
- b. A wider distribution network
- c. Demand-driven manufacturing and distribution processes

5) The importance of emerging markets

- a. New offerings aimed at patients in these markets
- b. More widely dispersed and robust supply chain

6) Increased public scrutiny

- a. More regulation
- b. Robust risk assessment and risk-management capabilities

7) Environmental pressures

- a. Sustainable eco-friendly processes
- b. Relocation of plant to less vulnerable regions

Source: Pharma 2020: Supplying the future. Which path will you take? PwC

product launch will become more phased. That in turn means the supply chain will need to adapt as the license alters.

Emerging markets create different challenges for the supply chain. Companies will need to adjust to the needs of patients in these countries and ensure their supply chain can deal with greater geographic reach and increased problems around counterfeiting and theft of medicines.

Blockchain and the Supply Chain

One technology that is emerging as an important tool in the supply chain is blockchain. Uses can include:

- ▶ Ensuring the authenticity of returned drugs. A portion of drugs are returned to the manufacturer due to unsold stock. In order to re-sell these products, companies must determine they are authentic. One way to do this is to have serial numbers on

the package on a blockchain, creating a distributed ledger that can be verified as authentic.

- ▶ Dealing with counterfeits. By recording transactions on a blockchain as drugs move through the supply chain, companies have a distributed provenance ledger that allows all stakeholders to track drugs across the supply chain life cycle.
- ▶ Cold chain monitoring. Blockchain can be used to ensure products are stored as required – based on temperature, humidity, vibration, and environmental conditions. Since the record is tamper-proof, anything that deviates from the required conditions can immediately be seen by each member of the blockchain.
- ▶ Ensuring compliance across the value chain. Logistics companies follow drug handling, storage, and transport requirements, and one trusted way to ensure this is carried out is using blockchain to manage compliance and governance. That's because blockchain is a transparent and immutable record.

- ▶ Transparency in clinical trials. Blockchain solutions ensure data integrity and reproducibility across the clinical trial process — from protocol setup and registration, to enrolment, data collection, data analysis, report development, and publishing of results. It can be deployed to empower patients to share their data with care providers and with researchers. It can also be used to improve adherence to reporting requirements, such as posting data collected to a registry. And it can assist with interaction between researchers and oversight bodies, such as ethics boards.

The changes facing pharma companies will have a huge impact on the supply chain. Tapping into technologies such as blockchain for data integrity, cloud to enable data to be shared securely and cost-effectively across global suppliers, and tracking technologies such as barcodes and RFID, will be key to protecting the supply chain, and consequently the company's bottom line. ^{PV}

EXECUTIVE VIEWPOINTS



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Minimizing Risk

Minimizing risk in the supply chain not only enables companies to reduce and prevent financial loss, it can also help protect their brand and reputation. Companies make significant investments in building their brands, but if they experience ongoing issues with damaged or lost products, it may negatively impact how customers regard them. One of the best ways to reduce corporate exposure is to look for ways to minimize the number of product touches in the supply chain, which in turn can reduce potential risk and increase the predictability for success. By carefully examining the various risk scenarios on the product journey from point A to point B and developing and testing contingency plans for each

scenario, companies can ensure they are appropriately prepared for an unexpected disruption in the supply chain.

Real-World Blockchain Applications

While I'm not a blockchain expert, it is clear we need to drive broader awareness and understanding of how blockchain works and define the real-world applications within our industry. We also need blockchain solution providers to come together to align on operating standards to drive interoperability. Getting competitors to work together for the greater good of the industry may be one of the most significant obstacles to success.



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Securing the Supply Chain

Establishing an integrated supply chain operation ensures a secure, responsive,

and streamlined pathway for product distribution. A single, independent partner aligned to the manufacturer's needs, enabled by technology, and focused on transparent communication can provide innovative solutions that safeguard the company throughout the supply chain on a product-by-product basis. Combined with continuous regulatory supervision, comprehensive serialization solutions and optimized processes, manufacturers can ensure product authenticity and integrity.

Analyzing the Risk

Corporate exposure directly impacts the overall value of the brand in the eyes of the public and stakeholders. To minimize exposure, corporations need to conduct a risk assessment analysis and develop a business continuity management program across the entire enterprise. Supply chain as a key function of many businesses should then holistically create value by deploying safeguards around the four main areas of risk: quality, compliance, financial, and service.