

BUILDING THE SUPPLY CHAIN FOR COVID-19 VACCINES

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ABSTRACT

• In November 2020 as the world grappled with a over 50 million cases of Coronavirus disease 2019 (COVID-19) and over 1 million deaths, all eyes were focused on the development and manufacturing of COVID-19 vaccines. This case traces the complex set of activities involved in the development, regulatory approval, production, and distribution of COVID-19 vaccines. It describes the resources, information, cooperation, and decision making that went into this unprecedented effort. It poses some of the difficult strategic and operational decision dilemmas faced by country governments, purchasers, vaccine developers, and manufacturers in designing the overall supply chain for COVID-19 vaccines.

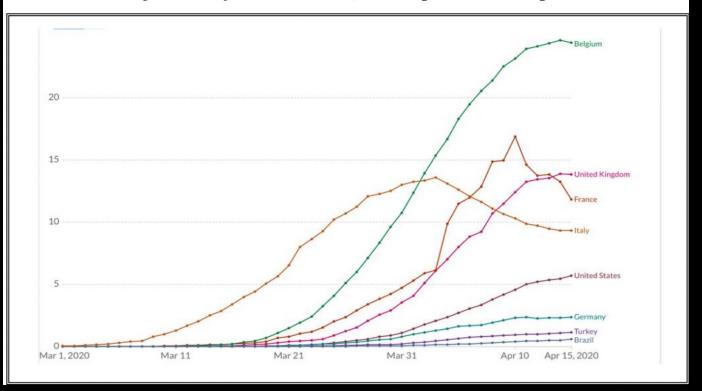
COVID-19

- The COVID-19 coronavirus was first detected in Wuhan, China, in December 2019. By April 2020.
- China and Italy experienced major outbreaks early and saw hospitals flooded with COVID-19 patients, causing major shortages of vital intensivecare materials.
- The pharmaceutical industry typically identified a vaccine proven to work in clinical trials and then built plants to produce it at scale, a years-long process. The world didn't have years, so factories were being built speculatively for the most promising vaccine candidates.
- Shortages of apparently minor components, such as glass vials and syringes, could impede this process.

COVID-19

 Many experts predicted at the time that the first vaccines approved for public use would likely be only partially effective against infection, so to fully resolve the crisis governments and industry would need to plan for flexibility in manufacturing and distribution systems and to continue to invest in further development beyond the first generation of vaccines.

Exhibit 1 Daily New Confirmed COVID-19 Deaths per Million People*



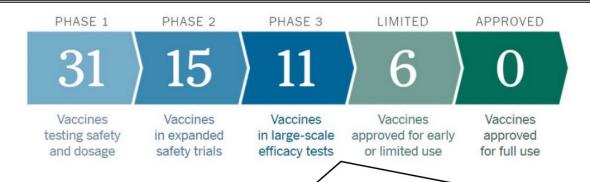
VACCINE DEVELOPMENT EFFORTS

- The World Health Organization (WHO) proclaimed COVID-19 a worldwide epidemic and
- COVID-19 vaccine development has advanced quicker than any other time in history by
- November 2020, owing to unprecedented levels of collaboration between governments, international organizations, research institutes, and major and small businesses.
- There were three phases of clinical trials within the testing stage.
- Phase I clinical trials: Involved 20–80 subjects under controlled conditions and careful
- monitoring
- Phase II trials: Involved several hundred individuals in a more rigorous evaluation of safety and effectiveness with more statistically exacting placebo controls
- Phase III trials: Involving tens of thousands of human subjects

CHALLENGES IN DEVELOPING SECOND-GENERATION VACCINES:

- Virus that is entirely new or updated
- • Economic concerns
- Lack of good clinical trial outcomes

Exhibit 3 Coronavirus Vaccine Global Portfolio as of October 16, 2020



By mid-October 2020, nine likely COVID-19 vaccine candidates for had been identified:

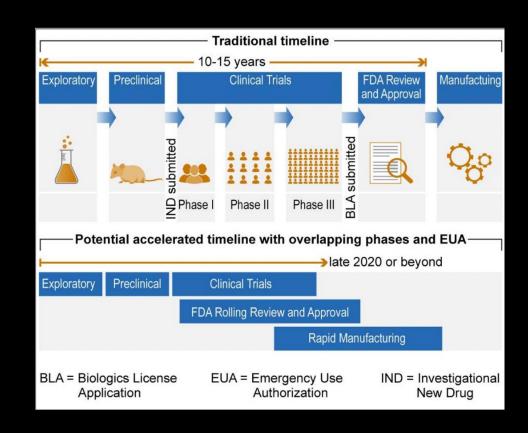
- 1) Moderna/National Institute of Allergy and Infectious Diseases (US)
- 2) Pfizer-BioNTech/Fosun Pharmaceutical (US)
- 3) University of Oxford/AstraZeneca (UK)
- 4) Sputnik V by the Gamaleya Institute (Russia)
- 5) Johnson & Johnson's Janssen Pharmaceutical Companies (US)
- 6) CanSino Biologics/Beijing Institute of Biotechnology (China)
- 7) Novavax (US)
- 8) Sinopharm (China)
- 9) Sinovac Biotech (China)

By mid-November 2020, two vaccine candidates, Pfizer-BioNTech's and Moderna's, had announced early results from Phase III trials indicating that they were highly effective in protecting people against symptomatic COVID-19 infection.

MANUFACTURING OF VACCINE

There are several factors need to consider in manufacturing;

- Process
- Production Sites and Economic
 Geography of Vaccine Manufacturing
- Financing and Incentives
- Raw Material and Component Supply
- Risks Scaling
- Agile Capacity



<u>DISTRIBUTION</u>

- Equitable International Distribution and Vaccine Nationalism:
- Despite early on in the crisis, substantial global coordination, rising economic and political tensions were enticing countries along a "me-first" path. As a result, there had emerged two groups of distribution:
- 1. multilateral cooperation
- 2. Bilateral agreements between a country and a drug company

VACCINE TRANSPORTATION CHALLENGES:

The major challenges in vaccine transportation:

- Temperature requirements
- The enormous volumes to be shipped
- Trained personnel
- Rigorous logistical planning
- Distribution and complicated infrastructure-building
- Refrigerated warehouse capacity

ASTRAZENECA VS PFIZER

- In 2014, Pfizer proposed a friendly acquisition of AstraZeneca, but AstraZeneca resisted over price and strategy concerns. Pfizer, like pharmaceutical companies, faced difficulties in growing sales due to the challenges of developing new drugs.
- Pfizer had pursued acquisitions as a way to acquire new drugs, increase sales, and to reduce costs by combining operations and cutting staff. Pfizer, a U.S. company, was also interested in AstraZeneca, a U.K. company, as a way to reduce its corporate taxes.
- In recent years, AstraZeneca had significantly strengthened its pipeline of potential new drugs and its board felt it was in a strong position to go it alone

QUESTIONS THAT WERE STILL UNRESOLVED AT THAT TIME

- Large governmental investments in vaccine development and manufacturing capacity incentives—including advance purchases by countries—had expedited the risk at which the sector could generate sufficient global supply.
- A portfolio approach to purchasing, such as COVAX, helped vaccine purchasers diversify risks, but there was still a requirement for portfolio-level supply network management of capacity, raw materials, and ancillary supplies, and many questions remained:
- Would voluntary horizontal collaboration among vaccine inventors and producers result in portfolio-level supply coordination?
- Or, if so, how should an explicit portfolio-level supply network management function be developed?
- How could the United States and other countries accelerate the vaccine supply chain—from manufacturing to delivery—to mitigate the risk of variations emerging?

THANK YOU