SPER NEWSLETTER

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COVID-19: PHARMA SUPPLY CHAIN SECURITY, VISIBILITY & ROBUSTNESS IN VACCINE DISTRIBUTION

"Without Strategy, Execution is Aimless. Without Execution, Strategy is useless." - Morris Chang

Even after the miraculous invention of vaccines to tackle Covid-19, the world is not ready to handle the big challenge of shipping those from the drug makers to billions of people across the globe. Working organizations need to acknowledge the serious concerns arising due to the lack of a proper supply chain and logistics facilities.

The issues are:

- Exponentially more complex than many other supply chains
- Manufacturing deals are being extended
- Facilities are getting re-established to produce the still-experimental shots
- Refrigeration

The final aim is to build a successful immunization program through continuous availability of quality vaccines from manufacturer to service-delivery state. The role of the supply chain is to manage effective vaccine storage, handling, and management of stocks, variable temperature control in cold chain and maintenance of sufficient logistics management information. This can be achieved by the six rights of supply-chain management system:



Challenges & the approach that one can use to tackle them:

1. Demand Actualization: In order to cater to a population of 1.3 billion, there is a need to start with a focused yet aggregated approach and build progressively. We need data of people residing in the community, with addresses, communication means, and demographics of the sample.

a. Demand breakdown - The approach has to be structured and in phases, bifurcate the population into, people with digital demographic records and population with incomplete and no records & devise separate strategies.

b. Demographic breakdown - To prioritize people for vaccination, it becomes important to understand the characteristics which can be comprehended by the data available digitally and the data gathered on the ground at the ward. Age groups to be categorized into, *0-10 years, 11-60 years, and 60+ years groups*.

c. **Data Collection & Analysis** - Collecting the data of the entire population digitally is a crucial process. Encourage people with incomplete and inconsistent data to create digital records and enlarge the digital sample to break down demand and relate demographics.

2. Network Planning: A robust vaccine cold chain and logistics system is the cornerstone of this immunization strategy. Rigorous supply & planning based on accurate data is necessary for the right vaccines in the right place, at the right time, in the right quantities, in the right condition. This approach involves:



3. Storage Planning: Once manufactured, the vaccines need to be stored and handled based on protocols approved by ICMR. Storage planning will not only come for vaccines just manufactured but also for the first mile, hub, spoke storage, final distribution centers, mobile vaccine plans, and also for backhaul planning. Things to consider:



Facility Monitoring

4. Transportation Planning: This caters to the planning of vaccine deliveries from DCs to Vaccine centers but also relationships between Manufacturing Plants to DCs. Transportation needs to be efficient, safe and a cost-saving factor in the entire supply chain by optimizing the leg runs in each trip. Things to consider:

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Route Optimization

Vendor Analysis

First and Last-mile delivery

channels

Transportation

Infrastructure

5. Scenario simulation: Once we have the Manufacturing plants functional, Storage capacities up and running, and transportation mode connecting nodes, distribution following demand becomes critical. Demand & general market trends are always dynamic. The advantage is that the aggregate demand is in place, on the basis of which manufacturing can be planned.

6. Execution: Execution plans are built on network planning and demands across ship points. It needs to be proactive and agile in order to make corrections. The idea is to start small and build with a quick turnaround time. Our considerations:

- Demand supply sync
- Audit teams
- Transportation leg(s) execution

7. Wastage and reverse logistics: Optimal vaccine management entails maximizing coverage through high vaccine usage while minimizing wastage. Vaccine wastage considerations: Expiry of vaccines, Heat exposure, Freezing, Breakage, Missing inventory, Theft, Suspected contamination. Formula:

Vaccine Wastage rate = (No. of doses-Population vaccinated)/No. of doses* 100 Wastage multiplication factor = 100 / (100-Vaccine wastage rate) Vaccine dosage for one round = WMF * Target coverage

Other things considered:

- Remains management
- Monitoring
- Continuous improvement

Result: Providing service to the community, boosting the economic landscape, ramping up employment opportunities, functionally integrated supply chain networks, and structuring an unorganized logistics network which eventually works towards a sustainable and self reliant India. The path is waiting for the world to win against the deadly virus but eventually, we will overcome the difficulties by the right mind-set and approach. We hope that our problems and listed solutions would help the readers gain a better insight.

ADVANCEMENTS IN DRUGS FOR COVID

NASITROL - Amcyte Pharma

- Proprietary iota-carrageenan nasal spray
- Antiviral activity and clinical efficacy as a nasal spray in the treatment of colds.
- Interacts with the virus surface, preventing virus penetration and trapping virus particles released by infected cells.
- Designed to reduce the viral load in the upper respiratory tract and prevent virus proliferation and spread to the lungs.
- Proven to be effective in reducing COVID-19 infections in ICU staff in an independent clinical study and a previous study found the formulation inhibited the SARS-CoV-2 infection that the virus causes COVID-19, in vitro.

NITRIC OXIDE NASAL SPRAY - SaNOtize

- A self-administered nitric oxide nasal spray (NONS)
- Demonstrated a substantial reduction in COVID-19 viral load in infected patients after undergoing early-stage clinical trials (Canada and the United Kingdom).
- In the first 24 hours, patients had an overall viral reduction by 95 percent.
- Viral load dropped by more than 99 percent in just 72 hours.
- No side effects recorded in the UK study or earlier Canadian trials (7,000 patients tested).

BBV154 INTRANASAL VACCINE - Bharat Biotech

- Nasal spray vaccines are safer and less expensive than IV vaccines.
- Can also be conveniently given to infants since the nasal spray activates a broad immune response while neutralizing IgG, mucosal IgA, and T cell responses.
- A novel adenovirus vectored intranasal vaccine that has cleared its first phase.
- Findings of the first phase clinical trials, which were performed on 175 people in four cities across India, were very impressive.





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2-DEOXY-D-GLUCOSE (2-DG)



- Dr Reddy's Laboratories, INMAS under DRDO

- The anti-covid drug in powder form in a sachet that must be dissolved in water before being consumed orally.
- It accumulates in virus-infected cells and stops viral synthesis and energy production, preventing virus formation.
- Shows selective accumulation in virally infected cells.
- It was observed to reduce the dependence on oxygen and assisted in a faster recovery of patients.

VIRAFIN SC - Zydus Cadila

- Type I interferons mount a rapid antiviral response that includes viral replication inhibition and innate immune defense activation. Type I IFN- α , Type I IFN- β and Type I IFN- ω are all members of the Type I IFN family.
- Early interferon treatment was linked to earlier hospital release, early symptom improvement, and a lower incidence of extended virus shedding in glucocorticoid-treated patients.

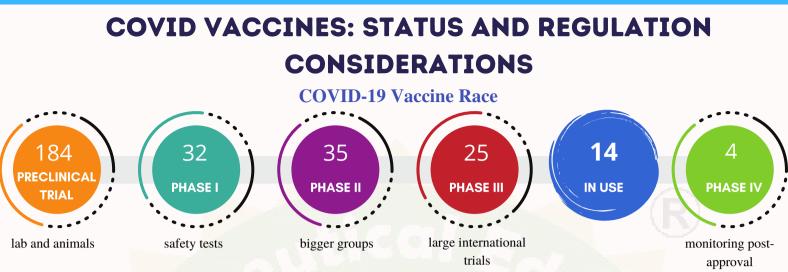


• The potency is approximately ten million times that of Remdesivir.



TOCILIZUMAB

- Conventionally, Actemra and Atlizumab.
- An immunosuppressive humanized monoclonal antibody.
- When injected intravenously, it inhibits IL-6 receptors, which are crucial cytokines that cause inflammatory storms. They can lead to alveolar-capillary blood-gas exchange dysfunction and oxygen diffusion is especially impaired, subsequently main to pulmonary fibrosis and organ failure.
- Tocilizumab can be a powerful drug appropriate to avoid this outcome for COVID-19 patients.



As of 3rd May 2021, India has been presented with three vaccine options- apart from the very well-known Oxford-AstraZeneca's Covishield (locally manufactured by the Serum Institute of India) and Bharat Biotech's Covaxin, citizens can soon opt for Russia's Sputnik V, which shows 92% protection against the virus as per the late-stage trial results, published in The Lancet. However, the Indian health ministry in its announcement informed that the first 100 recipients of the newer vaccines would be monitored for seven days before a greater rollout is sanctioned.

India Vaccine Rollout Phases

Smooth yet quick administration of Covid-19 Vaccine to the country's 1.38 billion is a herculean task faced by both the state and central ministry. Records indicate that up until 16th May 2021, more than **14.17 Cr** citizens have been vaccinated with at least the **first dose** while **4.04 Cr** people have been **fully immunized** against the virus, in which **7.46 Cr are male and 6.7 Cr are female.** This unparalleled feat would not have been possible to achieve without the relentless efforts of the country's leaders, frontline staff and a disciplined phaseal administration.

Phase 1 of Vaccination- 16th January 2021

- Part 1 one crore healthcare workers were vaccinated.
- Part 2 two crore frontline workers (security forces, municipal workers etc) were vaccinated.
- Before rolling out the vaccines, three phases of dry runs were conducted.

Phase 2 of Vaccination- 1st March 2021

- Part 1 (1st March 2021)- aimed at vaccinating elderly above the age of 60 years
- Part 2 (1st April 2021)- included vaccination of people over 45 years with comorbidities.
- 5th of April- more than 43 lakh citizens were vaccinated making it the highest single-day coverage till now.
- 8th of April- the Prime Minister called for a four-day Teeka Utsav (Vaccine Festival) from 11–14 April to increase the pace of the program. Towards the end of the Teeka Utsav, a total of over 111 million vaccine doses were administered.

Phase 3- 1st May 2021

- 28th April 2021- Registration for vaccination for adults above the age of 18 years opened through online CoWin Portal
- This scheme was able to make the highest single-day record of registering nearly 13.3 million people.
- 1st May 2021- COVID vaccination for all adults commenced throughout the country.

Regulatory affairs over Covid-19 vaccines:

National Regulatory Authorities: The National Regulatory Authorities are the regulatory agencies of a particular nation that ensure that the products released for public distribution such as vaccines are properly evaluated, tested and meet international standards of quality and safety. 6 critical control functions are to be followed by vaccine-producing countries competently and independently, backed up with enforcement power. These functions are as follows:

- a published set of requirements for licensing;
- surveillance of vaccine field performance;
- system of lot release;
- use of laboratory when needed;
- regular inspections for GMP;
- evaluation of clinical performance.



The vaccine quality is guaranteed by a documented performance of these functions according to specialized indicators. These critical control functions depend on vaccine source.

Vaccine source	License	Surveillance	Lot Release	Lab Access	GMP Inspections	Clinical Evaluation
UN agency	х	х				
Procure	х	х	х	х		
Produce	х	х	х	х	х	х



WHO can and is providing technical assistance for the development and implementation of these plans. WHO is continuing to support countries to assess the functions of NRAs.

According to the policies set by WHO, no technical or financial support for production of vaccines will be provided to facilities unless they have a functional NRA and have developed a strategy to achieve viability.

<u>What are Vaccine Indicators</u>: Three main sources of vaccines as identified in 1997 by WHO were :

- countries sourcing their vaccines through UN agencies
- countries with direct procurement
- producing countries

An assessment tool using indicators building on existing drug regulatory authorities has been developed to serve as a benchmark and to monitor progress for all countries, which is also used for prequalifying products that will be purchased by UN agencies.

The current assessment tool is based on commonalities that were identified in the areas of drugs, vaccines and medical devices.

TOP ONLINE PHARMACY STARTUPS

The Indian retail pharma market is currently at a propitious stage, as it is associated with generic drugs, OTC (over-the-counter) drugs and patented products. Several factors have contributed to the growth of e-pharmacy including the internet/digital penetration in India, the Digital India program and several initiatives taken up by the Indian government to integrate IT and public healthcare system.

However, there are certain drawbacks faced by this sector which include low margins, drug abuse (sale of medicines without prescriptions), counterfeit medicine sale, poor documentation and tracking by the company and poor inventory management leading to inefficiencies and higher costs.

The e-pharmacy concept helps tackle all these drawbacks because of the following reasons:

- e-pharmacies purchase in bulk and at a substantial discounted rate, which enables them to provide medicines at a discount while also increasing their profit margins.
- The sale of counterfeit and substandard medicines can be prevented through tracking mechanisms.
- Provide increased compliance and accessibility for the patients to purchase their medicines from the comfort of their homes.
- e-pharmacy websites provide all the information regarding the drug, interactions and its side-effects that make the consumers more aware about the prescribed medication.



Legal Procedure

All the new and existing e-pharmacies are being regulated by the following draft guidelines:

1. Regulatory Authority: e-pharmacies are currently governed by state drug regulators. The draft proposes that the DCGI should be the sole agency granting approvals to e-Pharmacies. The DCGI will be regulated under the Drugs and Cosmetics Rules 1945 as well as the Information Technology Act 2000 under which all other e-commerce companies are regulated.

2. Registration of e-Pharmacy: Any person who intends to conduct the business of e-Pharmacies will have to apply for registration to the Central Licensing Authority (CLA) by filling up Form 18AA along with a fee of INR 50,000 and furnishing the required documents through the online portal of the Central Government. This process is mandatory for the selling, distribution, stocking, exhibition, or offering for sale of drugs through the e-pharmacy portal by any individual.

3. Verification: The registered pharmacist must verify the details of the patient, registered medical practitioner, and arrange for the dispensing of drugs as per the instructions of the registered medical practitioner. The details of the drugs dispensed along with the patient details are to be recorded on the e-pharmacy portal.

Name of Company	Inception:	<u>Founders</u> :	<u>Based in:</u>	<u>e-Pharmacy Model</u> :	Valuation:
1mg	2014	Prashant Tandon, Vikas Chauhan, Gaurav Agarwal	Gurugram	Market place-based model	240 million USD
CareOnGo	2015	Ritu Singh, Aditya Kandoi and Yogesh Agarwal	Delhi	Inventory based model	11 million USD
Medlife	2014	Tushar Kumar (son of Prabhat Narain Singh, one of the founders of Alkem Laboratories) and Prashant Singh	Bengaluru	Inventory based model	375 million USD
Netmeds	2012	Pradeep Dadha and Bruce Schwack	Chennai	Inventory based model	120 million USD
PharmEasy	2015	Dharmil Sheth and Dhaval Shah	Mumbai	Market place-based model	1.5 billion USD
Myra	2015	Faizan Aziz and Aniruddh Coontoor	Bengaluru	Inventory based model	30 million USD

Top Online Pharmacy Startups

1mg

The venture was launched by the name 'HealthKart Plus' as a part of the HealthKart family which focuses on health and nutrition. It now supplies non-prescription, over-the-counter and health products Pan India.

Acquisitions:

- In 2015 it acquired a web platform for homeopathic medicines to expand its reach in AYUSH medicines.
- In July 2016 it acquired Medd.in, a diagnostics and imaging tests marketplace and in the same year, it acquired MediAngels to offer consultations, corporate health services and insurance partnerships.
- In 2017 it acquired Dawailelo, run by DL Lifecare Private Limited which helps users connect with medical stores, doctors and pathology labs through its website and app.
- It has tie-ups with laboratories like Thyrocare, 1mg labs, SRL labs and Metropolis.

CareOnGo

India's first and largest e-distributor of medicines and general wellness products. Zotik, a sister concern of CareOnGo, has partnered with more than 150 brands to provide a seamless one-stop procurement platform to all its partner retailers. It aims to be a one-stop destination for one's pharmacy procurement needs and is an aggregator for all the distributors.

Medlife

Supplies medicines Pan India. It has expanded by adopting a franchise model. It also offers e-consultation, laboratory services, app-based healthcare-related services, private label generics and ayurvedic brands to become an integrated healthcare service provider with a pan-India presence.









PharmEasy

MYRA

Netmeds

Dadha Pharmaceuticals, located in Tamil Nadu was merged with Sun Pharma in 1996. The group then started selling drugs wholesale in Kerala and retail in Tamil Nadu. It has now ventured to the online model. It supplies medicines all over India and has fulfillment centers in Chennai, Bengaluru, Hyderabad, Delhi, Pune, Ahmedabad, Raipur. It is looking to strengthen its technology platform and warehousing facility to boost online sales.

<u>Acquisitions:</u>

- It has expanded by adopting a franchise model
- In 2016, it acquired Delhi-based hyperlocal drugs delivery app Plus.
- In 2018, it acquired JustDoc to add diagnostic and telemedicine services to the already existing delivery of drugs and medicines.

PharmEasy

The company was started with a vision to deliver genuine medicines at affordable rates by optimizing the supply chain and logistics. It supplies medicines all over India to more than 1000 cities and towns covering 22000+ pin codes all over India.

Unique Selling Point: It has medicine reminders, medicine refills (subscription), digital prescription records, free E-Doctor-Consultation, sample collection from home for laboratory tests and an easy return policy.

Myra

As of now, Myra operates only in Bengaluru and Mumbai but plans to expand to other cities. It has its automated warehouses. The founders wish to make medicines accessible at the time of need and also ensure quick and timely delivery.

FACTS ON COVID-19 MUTATIONS/STRAINS AND VACCINES

- Currently available vaccines are directed to the spike protein for immunity. The spike protein of CoV-2 has amino acids that make up all the proteins for viruses and humans alike. These amino acids force the spike protein to form a globule shape which enables the binding of CoV-2 to human cells via the ACE2 receptor.
- A Chinese study on hospitalized Covid-19 positive individuals revealed that the proportion of sick people with type O blood was significantly lesser than the proportion constituting type A blood.

The Double Mutant Strain comprises of:

- L425R mutation- Also seen in California variant; increases infectivity and hinders immune response.
- E484Q mutation- Similar to E484K in UK, South Africa variants; makes antibodies less effective.
- B.1.617- first found in India (October), now in multiple countries, including Australia, UK, USA.

Triple Mutant Strain:

- The B.1.618 strain- also known as the Bengal Strain
- Includes the E484K mutation found in the UK, South African variants

New strains: What we know so far There may be three widespread strains with the N501Y mutation

UK'S B.1.1.7 (or VOC202012/01)

- It has 17 changes, and new projection showed it could 56% more transmissible than existing strains
- It has become the dominant strain in several parts of UK, such as London and the south-east
- This variant is now believed to be in at least 7 countries

SOUTH AFRICA'S 501.V2

- This too has a large number of changes, including in the spike protein that could enhance its transmissibility
- Its lineage is distinct from the B.1.1.7 and does not include some of the same changes
- So far, the variant has only been seen in South Africa, according to genomic surveillance

Source: Hindustan Times





VARIANT This virus too has

WELSH 501Y

- the spike protein mutation Its lineage too is
- distinct from the B.1.1.7 and does not include some of the same changes
- This variant has been around in UK's Wales since autumn but has not spread rapidly

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FACTS RELATED TO COVID-19

- COVID-19 is caused by a type of coronavirus, which have crown-like spikes on their surfaces. Studies, including genetic analyses of the virus, help the scientists to understand the effect of structural changes on the spread and the subsequent reaction in the people who are infected with it.
- Rapid Antibody tests cannot be used for the diagnosis of an active COVID-19 infection, as they only look for antibodies that may have been developed while fighting COVID-19 in the body. The throat and nasal swab test is widely used to detect the infection more accurately.
- The risk of reinfection with SARS-CoV-2 varies from person to person and depends on the specific strain or variant the person is exposed to. Natural immunity is thought to last from 6 to 12 months.
- Recent reports suggest that children are at a higher risk of getting infected in the third wave of COVID-19. A multisystem inflammatory syndrome (MIS) is affecting some children that have tested positive for COVID-19. It is characterized by gastrointestinal symptoms and cardiac (or other systems) inflammation. COVID-19 VACCINES

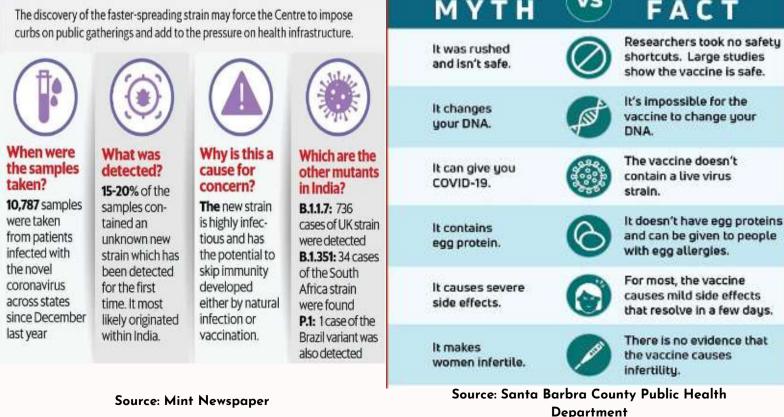
VACCINE

DEBUNKING THE MYTHS

VACCINE

TWIN BLOW

The discovery of the faster-spreading strain may force the Centre to impose



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STRATEGIES TO CURB COVID-19

1) If you do have COVID-19's symptoms isolate yourself from others and stay at



home. VISINFECT

 Regularly clean and disinfect touched surfaces.

 Wash your hands frequently and for 20 seconds.



 Cover your mouth while coughing and sneezing.

5) Limit non-essential work travel





6) Consider tele-learning or telework opportunities, where feasible.

7) Limit visitors at hospitals and other health care facilities.





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Vaccine Phases

Online

COVID

chain

COVID Drugs

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