Securing Suply Chain for COVID-19 Vaccine

Prepared by GS1 India

Background

We find ourselves in a time unlike any we have seen in the last 50 years. The COVID-19 virus was first named just eight short months ago; since then it has infected more than 23 million people and taken the lives of more than 800,000 worldwide.

Researchers worldwide are working around the clock to find a vaccine against SARS-CoV-2, the virus causing the COVID-19 pandemic. The Herculean effort means that a fast-tracked vaccine could come to market anywhere between April-August 2021.

Till October 2020, just two coronavirus vaccine has been approved. Sputnik V – formerly known as Gam-COVID-Vac and developed by the Gamaleya Research Institute in Moscow – was approved by the Ministry of Health of the Russian Federation. A second vaccine in Russia, EpiVacCorona, has also been granted regulatory approval. Experts have raised considerable concern about the vaccine's safety and efficacy given it has not yet entered Phase 3 clinical trials.

In India, as per ICMR reports, human clinical trials for a vaccine against SARS-CoV-2 have been initiated in the country with approximately 1,000 volunteers participating in the exercise for each of the two indigenously developed vaccine candidates.

On global front, Operation Warp Speed (OWS) has selected three vaccine candidates to fund for Phase 3 trials: Moderna's mRNA-1273, University of Oxford and AstraZeneca's AZD1222, and Pfizer and BioNTech's BNT162.
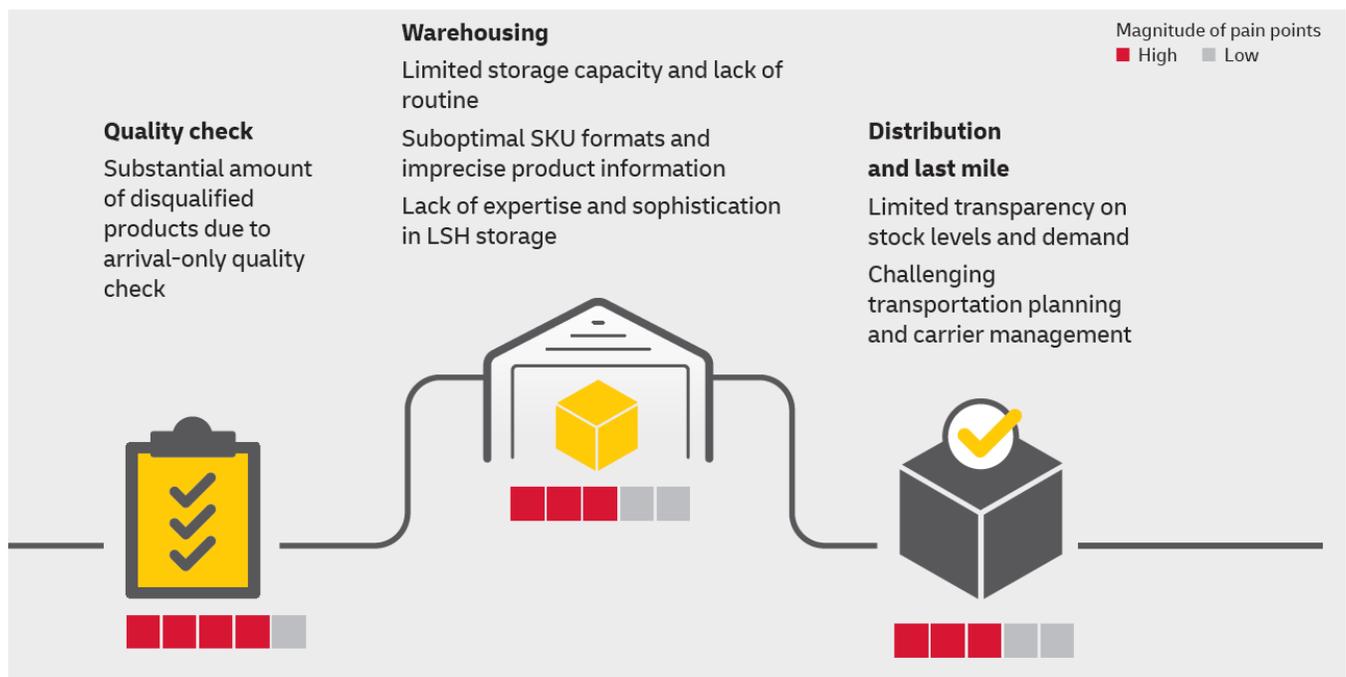
The COVAX initiative, part of the World Health Organization's (WHO) Access to COVID-19 Tools (ACT) Accelerator, is being spearheaded by the Coalition for Epidemic Preparedness Innovations (CEPI); Gavi, the Vaccine Alliance; and WHO. The goal is to work with vaccine manufacturers to offer low-cost COVID-19 vaccines to countries. Currently, CEPI's candidates from companies Inovio, Moderna, CureVac, Institut Pasteur/Merck/Themis, AstraZeneca/University of Oxford, Novavax, University of Hong Kong, Clover Biopharmaceuticals, and University of Queensland/CSL are part of the COVAX initiative. There are further candidates being evaluated in the COVAX Facility from the United States and internationally.

Challenges

As the world is gearing to ensure smooth roll out of vaccine across countries, to control the spread of SARS-CoV-2, India is lagging behind. To make matters worse, we lack infrastructure required for temperature-controlled storage and transportation of vaccines at a large scale. This adds further responsibility on State and Central health ministries, departments, regulators (CDSCO), NITI Aayog, etc., to ensure that no wastage happens.

Looking at the possible timeline vaccine hitting the market by second quarter of the next year, we need to be prepared for nation-wide roll-out. The risks of low performing supply chains are detrimental for effectiveness of vaccines, leading to risks to health and live of people, which may further impact the government's reputation and economy of the country.

Quality check
Substantial amount of disqualified products due to arrival-only quality check

Warehousing
Limited storage capacity and lack of routine
Suboptimal SKU formats and imprecise product information
Lack of expertise and sophistication in LSH storage

Distribution and last mile
Limited transparency on stock levels and demand
Challenging transportation planning and carrier management

Magnitude of pain points
■ High   ■ Low

The exact logistical requirements for transport and storage differ between different vaccines and/or technology platforms, as well as between the different supply chain steps. Nevertheless, it is important to plan ahead and understand in detail the potential temperature requirements and their implications for logistics.

Storage and transportation conditions for future COVID-19 vaccines will likely differ depending on temperature-requirement scenarios along the supply chain. Out of caution, producers of certain vaccines and their logistics providers can choose to adhere to extreme temperature requirements (as low as -80 °C) to ensure that the efficacy of the vaccines is maintained during storage and transport. These conditions are in line with the ones used for certain COVID-19 vaccine clinical trials today.

LOGISTICAL IMPLICATIONS OF COLD CHAIN REQUIREMENTS – EQUIPMENT EXAMPLE FOR A POTENTIAL SUPPLY CHAIN SETUP

Source: DHL, McKinsey

Drug substance ▼   Drug product ▼

| Intermediate transport | Intercontinental shipment | Warehouse delivery and interim storage | Downstream distribution | Short-term storage and application |

Logistical equipment

Liquid tanks | Pallet shippers with cooling packaging | Cooling warehouse | | Cooling boxes

Risk of potential bottleneck

Low ———————————————————— High

Currently, large parts of Africa, South America and Asia could not be readily supplied at scale due to lack of cold-chain logistics capacity suitable for life science products. Governments and NGOs would need to implement special measures to ensure vaccine distribution. Capacity would have to be increased and scaled in order to reach the global population.

Executing the last mile in line with conventional transportation requirements (assuming sufficient shelf life at +2–8°C) is much more feasible; it allows for a more efficient distribution to end users globally since transport can rely on available capabilities and capacities, as well as prior experience and knowledge. Scale at which all this is required would need alliance with various third parties. However, leaving it completely on regions which we know do not have this infrastructure and expertise, can prove fatal to the lives and reputation of the brand.

Solution

The COVID-19 crisis emerged with such unprecedented breadth and impact that governments have been compelled to transform – away from their traditional roles as regulators (and managing the societal impacts of a health emergency), and towards the role of active players in the medical supply chain.

Lessons learned since the start of the COVID crisis have demonstrated that sufficient planning and effective partnerships with supply chain partners can be important success factors for governments looking to secure critical medical supplies during health emergencies.

Vaccines are in development, but their ability to end this pandemic depends on an effective supply chain that can connect diverse production locations to the public. To tackle this and ensure that most of the people get benefitted out of the initial limited supplies, we need to work on enhancing the effectiveness of the vaccine supply chains. One way to bring in the visibility and enhance effectiveness of supply chains is to implement IT-enabled traceability systems encompassing all supply chain stakeholders (manufacturers, distributors, stockists, chemists, hospitals, etc.). This would enable all stakeholders to capture and share consignment information to enable complete end-to-end visibility – from the point-of-manufacturing to the patient.
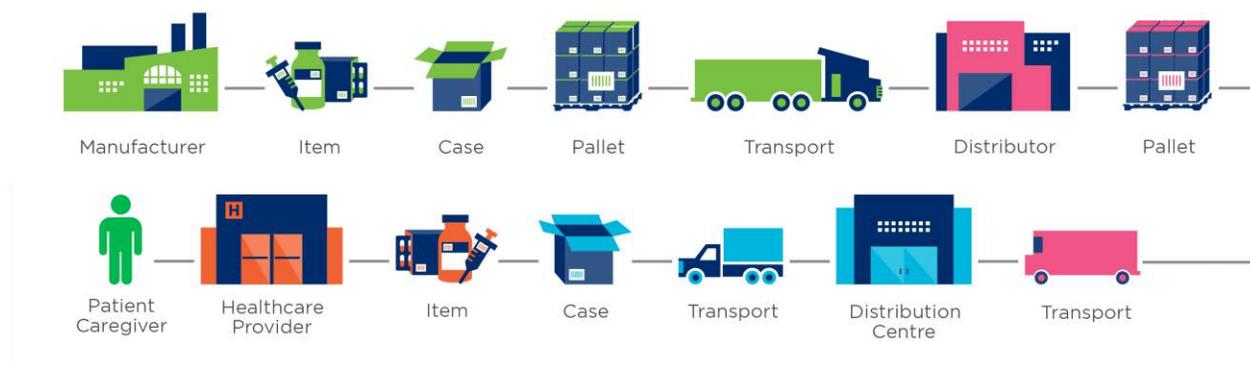
Benefits

Benefits of a multi-stakeholder traceability system in vaccine supply chain are:

- Real-time knowledge and recording of what (batch number, vaccine unit and dosage) is administered to whom (patient). This could be made possible by linking unit and dosage with digital ID / Aadhaar number.
- Ability to swift and targeted recalls, whenever required.
- Real-time knowledge of what stocks are lying where in the supply chain, from point of manufacturing to point of dispensing.
- Real-time monitoring and recording of temperature to ensure that right temperature was maintained throughout the supply chain – storage and transportation.
- Enable counterfeit detection at the point of entry in the supply chain and mitigation of risks through investigating.

Success of any immunization program depends on effectiveness as well as scalability of end-to-end supply chain system. In a large country like India, possible roll out can only happen in the staged manner. For this, a centralized portal for supply chain stakeholders to enter product details also needs to be scalable and flexible enough to cater to the needs of multiple parties.

Recommendation for traceability system

To build traceability solutions that are scalable as well as inter-operable to allow multiple stakeholders and enable trading partners can easily collaborate and share information across the entire chain. It enables end-to-end data visibility, which ensures supply chain efficiency through chain of custody and enable authentication of vaccines, as and when required.

Global standards based traceability solution (**EPCIS**) determines the ability to track vaccines through the supply chain from manufacturing unit to point of vaccination, including key information such as temperature log through the supply chain journey, expiry date, etc.

EPCIS is a GS1 & ISO (ISO/IEC 19987) open standard that helps share visibility data across and between organizations. It allows businesses to capture and share information and status of the goods.

EPCIS is used by healthcare supply chain stakeholders require to access transaction and product movement information in order to reliably document the chain of custody and ownership for supply chain security. This also facilitate inventory management, consumption history, wastage and demand forecasting, as well as being key for vaccine safety monitoring.

The four data points in an EPCIS event are:

What : **Instance level identification of individual objects (Serialized GTIN)**
When : **Date, Time, Time Zone of the event**
Where : **Place of occurrence and where are the objects thereafter**
Why : **Why did the event take place e.g. Shipping, In transit**

Examples of use from across the world

Global Regulatory authorities have also identified EPCIS-based traceability systems as a key tool to fight against falsification and illicit distribution of drugs and vaccines. WHO VPPAG (Vaccine Presentation and Packaging Advisory Group) in its recommendations released in April 2019 has mandated use of barcodes printed on secondary and tertiary levels of packaging. It requires GTIN (Unique Product Identification) along with Batch No and Expiry Date encoded in a Data Matrix format.

The Interagency Supply Chain Group (ISG) comprising of GAVI, UNDP, UNICEF, World Bank & WHO has committed to the use of EPCIS in vaccine traceability.

Recommendations for markings on product labels

To link the product information with the physical supplies, it is important to have required markings, with required information, on the product packaging. This would enable all stakeholders in the supply chains – manufacturing plant, distributor, logistics provider, transporter, stockist, etc., to capture and record the information through a scan of the barcode.

For this reasons, it is important that the markings at the product labels, at all packaging levels – mono cartons, intermediate packaging, cartons and pallets, are done by the manufacturer. This would enable complete access the complete trail of the product, whenever required and in real time. Additionally, real-time/near real-time information of stocks in the supply chain enable manufacturers to manage production better with more accurate sales forecast.

Types of packaging levels and markings required at each level

Packaging Level	Illustration	Information captured	Barcode
Mono-carton carrying Vaccine		• GTIN (unique product code • Expiry Date • Batch Number • Serial Number	(01) 0 8906000 99012 4 (17) 220731 (10) A1256568BN (21) 12548UJHGSR875 **(Data matrix)**

Intermediate Bundle pack carrying multiple Mono-cartons		(01) 0 8906000 99012 4 (17) 220731 (10) A1256568BN (21) 12548UJHGSR875 **(Data matrix)**
• GTIN (product code) • Expiry Date • Batch Number • Serial Number		
Tertiary pack or logistic unit		(00) 1 8901072 861155889 3
• SSCC (Carton code)		

The numbers written in bracket in the above table, below barcodes, are Application Identifiers. There are different application identifiers for capturing different product information, such as:

00   Serial Shipping Container Code
01   GTIN (product code)
17   Expiry Date-YYMMDD
10   Batch No

Note: To gain complete visibility, it is recommended to have aggregation data. Aggregation is defined as the parent-child mapping between different levels of packaging. The mono carton serial number will be linked to the intermediate secondary pack serial number while packaging and with tertiary pack serial number i.e. SSCC during packaging process. This would enable scanning of only tertiary barcodes and knowing what units are inside it without opening the tertiary pack. This helps in speedier dispatch and receiving of stocks at all intermediate points.

Aggregation relationship need to be made between the highest levels of packaging e.g., the pallet, shipper carton, all the way down to the Mono-carton.

Way Forward

As the world anxiously awaits the arrival of an effective COVID- 19 vaccine, there is a need to enhance the efficiency of vaccine supply chains in India to ensure that genuine vaccine are reaching to maximum people, without wastages and pilferages.

To tackle this, supply chain efficiency must be enhanced by adopting a traceability system that encompasses multiple stakeholders and enable them to capture information on dispatch and receiving of consignments through a simple scan of the barcode.

Considering the possibility of vaccine against SARS-CoV-2 hitting the market in Q2 of 2021, the process need to be initiated now to streamline the existing vaccine supply chain and supply chains of possible alliances for vaccine distribution. This is required to gain the complete visibility of stocks in the supply chain, warehouse conditions, and maintenance of required temperature, to ensure effectiveness of vaccine and enhanced brand image of the organizations.

About GS1 India

GS1 India is a global standards organization, setup in India by the Ministry of Commerce and Industries, along with apex trade organizations. It closely works with State and Central Health departments, Regulators, hospitals, pharmaceutical & medical devices manufacturers to enhance patient safety by bringing in visibility and efficiency in supply chains.

GS1 India is affiliated to GS1 Global, headquartered in Brussels, which oversees operations of 115 GS1 member organizations across the world. Over two million companies, across 25 industry sectors such as Retail, Healthcare, Transport and Logistics use GS1 standards These standards facilitate unique and universal product identification.

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