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Research Article

Status of Covid- 19 Vaccines Innovation and Availability in India

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Abstract

Background: Vaccine R&D is a process of testing ideas and products. It is developed through a series of experiments designed to answer scientific questions and evaluate possible vaccine concepts. The research effort involves several players from the private and public sectors - scientists and clinicians working in private companies and research agencies, government officials and community groups. The Vaccine concepts are tested and improved many times before they are ready for use.

Methods: Specific information on the initiative of government organisation and policy to develop a Covid-19 vaccine has been gathered through different secondary sources available in the public domain during the outset of the pandemic. Information on availability of Covid-19 Vaccine is based on the newspaper reports. The objective of this paper is to briefly comprehend the ongoing scenario of Covid-19 vaccines availability and the role of different stakeholders in converting the ideas of covid-19 vaccine into product. The paper is not discussing the vaccination drive which can be a limitation of this research. The information in the paper suffices the need of government, Non-Governmental Organisations (NGOs), Health Care Workers (HCWs), Policy makers, Media and the common people in knowing and having various choices for getting vaccinated by Covid-19 vaccines.

Conclusion: The pandemic has proved the need and importance of the relationship between different players, agencies, institutions and the functional linkages to develop the Covid-19 vaccine in India. The contribution of DBT, along with the other players, has proved to be a precursor in the development of covid-19-vaccine. It must be considered that vaccines and drugs are not similar. The Coronavirus spread is not limited to territorial and political boundaries, race, caste, class, religion, gender and age. Therefore, the development of vaccines will be successful with the collaborative effort among all the stakeholders. Covid-19 vaccine development and vaccination is realized by the role of science, networks, division of innovative labour, universities, venture capital, national health systems and community and public health personnel.

Keywords: Covid-19 Vaccine; Department of Biotechnology (DBT); DNA technology; WHO

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Introduction

National regulatory authorities have approved COVID-19 vaccines, and through WHO Emergency Use Listing (EUL), Vaccination has begun in most countries, bringing the prospect of reducing severe disease and mortality. Initial observational studies following the roll-out of vaccines suggest that vaccines may lead to protection against infection and a reduction in transmission. Four WHO-classified Variants of Concern (VOCs) have emerged since December 2020, which are more transmissible and some of which may cause more severe disease. Several other Variants of Interest (VOIs) are also being monitored. Evidence is now available on the effectiveness of a range of individual and community-level measures.

Control of SARS-CoV-2 will depend on the:

I. Prevalence of infection and circulating variants.

II. Rate of growth or decline in incidence.

III. Types, use of and adherence to control measures in place.

IV. Speed with which vaccination occurs.

V. Targeting and uptake of the vaccines among high-risk groups.

VI. Effectiveness and natural immunity in the population.

National vaccination strategies should prioritize older individuals at the highest risk of severe outcomes and health workers to reduce mortality and disease burden and protect health care services. However, with successful COVID-19 vaccination of older populations following the prioritization of vulnerable groups, the virus may continue to spread among unvaccinated younger population groups. After achieving high vaccination coverage of SAGE priority groups for stage I and stage II across all countries, accelerating vaccination of other priority groups will be required to lower the infection rate, especially in areas of high population density [1].

India took 85 days to touch the figure of 10 crores dosages administered to the people [2] Table 1. (TOI, 2021). In the preceding context, the following table highlights some of the initiatives taken by the government of India in the development of the covid-19 vaccine.

Methods

Specific information on the initiative of government organisation and policy to develop a Covid-19 vaccine has been gathered through different secondary sources available in the public domain during the

Serial Number	Month/ Year	Recent Developments/Investments
1	November 2020	A tripartite MoU was signed between the Serum Institute of India, Bangladesh-based pharmaceutical company Beximco Pharmaceuticals Ltd., and Bangladesh's Government for procurement of the Oxford/Astrazeneca COVID-19 vaccine.
2	November 2020	Bharat Biotech plans to produce ten vaccines, including malaria and COVID-19, with a total investment of Rs. 300 crore (US$ 40.54 million) at its upcoming unit in Bhubaneswar, Odisha.
4	September 2020	Aurobindo Pharma announced collaboration with BIRAC to develop the COVID-19 vaccine. The company is developing the vaccine through its wholly-owned US subsidiary, Auro Vaccines.
5	November 2019	Advent International, a private equity investor, acquired a majority interest in Bharat Serums and Vaccines Limited. This acquisition was aimed to strengthen and expand Bharat Serums offerings in India and global markets.

Table 1: Recent Developments and Investments in the Indian Covid-19 Vaccine Sector.

Source: Adapted from Indian Brand Equity Foundation (IBEF), 2021

outset of the pandemic. Information on availability of Covid-19 Vaccine is based on the newspaper reports. The objective of this paper is to briefly comprehend the ongoing scenario of Covid-19 vaccines availability and the role of different stakeholders in converting the ideas of covid-19 vaccine into product. The paper is not discussing the vaccination drive which can be a limitation of this research. The information in the paper suffices the need of government, Non-Governmental Organisations (NGOs), Health Care Workers (HCWs), Policy makers, Media and the common people in knowing and having various choices for getting vaccinated by Covid-19 vaccines.

Results

Availability of covid-19 vaccines

Eight vaccines have been granted Emergency Use Authorization (EUA) [1] by the Central Drugs Standard Control Organization (CDSCO) in India.

Covishield

It was developed by Oxford University in partnership with British-Swedish firm AstraZeneca. It is being manufactured in India by the Pune-based Serum Institute of India (SII). It is a Viral Vector-based Technology that is also used to manufacture the Ebola vaccine. Composition of Covishield includes inactivated adenovirus with segments of Corona Virus, Aluminium Hydroxide Gel, L-Histidine, L-Histidine hydrochloride monohydrate, Magnesium chloride hexahydrate, Polysorbate 80, Ethanol, Sucrose, Sodium chloride, and Disodium Edetate Dihyd Rate (EDTA). It is based on the same patent technology as the United Kingdom (UK) Astra Zeneca vaccine. As per the permission granted by the Drug Controller General (India), the second dose is to be administered 4-6 weeks after the first dose. It has been authorized in 117 countries, including the European Union, the UK, Australia, Canada, Japan, and Saudi Arabia. It has received World Health Organisation (WHO) authorization. Countries like South Korea, Dubai, Switzerland, and 10 European nations (Austria, Estonia, Germany, Greece, Ireland, Netherlands, Slovenia, Spain, Switzerland and Iceland) have opened their borders to Indians fully vaccinated with Covieshield. It has not been authorized for use in children yet in India [3].

Covaxin

It is manufactured by Bharat Biotech Limited. It is a whole-Virion Inactivated Corona Virus Vaccine which is also used to manufacture vaccines like Influenza, Rabies and Hepatitis A. Composition of Covaxin includes inactivated Corona Virus, Aluminum Hydroxide Gel, TLR 7/8 agonist, 2-Phenoxyethanol and Phosphate Buffered Saline [NKA1]. It is stored and transported at +20 to +8º Celsius. The cold chain is maintained by active and passive cold chain equipment available at approximately 29000 cold chain points across India. It is administered in two doses intervals of day 0 and day 28 [4]. It is an indigenous vaccine developed by Hyderabad-based Bharat Biotech International Limited in collaboration with the Indian Council of Medical Research (ICMR) and the National Institute of Virology, Pune (NIV).

Sputnik V

The Sputnik V vaccine has been developed by Gamaleya National Research Institute of Epidemiology and Microbiology in Moscow, Russia, in partnership with the Russian Direct Investment Fund (RDIF). It is being distributed in India by Dr Reddy's Laboratories, based in Hyderabad. RDIF has tied up with other Indian companies Hetero Biopharma, Gland Pharma, Stelis Biopharma and Virchow Biotechfor its production.

It is also a viral vector vaccine. However, it uses two human recombinant adenovirus vectors for its two doses to provide longer protection. The vaccine delivers a code for making the coronavirus spike protein. Thus, when the real virus enters the body, it mounts an immune response in the form of antibodies. It is administered in two doses at a gap of 21 days. According to results published in The Lancet, the efficacy of Sputnik V was found to be 91.6 per cent after Phase 3 trials. It has been authorised in over 60 countries. It has not yet been approved by the EU's European Medicines Agency or the World Health Organisation (WHO), and thus Indians vaccinated with Sputnik V may not be welcome in most countries in India [3].

Moderna

The Covid-19 vaccine, also known as Spikevax, has been developed by Massachusetts-based Moderna Therapeutics in collaboration with the US National Institute of Allergy and Infectious Diseases. It uses mRNA or messenger RNA technology. It is administered in two doses (100 µg, 0.5 ml each) at a gap of 28 days. Drug manufacturer Cipla is importing it. It has an efficacy of 94.1 per cent in protecting against Covid-19, starting 14 days after the first dose. It is 100 per cent effective for adolescents in the age group of 12-17 years. It has sought emergency use of its Covid-19 vaccine in adolescents aged 12-17 years from the US FDA and European and Canadian health regulators India.[3]

Janssen

The Janssen Covid-19 vaccine has been developed by American pharma giant Johnson & Johnson's subsidiary Janssen Pharmaceuticals. The vaccine will be brought to India through a supply agreement with Hyderabad-based firm Biological E Ltd. The Johnson & Johnson vaccine is a viral vector vaccine-like Oxford-AstraZeneca developed. The vaccine uses a modified adenovirus to deploy the SARS-CoV-2 virus's "spike protein" to human cells, which triggers an immune response. While the Oxford vaccine uses a genetically engineered chimpanzee adenovirus, the J&J vaccine uses a variant of a human adenovirus known as Ad26. The timeline of the vaccine's availability

is not yet clear. It is 85 per cent effective in preventing severe disease in Phase 3 human clinical trials. The company would start studying its vaccine among children ages 12 to 17 this autumn in India [3].

Astrazeneca

Several other names in scientific papers also know the Astra Zeneca (AZ) vaccine as ChAdOx1, AZD1222, Vaxzevria. It is given in two doses. The second dose is given between 28 to 84 days (4 to 12 weeks) after the first dose. It is delivered using an adenovirus vector. This is the same type of technology that the Johnson & Johnson COVID-19 vaccine uses. This type of vaccine uses a deactivated adenovirus that's been modified to deliver the vaccine contents into a host cell. Once the contents enter the cell, the adenovirus breaks down. This means that it can't cause disease in humans or interact with our DNA in India [5].

ZyCoV-D

India's drug regulator has granted emergency use approval for Zydus Cadila's COVID-19 vaccine, the world's first DNA shot against the coronavirus, in adults and children aged 12 years and above. It uses a section of genetic material from the virus that gives either DNA or RNA instructions to make the specific protein that the immune system recognises and responds to. It has been developed in partnership with the Department of Biotechnology. It is the second home-grown vaccine to get emergency authorization in India after Bharat Biotech's Covaxin. The generic drugmaker, listed as Cadila Healthcare Ltd, aims to make 100 million to 120 million doses of ZyCoV-D annually and has already begun stockpiling the vaccine. The firm had applied for the authorization of ZyCoV-D on July 1, based on an efficacy rate of 66.6% in a late-stage trial of over 28,000 volunteers' nationwide [6].

Corbevax

The Drugs Controller General of India (DCGI) has already approved Corbevax, which is India's first indigenously developed RBD protein sub-unit vaccine against COVID-19, for restricted use in emergency situation among adults on December 28. Biological E Limited had received approval for conducting phase 2/3 clinical study of Corbevax among children and adolescents aged 5-18 years in September. The Corbevax vaccine is administered through intramuscular route with two doses scheduled 28 days apart and is stored at 2 to 8 degrees Celsius temperatures and presented as 0.5 ml (single dose) and 5 ml (10 doses) vial pack [7].

Discussion

Vaccine R&D is a process of testing ideas and products. It is developed through a series of experiments designed to answer scientific questions and evaluate possible vaccine concepts. The research effort involves several players from the private and public sectors - scientists and clinicians working in private companies and research agencies, government officials and community groups. The Vaccine concepts are tested and improved many times before they are ready for use.

The process of developing ideas into usable vaccines can be divided into five stages

Idea generation (Basic Science) or R&D

The first stage of vaccine development occurs in universities, research institutes and private companies. Scientists working with existing scientific knowledge and laboratory tools develop ideas for how a vaccine could function. They examine cells from the human immune system and parts of the virus to determine what might work and how a vaccine might be designed. Hundreds of scientists all over the world are now contributing to this stage of vaccine development. Many new designs are generated each year; very small number move forward to the next stage.

Pre-Clinical Development

In the second stage, scientists test vaccine preparations in cell culture. If the results are promising, the vaccines are then tested in animals. At this stage, animals are used to see if the vaccine is safe and works in the way scientists believe. Scientists also use the information from animal studies to improve the design of experimental vaccines. Only a tiny percentage of the vaccines that make it to the preclinical development stage are deemed safe enough and promising enough to be evaluated in people. Preclinical R&D is carried out in the laboratory and uses in vitro or in vivo techniques in animals. Preclinical and laboratory research data include details of the development and production of a vaccine together with reports of control testing, which should be adequate to justify clinical studies in humans.

Preclinical evaluation of a vaccine is a requirement for the initiation of clinical trials. Laboratory evaluation should be continued in the preclinical and clinical phases of vaccine development. The primary goal of preclinical testing a new vaccine product, a unique combination vaccine comprising of previously licensed antigen(s), or vaccines presented in new formulations or new delivery systems should demonstrate that the vaccine is suitable for testing in humans. Preclinical and laboratory studies aim to define the characteristics of a product, including the indicators of safety and immunogenicity in an appropriate animal model.

When preclinical animal testing is performed, there should be a clear rationale for doing so. The study should be conducted in compliance with Good Laboratory Practice (GLP) guidelines and National Guidelines on animal experimentation. Preclinical and laboratory studies are necessary to establish the characteristics (physical, chemical and biological) of the candidate vaccine, identify possible risks to the vaccines, and help plan protocols for clinical studies in human subjects in which the safety and efficacy of the candidate vaccine may be evaluated. Close collaboration between the preclinical and the clinical investigators is essential in assessing the first results of the administration of vaccines in humans. The clinician and the appropriate advisers are responsible for satisfying themselves that the preclinical experiments are adequate in scope, and they should request a complete account of all relevant data [8].

Clinical

If a vaccine is safe and promising in laboratory and animal testing, it moves to the third stage: clinical trials in humans. Human testing involves three different phases of clinical trials. The whole process can take many years.

All clinical trials should adhere to standards described in good clinical practice. WHO Guidelines for Good Clinical Practice is already in place for trials of pharmaceutical products, and these general principles also apply to vaccine studies. However, vaccines have special aspects, which demand special consideration, such as:

- Vaccines are given to healthy individuals, mainly in the paediatric population.
- Vaccines are given to prevent disease, which thus limits tolerance to adverse events.
- Vaccines are biological products that are highly complex substances derived from living materials, comprising of living organisms, requiring specialized assays and testing to assure their quality and safety.

Understanding the entire clinical spectrum of illness, optimization of diagnostic criteria, and the high-risk groups defined by age, gender, ethnic or population group membership, geography, social characteristics or seasonality is essential for accurate vaccine evaluation.

Licensing

If the clinical trials are successful and the company decides to market the vaccine, it first must obtain a license. This involves making an application to the department of government responsible for regulating pharmaceutical products. If the company wants to sell its product in many different countries, it will usually have to obtain licenses in each of these countries. This process can take several years.

Delivery

If a safe and effective vaccine can be developed, the challenge will be to produce it and make it accessible to people who need protection from the disease. Historically, the delivery of vaccines to people around the world has proved to be a difficult task. In fact, even today, many safe and effective vaccines are unavailable to most people worldwide. The delivery of safe, effective vaccines is a vital component of the vaccine development effort.

The following Table 2 reflects the time taken to complete different vaccines pertaining to different diseases.

Infectious Agents & Disease	Year when Agent linked to Disease	Vaccine Licensed in USA	Years Elapsed
Bordetella pertussis (Whooping Cough)	1906	1948	42
Poliovirus (Polio)	1908	1955	47
Measles virus (Measles)	1953	1963	10
Hepatitis B Virus (Hepatitis)	1965	1981	16
Haemophilus influenzae (Meningitis)	1889	1981	92
Salmonella Typhi (Typhoid Fever)	1884	1989	105
Varicella zoster virus (Chickenpox)	1953	1995	42
Rotavirus (Diarrheal disease)	1973	2006	33
Human papillomavirus (Cervical cancer)	1981	2006	25
Human immunodeficiency virus HIV (AIDS)	1983	–	25+
Human cytomegalovirus (birth defects, mononucleosis)	1960	–	48+
Mycobacterium tuberculosis (tuberculosis)	1882	*	126+
Plasmodium spp. (Malaria)	1880	–	128+

Table 2: To Create a Vaccine: Always Years, Sometimes Decades.

* Although the BCG vaccine is effective and widely used in children, no highly effective licensed vaccine against adult tuberculosis is currently available. Source: IAVI (2008) [9-12].

Covid-19 vaccine development in India

The collaborative efforts by the Department of Biotechnology (DBT), Government of India, implemented by a dedicated Mission Implementation Unit at Biotechnology Industry Research Assistance Council (BIRAC), the existing activities under National Bio-Pharma Mission (NBM) and Ind-CEPI Mission are also providing complementary strengths to Mission COVID Suraksha. *The Indian COVID-19 Vaccine Development Mission* facilitates preclinical development, clinical development and manufacturing and regulatory facilitation for deployment and consolidates all available resources towards accelerated product development. The highlights of the COVID-19 R&D efforts include support for >100 projects in the thematic areas of vaccines, diagnostics and therapeutics, enabling seven vaccine candidates by industry and eight candidates by academia, development of clinical trial sites and centralized laboratories to facilitate vaccine development [9].

The Finance Minister announced mission COVID Suraksha for R&D of Indian COVID-19 vaccines on 12th November 2020. The Mission is being implemented at a total cost of Rs. 900 Cr. for 12 months by BIRAC, a PSU of DBT. The grants for the candidate vaccine were sanctioned on the following indicators [10] Table 3.

FACILITIES	CAPABILITIES
• Animal challenge facilities • Immunoassay labs • Clinical trial sites	• Process and cell line development • GMP manufacturing (Toxicology and clinical trials) • Regulatory guidance

Table 3: Indicators for Grant of Candidate Vaccine.

Source: Adapted from DBT (2021) [9,10]

Moreover, three Requests for Expression of Interest (REOI) were announced for accelerating Indian COVID-19 vaccine development [9,10] Table 4.

REOI-1	REOI-2	REOI-3
Accelerated development of 5-6 vaccine candidates that are closer to licensure and introduction in the market within the next 12 months.	Strengthening service facilities for conducting animal studies and immunological assays and make them available for COVID-19 vaccine developers	Strengthening Capacities to conduct Clinical Trials for COVID-19 Vaccine Candidates

Table 4: Requests for Expression of Interest for Covid-19 Vaccine Development.

Source: Adapted from DBT (2021) [9]

The following Table 5 depicts the current status of the candidate vaccines in relation to the Scale-up Feasibility, Delivery Feasibility, Company Experience and Existing Dose Commitment.

Serial Number	Candidate	Scale-up feasibility	Delivery feasibility	Company Experience	Existing Dose Commitment
1	*SIIPL (ChAdOx1/ AZD 1222)*	No non-replicating viral vector vaccine licensed in India	2 doses, IM, 2-8 degree C	WHO PQ, supplying vaccines globally – NRA by ANVISA, INVIMA, SAHPRA, PICS	100 million doses committed to GAVI
2	*Biological E protein subunit)*	Established platform	2 doses, IM, 2-8 degree C	WHO PQ facilities, FDA, EMA approved DP facilities	Min. 21% of annual production to GAVI eligible countries and 49% to India
3	*Bharat Biotech ICMR/NIV*	Need for BSL-3 facilities	2 doses, IM and ID	WHO PQ facilities; Have BSL-3 facilities	MoU with ICMR states priority is to provide vaccines to GoI
4	*Gennova (Sa mRNA)*	Time to manufacture a risk as facility under development. regulatory clearance needs clarity	2 doses, IM, 2-8 degree C	The first vaccine to be commercialized. Strong in biotherapeutics	No

Table 5: Status of the Candidate Vaccines.

Source: Adapted from DBT (2021) [9]

The following Table 6 highlights ongoing R&D in Covid-19 Vaccine.

	Preclinical	Phase 1	Phase 2	Phase 3
Non-replicating viral vector				
BHARAT BIOTECH/ THOMAS JEFFERSON	Y	Y but not completed	x	x
SIIPL (CHADOX1/AZD 1222)*	Rolling review of CHMP			
Protein subunit				
BIOLOGICAL E/COLLABORATION	Y	x	x	x
Inactivated virus				
BHARAT BIOTECH-ICMR/NIV*	Y	Y	Y but not completed	x
Replicating viral vector				
AUROBINDO PHARMA	Y	x	x	x
ZYDUS CADILA	Y	x	x	x
BHARAT BIOTECH/ FLUGEN	Y	x	x	x
SIIPL	Y	x	x	x
Live attenuated				
INDIAN IMMUNOLOGICALS	Y	x	x	x
SIIPL/CODAGENIX	Y	x	x	x
DNA Vaccine				
ZYDUS CADILA	Y	Y	Y	Y but not completed
RNA Vaccine				
GENNOVA	Y	Y but not completed	x	x
Repurposing				
SIPL (RBCG)	Y	Y	Y	Y but not completed

Table 6: Covid-19 Vaccine R&D Pipeline.

Y refers to **'Yes'**.

*Granted permission for restricted use in an emergency situation

Source: Adapted from DBT (2021) [9]

The pandemic has proved the need and importance of the relationship between different players, agencies, institutions and the functional linkages to develop the Covid-19 vaccine in India. The contribution of DBT, along with the other players, has proved to be a precursor in the development of covid-19-vaccine. It must be considered that vaccines and drugs are not similar. Differences affect the drivers and barriers to technology transfer and the impact technology transfer can have on access. Vaccines lack a true generic version where a generic can be made and licensed on chemical equivalence for drugs, a vaccine made in a new facility is treated as a new vaccine and have to go through preclinical and clinical studies before being put to use as vaccines are complex biological entities, and simple bioequivalence is not sufficient proof that a vaccine will be safe and efficacious. This has to pass through the preclinical and clinical development path, coupled with a manufacturing facility that makes that specific vaccine, which means that establishing new manufacturing sites and approving a copy of an existing vaccine is both costly and time-consuming.

Know-how rather than Intellectual Property (IP) has been the main barrier to the local production of vaccines. Making vaccines requires a skilled workforce with experience in a broad range of areas specific to a particular vaccine. Skills are learnt in vaccine manufacturing facilities or through technology transfer and are not available in most countries. For most approved vaccines, any intellectual property has been on specific processes, where alternative manufacturing methods can provide a work-around but require R&D infrastructure. The market for vaccines is different from those for drugs. Vaccines are purchased and distributed by the public sector through procurement agencies or governments, and there are only a limited number of vaccine suppliers. Vaccines are always cost-effective in public health outcomes, while for drugs, cost-effectiveness and public health outcomes are not linked [8].

The ongoing research for the covid-19 and other vaccines should consider the questions below raised by Archibugi and Bizzari [11], which may pave the way for the successful development of the vaccines. In the context of the importance of preventative immunization, why research in this field is so minimal? Why is the current state of scientific knowledge impeding the discovery of an effective vaccine against these diseases? Could the lack of investment in the field reflect a rational evaluation of the expectations of hitting the target? Scientific investigation is by nature surrounded by uncertainty when

searching for major scientific breakthroughs. According to Archibugi and Bizzari (2004) [11], three scenarios can be identified about the investment of targeted scientific research. These scenarios can also be applied to the ongoing coronavirus vaccine R&D across the globe.

One searches for something but never finds it

In spite of the whole hearted commitment, research does not yield the desired results. The research carried out may stimulate learning and build investigative capacities. In some cases, it may even lead to the identification of blind alleyways, though the problem remains unsolved. The case of an anti-tumour vaccine falls within this category.

One search for something and finds something else

The investments destined for scientific research do not lead to the objective set, but the results obtained are still relevant to different research areas despite their failure. Kroto's discovery of the C60 molecule is a perfect example of serendipity (discovery by chance).

One finds what being looked is for

The massive concentration of human and economic resources on specific projects allows one to obtain the results one is aiming for. The Manhattan project and the conquest of the moon are examples of scientific results obtained due to strong financial and political commitment.

Economics of scientific research suggests no clear linear relationship between input and output since any scientific investigation is dominated by incertitude. The opinion of experts in the field that the major impediment to basic vaccine science appears not to be so much related to a knowledge gap as to a lack of severe financial commitment.

Conclusion

The Coronavirus spread is not limited to territorial and political boundaries, race, caste, class, religion, gender and age. Therefore, the development of vaccines will be successful with the collaborative effort among all the stakeholders. Covid-19 vaccine development is realized by the role of science, networks, division of innovative labour, universities, venture capital and national health systems. Large firms, new biotech firms, small firms, regulation, IPR, national health systems, and demand have played a crucial role in vaccine innovation. Science, engineering and their allied fields are playing an imperative role in renewing the space for Covid-19 vaccine sector in India. New firms have entered the sector and are cooperating with the established large firms. Recent changes in regulation and demand are squeezing firms' profitability, rendering new opportunities for collaborations, learning, and investment among the firms engaged in Covid 19 vaccine development. International dimensions are gaining greater significance, and globalization is holding wider influence. The interlinkages require serious attention for evolving a balanced Science, Technology and Innovation Policy for the Covid-19 vaccine sector. India also came up with the National Vaccine Policy 2011, which addresses broad issues of strengthening the institutional framework, processes, evidence based, and framework required for maintaining and streamlining the decision-making process on new and underutilized vaccine Introduction. The policy also aims to address the issues of vaccine security, management, regulatory guidelines, vaccine R&D and product development. India's Covid-19 vaccine market is one of the fastest emerging markets in the world. The market is witnessing unprecedented growth driven by "Prevention is better than cure" concept; large population, combination vaccines, increased diseases severity, and rapid epidemiological transitions have made this a reality. The market is expected to be the major player in the global covid-19 vaccine market both in terms of value and volume and also as an export hub.

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