What a Global Pandemic Taught Us About the Pharmaceutical Supply Chain

As global supply chains strained under the pressure of intense demand and thinning resources created by the COVID-19 pandemic, both the public and private sectors had to think quickly and creatively about how to preserve the pharmaceutical supply chain. Along the way, we learned many lessons.

Over the last several decades, the pharmaceutical supply chain has become increasingly complex. To be successful, it relies heavily on global trade and international logistics. The COVID-19 pandemic highlighted some of the inherent strengths of the pharmaceutical supply chain but also exposed some of its weaknesses.

It has been said that experience is a hard teacher because it gives the test first, the lesson afterwards.[1] The events of the last year and a half provide evidence to support this notion.

How the Pandemic Changed the Regulatory Landscape

Looking back on 2020, it is hard to believe how quickly the regulatory landscape can change when faced with a global threat. It is no secret that regulatory change is usually a slow and tedious process. Even the slightest amendment or procedural adjustment can take months, if not years, of fleshing out, drafting and submitting through rounds of approvals before it can finally pass. However, the COVID-19 pandemic forced governments to discover a new capacity for regulatory decisiveness and swift action: a muscle they have always possessed but found difficult to flex.

Trade Facilitation

When it became apparent early in the pandemic that PPEs were in dangerously short supply, the World Customs Organization (WCO) strongly urged international customs administrations to facilitate the clearance not only of COVID relief goods, but goods in general, to help minimise the overall impact to the global supply chain.[2] The U.S. and other countries quickly reacted by amending and or simplifying import and export rules to allow for faster global distribution of relief goods.

In the U.S., for example, Customs and Border Protection (CBP) did a remarkable job of providing the trade community with resources to help expedite the import clearance of PPE. The agency created a CPB COVID-19 Updates and Announcements page on its website to guide importers and customs brokers on what they could do to ensure the timely release of PPEs and other relief goods.[3] In turn, CBP prioritised the processing of COVID-related import shipments. Many other countries also implemented similar procedures to facilitate trade.

Regulatory Flexibility

The pandemic also forced public health agencies to embrace regulatory flexibility. Public health officials mobilised to expedite the regulatory approval and import admissibility, even if only temporarily, of relief products such as PPE and medical devices to address national shortages.

U.S. FDA, for example, invoked its Emergency Use Authorization (EUA) authority and enforcement discretion policies to lift some of the restrictions that apply to the manufacture, approval and import of specific PPE and medical devices.[4] The agency also provided outreach to support the trade community and help clarify the import requirements that apply to these products.

This additional support from customs administrations and public health regulators was vital for many companies relying heavily on sourcing PPE and other relief goods from around the world to meet demands.

International trade was not the only area to implement regulatory flexibility. Regulators such as the FDA and European Medicines Agency (EMA) also advanced what the EMA called “the necessary flexibility and procedural simplifications needed to maintain the integrity of the trials, to ensure the rights, safety and well-being of trial participants and the safety of clinical trial staff during this global public health crisis.”[5]

The aim was to give clinical trial sponsors the freedom to explore new avenues for continuing clinical trials during a time when government authorities were enforcing travel bans and widespread shelter-in-place orders. As a result, innovations such as patient virtual site visits and direct-to-patient (DTP) models of investigational drug distribution moved from the frontiers of clinical trial study design to become commonplace and, in many cases, the only feasible approach.

Not a Free-for-all

While customs organisations and public health regulators were committed to facilitating trade and limiting regulatory barriers, they also clarified that flexibility did not mean a free-for-all approach to placing products on the market.

Soon after the initial efforts to liberate trade, country officials began to reel in some of the slack and scrutinise COVID-related supplies more closely to avoid the introduction of unsafe products into the supply chain. For example, by May of 2020, the EU reminded the trade community that PPEs placed on the EU market must comply with PPE Regulation (EU) 2016/425 even when imported for COVID-19 relief.[6] Here again, many other countries followed suit and issued similar announcements and enforcement policies.

The regulatory changes continued well into 2021. As production of COVID-19 vaccines ramped up and global distribution loomed near, the EU Commission announced its intention to monitor the export of certain COVID vaccines and related materials. The commission would require EU countries to authorise the export of vaccines and associated materials manufactured under the EU Advance Purchase Agreement (APA): a European Commission programme that financed part of the upfront costs faced by vaccine producers in the form of funding in return for the right to buy a specified number of vaccine doses.[7]

The new export authorisation rule went into effect on January 29, 2021 and remains in force until June 30, 2021.

The pandemic taught the trade community that commerce and regulatory policies can be elastic when necessary but that at some point, that elasticity must rebound. Trade regulations often shift and move in response to local and global pressures, so businesses involved in international trade must be ready to traverse the changing regulatory currents.

Many companies learned that having a solid trade and regulatory team or department can mean the difference between navigating the storms of regulatory uncertainty or capsizing in their turbulent waves.

Logistical Challenges
One cannot understate COVID-19's impact on global supply chains. Soon after the pandemic reached critical mass, many industries struggled as supply lanes became anaemic under pressure. The pharmaceutical supply chain was no exception.

Travel bans, strained resources and a dwindling workforce threatened to put a chokehold on pharmaceutical and clinical supply distribution channels that have historically relied on well-established intermodal transport routes. Logistics companies, the pharmaceutical industry and regulators all had to think and act fast to find solutions.

Logistics companies found ways to do more with fewer resources while ensuring the safety and wellbeing of personnel. The pharmaceutical industry embraced alternative and often costly transport methods to maintain the supply chain. For example, when commercial flight cargo capacity began to evaporate, several companies switched to private charter aircraft, which came at a premium, but ultimately prevented critical drug supply shortages.

Civil aviation regulators also played an important role. When commercial airlines reeled from the sudden decline in passenger travel, the Federal Aviation Administration (FAA) responded by allowing airlines to remove passenger seats from aircraft to accommodate more cargo transport capacity;[8] a move that would simultaneously increase the bandwidth of cargo flight options and provide airlines with much-needed support during an unprecedented economic downturn.

Maintaining Quality
This collaborative effort to find novel solutions to supply chain disruptions, while laudable and necessary, did create some risks. While pharmaceutical companies rapidly pivoted to adopt alternative shipping and product storage arrangements, it was also incumbent upon them to ensure that their quality systems were robust enough to safeguard the integrity of products.

EU regulators reminded the industry that any alternate shipping and storage methods for pharmaceutical products must comply with Good Manufacturing Practices (GMP) and particularly EU GMP Annex 13 for the distribution of investigational medicinal products.[9]

To meet these new regulatory demands, pharmaceutical companies closely examined their quality system to ensure it could and would cope with their new distribution models. They also had to confirm that their supply chain partners had quality systems that were equally robust and up to the challenge. Companies that had previously invested in quality-driven trade and global logistics strategies were uniquely equipped to face this new global threat.

Transport Security

Maintaining quality was not the only challenge faced by the industry. As global vaccine distribution commenced, transport security became a significant concern. Supply chain security has always been an essential part of worldwide trade and indeed the pharmaceutical supply chain. However, because of the pandemic, the stakes were higher than ever.

The International Air Transport Association (IATA), with the support of other organisations such as the International Civil Aviation Organization (ICAO), WCO, WTO and World Bank, to name a few, published guidance in which quality and security of vaccines and pharmaceutical products were central themes.[10] The guidance emphasised that vaccines are highly valuable commodities, so risk assessments should be performed to determine vulnerabilities and threats in the supply chain.

Pharmaceutical companies had to coordinate quickly and carefully with their logistics service providers to ensure that transport lanes were secure. In several countries, even national and local law enforcement became directly involved in protecting vaccine transport by offering armed escorts and surveillance. In the U.S., for example, U.S. Marshals protected COVID-19 vaccines as they travelled throughout the country.[11]

Where We Go From Here

The challenges faced in the last year and a half will change how both the public and private sectors think about the global pharmaceutical supply chain for many years to come.

The pharmaceutical and trade community learned many lessons throughout the thick of the COVID-19 pandemic. Many of these lessons validated the merits of having a solid global logistics strategy, while others highlighted the need for better planning and disaster preparedness. As a result, many pharmaceutical companies are evaluating their supply chains and trading partners to see how they can improve disaster preparedness, security and overall quality.

Governments are also examining the COVID-19 pandemic response as a study in how to strengthen national supply chains. In fact, under the Executive Order on America's Supply Chains, the Biden administration has requested a full review of the nation's supply chains.[12] The goal is to ensure that the U.S. has more resilient supply chains that are secure and diverse and include greater domestic production, a range of supply, built-in redundancies, adequate stockpiles, safe and secure digital networks, among many other things.

As the world slowly and gleefully returns to pre-COVID normalcy and as the dust settles, one question remains: Now that we have been tested, have we learned the lesson?

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