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Supply Chain Operations

THE COVID-19 VACCINE DOWNSTREAM SUPPLY CHAIN

WHAT ARE THE CHALLENGES ?

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Introduction

The last seven months in the COVID-19 pandemic has not only revealed the importance of an efficient healthcare supply chain but also various challenges in the manufacturing, procurement and distribution of the vaccine. Efficient availability and distribution of Covid-19 vaccine has become a top priority on the agenda of Health Authorities, governments, politicians and to **all of us 8 Billion people around the world**. What are the challenges to get these vaccines manufactured and distributed? What are the temperature controlled storage requirements for warehousing and transportation? What about the production at risk? And, which country will get the vaccine the soonest? This fourth article is about the **Downstream Supply Chain Challenges.**

The Downstream Supply Chain Landscape

After the manufacture and labeling of the vaccine into a finished product, the downstream supply chain consists of a number of activities all linked to the distribution of vaccines. It starts by transporting the vaccine from manufacturer to the country of destination. This is done using airfreight to ensure product is transported quickly in temperature-controlled conditions and monitored using data monitoring devices. Once the product arrives in the destination country the vaccines are stored at a GDP compliant Distribution Center (DC) either managed by a pharmaceutical compliant 3PL or insourced at a government GDP facility. Once the vaccine has been released by the local regulatory authorities the vaccine is distributed from this DC to hospitals, clinics, pharmacies and in some cases to community locations such as retirement homes, schools, remote villages etc.

As for any pharmaceutical distribution chain all the steps are defined in the CMC (Chemistry, Manufacturing, Controls) Regulatory file and must be compliant to GDP (Good Distribution Practices), which may have different names across different geographies. Any GDP compliant distribution chain involves many licensed and specialized service providers such as forwarding agents, shipping container providers, airlines, logistics service providers, etc. All the designed processes will need to adhere to global, regional and local regulations in terms of quality processes, temperature-controls, serialization requirements, trade compliance and overall product release processes (QP/RP) and quality management to ensure product integrity and public safety.

THE CHALLENGES

Channel to Market and to Customers

T° Controlled Chain

Serialization

Quality and Release

Security and Anti-Counterfeiting

GDP and Other Country Regulations

Equitable and Timely Distribution of Vaccine

Channel to Market and to Customers

The downstream supply chain strategy is the first enabler of the distribution strategy that a manufacturer wishes to put in place. In the Covid-19 vaccine scenario, new distribution channels to market such as drive-in, external medical tents, converted medical facilities dedicated to the Coronavirus pandemic were introduced by many governments and authorities to segregate the COVID-19 patient flows from the traditional healthcare routes.

These COVID-19 testing structures may very well be considered as part of government immunisation programs. However, due to the pharmaceutical nature of vaccines these facilities in many cases will need to be reorganized into GDP compliant vaccine operations. This could create an additional challenge to set up quickly and operationalize. For example, a temperature-controlled chain for large quantities of vaccines needs to be put together quickly, taking into consideration all the safety and security features to guarantee vaccines' quality and integrity.

Moreover, the actual transportation of vaccines from the country of origin to the country/location of destination will pose a huge challenge due to complexity and scale. Suppliers of multiple potential vaccines have already started scaling up their production capacity "at risk" by joining hands with different countries and distribution partners initiating production in various geographical locations. However, in order to deliver the vaccines to all parts of the world especially to countries with limited cold-chain infrastructure, strong logistical network and air cargo freight is required. Emirates recently shipped 25 tonnes of vaccines – approximately 1.8 million doses from Milan to Brazil in specialized containers to maintain a constant temperature of 5°C.

It is currently estimated that the first round of millions of vaccines will need to be distributed in more than 200,000 pallet shipments transported in refrigerated containers such as Skycell and Envirotainers. As per the recent announcement made by IATA, at least 8,000 fully loaded air-freighters will be needed to ship the vaccines. This is going to become the largest single transport challenge ever.

Source: BBC News, 10th September 2020

T° Controlled Chain

Keeping the product at the labelled registered temperature as indicated on the pack is the most critical aspect of the whole distribution process. While most of the vaccines are required to be kept at 2° to 8°C during storage and distribution, there are mRNA-based COVID-19 vaccines from Moderna and Pfizer that would need to be kept at temperatures as low as -80°C– although these requirements might be scaled back to -20°C or higher with potentially different T° requirements for the last mile delivery and this only for a short period of time. Each hand over to a new location in the supply chain creates a potential risk to temperature excursions which need to be carefully controlled and monitored.

Given traditional distribution channels, it is already difficult to be in compliance while using normal qualified shipping lanes. The distribution of the Covid-19 vaccines will require new storage locations and new shipping routes with different final destinations where doses will be administered. These regulated activities will take time to design and operationalize. Expert resources will be needed to put in place and validate new transport lanes, shipping systems and storage locations before actual distribution takes place.

It is therefore important for government authorities to work with pharmaceutical compliant logistics service providers who bring expertise and global logistics resources to support immunisation distribution programs related to:

GDP compliant and temperature-controlled facilities and equipment for both storage and distribution.

Quality Management Systems including trained staff to efficiently handle time and temperature sensitive vaccines.

Monitoring capabilities to ensure that quality of vaccines is not compromised.

Serialization

In many countries around the world, biopharma products including vaccines need to be labelled with a unique identifier number printed directly on the packaging – typically through barcoding technology - which is registered in central databases. Serialization guarantees item-level traceability and ensures that items remain secure from potential tampering and theft. At the point of dispensing, a final check should be performed to control the authentication of the product to detect any counterfeit drug. Item level barcoding could play an important role here.

Potentially new distribution channels will have to ensure that only approved and legitimate COVID-19 vaccines are made available and dispensed. Authenticity of these vaccines must be determined throughout the supply chain. Given the high throughput volume, the only practical way to achieve this is to link these physical medicines with digital technology. Digital technology cannot only provide real-time item visibility but could also help flag any potential risks and bottlenecks pertaining to transportation, suppliers or warehousing.

Quality and Release

Another regulated activity is the overall quality management of the RP and QP releases of the biopharma products, which includes vaccines, to the markets, making sure that all the steps registered in the dossier have been fulfilled and all activities have been performed in compliance with the governing laws and regulations. End-to-end supply chain quality is a journey which needs constant and reiterated efforts to address deviations and fix changes through CAPA (Corrective Action Preventive Action) management.

Moreover, in order to release the vaccine safely, a sound end to end logistics system is required. Large global logistics service providers such as DHL, UPS, FedEx, CEVA, Schenker and Agility are establishing global network solutions around the transport of vaccines. For instance, UPS has started building two freezer farms and DHL has introduced an airfreight charter service to ensure they are ready to store and transport vaccines safely whenever it's ready.

Security and Anti-Counterfeiting

Keeping the product in a safe environment according to international standards and local regulations is critical to the whole distribution process. Using new types of distribution channels to get vaccines to the public and while manufacturers concentrate their efforts on producing large quantities of doses at risk creates new challenges. Internet purchasing and trading of vaccines is a potential weak point and could be the main point of entry into a country of counterfeited products and/or products which have not been kept at the registered and labelled conditions.

Parallel distribution channels via web-order have been used extensively during the Covid-19 crisis for the purchase of PPE type products and can also represent a high risk in the situation of vaccines to enable the cross border procurement of counterfeited medicines or diverted vaccines from their normal flows. In the situation where a large part of the population will be part of government immunization, some individuals might be keen to buy and trade on-line. This is an illegal activity but one we also see in other industries as people exploit the Covid-19 crisis for personal commercial gains. This could spark public safety concerns and "fake news".

GDP or Other Country Regulations

In many countries the distribution of vaccines like other medicines would be managed through commercial pharmaceutical companies working together with the medical authorities to ensure the vaccines are imported and distributed correctly.

The Good Distribution Practice (GDP - 2013/C 343/01) describes the minimum standards that a wholesale distributor must meet to ensure that the quality and integrity of medicines are maintained throughout the supply chain.

In the EU compliance with GDP ensures that:

- Only qualified partners and providers are involved in the distribution chain.
- medicines in the supply chain are authorized in accordance with European Union (EU) legislation;
- medicines are stored in the right conditions at all times, including during transportation;
- contamination by or of other products especially perishables is avoided;
- an adequate turnover of stored medicines takes place; and
- the right products reach the right addressee within a satisfactory time period.

The distributor should also put in place a tracing system to enable finding faulty products and an effective recall procedure.

In addition, GDP applies to the sourcing, storage and transportation of active pharmaceutical ingredients and any other ingredients used in the production of the medicines.

Equitable and Timely Distribution of Vaccine

Another major challenge in downstream supply chain of COVID-19 vaccine is equitable distribution between the developed, developing and undeveloped nations of the world. Currently, countries are trying to compete against each other for access to the supplies of any potential COVID-19 vaccine and

many developed countries such as the US and the EU have started providing heavy anticipated funding to the manufacturers to upscale their production at risk in return for guaranteed access to a specific number of doses. A number of countries have started receiving vaccines from manufacturers producing at risk in anticipation of getting approval as soon as possible from regulatory authorities around the world. This could make it difficult to get vaccines to developing and undeveloped nations and to areas of the world where it is most needed.

However, to combat this nationalistic approach, UNICEF is leading efforts to undertake the fastest and largest procurement efforts to supply COVID-19 vaccines under a new Global Access Facility called COVAX, led by Gavi, the Vaccine Alliance. To facilitate this program, 28 manufacturers with production facilities in 10 countries have shared their annual production plans for COVID-19 vaccines through 2023.

In a recent interview Henrietta Fore, UNICEF Executive Director said that, "This is an all-hands on deck partnership between governments, manufacturers and multilateral partners to continue the high-stakes fight against the COVID-19 pandemic. In our collective pursuit of a vaccine, UNICEF is leveraging its unique strengths in vaccine supply to make sure that all countries have safe, fast and equitable access to the initial doses when they are available."

CONCLUSION

The distribution steps within the downstream supply chain involve a number of steps and typically include many logistics providers across every country, region and continents to manage. It is highly complex and interconnected. Product quality may be at risk when establishing such steps under high (time) pressure. Use of GDP compliant qualified, validated and secured transport and storage locations through reputable logistics service providers is the key to ensuring public immunisation programs are successfully executed. Governments must also be vigilant to avoid counterfeited vaccines reaching the general public through unauthorized distribution channels. All these measures will help to address public concerns about immunisation and product safety.

The downstream supply chain will be constrained by vaccine availability, GDP compliant processes and logistics capacity. Once the first vaccines have been produced and released the challenge will be to prioritize the downstream volumes based on the global demand based on firm orders received from distribution partners and governments. This prioritization will be a major challenge since everybody around the world will want to receive their pre-ordered volumes first. It is important that governments around the world and the logistics industry are ready for this challenge.

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Europhia Consulting is an international management consulting company specialized in the logistics and supply chain industry in the life sciences sector. We operate global assignments for our clients. The opinions are based on the author's own experience and understanding of the dynamics within the sector.

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