REVIEW ARTICLE JPAR 2021

Journal of Pharmaceutical Advanced Research
(An International Multidisciplinary Peer Review Open Access monthly Journal)
Available online at: www.jparonline.com

COVID-19 Vaccines approved for use and under development in India: An overview

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Received: 22.05.2020 Revised: 10.04.2021 Accepted: 20.06.2021 Published: 30.06.2021

ABSTRACT: The whole globe is reeling under the coronavirus disease 2019 (COVID-19) pandemic now. A COVID-19 vaccine is intended to provide acquired immunity against Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2), the virus causing coronavirus COVID-19. India's vaccine-production capacity is the best asset for the World. India has so far given more than 100 million doses of two approved vaccines - Covishield and Covaxin. A third coronavirus vaccine has been approved for use in India amid a deadly second wave of infections. Russia's Sputnik V has been deemed to be safe, and works in a way similar to the Oxford-AstraZeneca jab which is being made in India as Covishield. Sputnik V gives around 92 % protection against COVID-19, late-stage trial results published in The Lancet revealed. Sputnik-V's approval came as India overtook Brazil to become the country with the second-highest number of cases globally. The present review article provides an insight into the various vaccines developed and approved for use in India for COVID-19.
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Keywords: COVID-19, Coronavirus, Covishield, Covaxin, Sputnik-V, SARS-CoV-2.
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INTRODUCTION:

On 30th January, 2020 World Health Organization (WHO) declared a severe respiratory disorder syndrome which originated in Wuhan city as a global public health emergency and on 11th February named the disease as COVID-19. The pandemic declaration by WHO was made on 11th March 2020. The spread of COVID-19 is now relentless and the spread in almost all the countries of the world is causing serious public health, social and economic upheaval [1].

The whole globe is reeling under the COVID-19 pandemic now. With the scale and severity of infection, number of deaths and lack of any definite medicine, the vaccine development has been accelerated at a never-before pace. COVID-19 vaccination will now only help to protect from getting COVID-19. A wide variety of vaccine technologies and platforms are being attempted [2].

In order to respond quickly and effectively to the COVID-19 pandemic, a broad range of candidate COVID-19 vaccines are being investigated globally using various technologies which includes viral-vectored, protein subunit, nucleic acid (DNA, RNA), live attenuated and inactivated vaccines.

Currently, there are more than 64 vaccine candidates, most of them aiming to induce neutralizing antibodies against the spike protein (S). These antibodies will prevent uptake through the human Angiotensin Converting Enzyme – 2 (ACE-2) receptor, thereby limiting viral entrance. Different vaccine platforms are being used for vaccine development, each one presenting several advantages and disadvantages [3].

Most of the first flushes of approved vaccines were based on two technologies never used in humans earlier. These include mRNA-based vaccines of Pfizer-BioNTech, Moderna, and the viral vector-based vaccines of Astra Zeneca/Oxford University, Sputnik V, Janssen of Johnson and Johnson, and Coronavac of CanSino Biologics from China.

India, one of the World's biggest suppliers of vaccines, is facing a COVID-19 vaccine crunch, partly due to an explosion of cases linked to new variants. This spells trouble for many countries relying on Indian-made vaccines supplied through the COVAX initiative for equitable access to vaccines, led by bodies including the World Health Organization.

On 16th January 2021 India started its national vaccination programme against the SARS-CoV-2 virus which has caused the COVID-19 pandemic. The drive priorities healthcare workers and frontline workers, and then those over the age of 60, and then those over the age of 45 and suffering from certain comorbidities. According to health officials, India has administered 138,379,832[b] vaccine doses across the country as of 21 April 2021 [4,5].

The objective of the present review was to collect and compile information about the vaccines which are currently approved in the India.

DEVELOPMENT OF VACCINE IN INDIA:

India has a long history of vaccine production and the Haffkine Institute for example has been recognized by the World Health Organization (WHO) as a prequalified vaccine producer before the country got independence from Britain in 1947. Haffkine, by the way, was the world's first plague vaccine producer in 1897. India's first privately-funded vaccine company, Biological E Ltd., came into existence in 1953 and since then, several companies have started promoting public-private partnership endeavors [6].

The Pune-based Serum Institute of India (SII) is the World's largest vaccine maker, and this existing capacity enabled India to be a major participant in the COVAX distribution strategy. As of late February 2020, SII had begun animal trials of vaccine candidates. This vaccine received Drug Controller General of India (DCGI) approval in early August 2020 for trial phases II and III. SII joined GAVI in a partnership with the Bill and Melinda Gates Foundation to produce 100 million doses of vaccine for developing countries. As of early May 2020, there were over 30 vaccine candidates in development in India, many of which were already in pre-clinical tests.

Zydus Cadila began its vaccine development in March 2020. It was replicating a viral vector vaccine and developing a DNA plasmid vaccine. In mid-July 2020, Zydus Cadila had human trials of its vaccine named ZyCoV-D [7].

ICMR partnered with Bharat Biotech in May 2020 to develop a COVID vaccine entirely within India. ICMR has developed BBV152 COVID vaccine or COVAXIN, India's first COVID-19 vaccine. COVAXIN was reported to build immunity against COVID-19 in pre-clinical trials on animals.

COVID-19 VACCINES WITH APPROVAL FOR EMERGENCY OR CONDITIONAL USAGE IN INDIA:

Covishield:

The Oxford–AstraZeneca COVID-19 vaccine, code named AZD1222, and sold under the brand names Covishield and Vaxzevria among others, is a viral vector vaccine for prevention of COVID-19. Developed by Oxford University and AstraZeneca, it is given by intramuscular injection, using as a vector the modified chimpanzee adenovirus ChAdOx1 [8].

The vaccine has a good safety profile, with side effects including injection-site pain, headache, fatigue, myalgia,

malaise, pyrexia, chills, arthralgia, and nausea, all generally resolving within a few days. More rarely, anaphylaxis may occur. In very rare cases the vaccine has been associated with an increased risk of blood clots in combination with low levels of blood platelets.

On 30th December 2020, the vaccine was first approved for use in the UK vaccination programme, and the first vaccination outside of a trial was administered on 4th January 2021. The vaccine has since been approved by several medicine agencies worldwide, such as the European Medicines Agency (EMA), and the Australian Therapeutic Goods Administration, and was approved for an Emergency Use Listing by the World Health Organization (WHO). Some countries have limited its use to elderly people at higher risk for severe COVID-19 illness due to the risk of clotting problems in younger individuals.

The Oxford-AstraZeneca COVID-19 vaccine is used to provide protection against infection by the SARS-CoV-2 virus in order to prevent COVID-19 in adults aged 18 years and older. The medicine is administered by two 0.5 ml doses injected intramuscularly into the deltoid muscle (upper arm) four to twelve weeks apart, with the WHO recommending the second is given 8 to 12 weeks after the first for optimum efficacy [9,10].

An analysis published on 19th February 2021 showed an efficacy of 76.0 % at preventing symptomatic COVID-19 beginning at 22 days following the first dose, increasing to 81.3 % when the second dose is given 12 weeks or more after the first [11].

The Oxford–AstraZeneca COVID-19 vaccine is a replication-deficient simian adenovirus vector, containing the full-length codon-optimized coding sequence of SARS-CoV-2 spike protein along with a tissue plasminogen activator (tPA) leader sequence [12,13]. The adenovirus is called replication-deficient because some of its essential genes were deleted and replaced by a gene coding for the spike protein. Following vaccination, the adenovirus vector enters the cells and releases its genes, which are transported to the cell nucleus; thereafter the cell's machinery does the transcription into mRNA and the translation into proteins [14].

The protein of interest is the spike protein, an external protein that enables the SARS-type coronavirus to enter cells through the enzymatic domain of ACE2. Producing it following vaccination will prompt the immune system to attack the coronavirus through antibodies and T-cells if it later infects the body [15]. The working of Covishield is depicted in Fig. 1.

The ingredients present in COVISHIELD™ Vaccine includes L-Histidine, L-Histidine hydrochloride monohydrate, Magnesium chloride hexahydrate, Polysorbate 80, Ethanol, Sucrose, Sodium chloride, Disodium Edetate Dihydrate (EDTA), and Water for injection.

On 1st January 2021, the DCGI approved the emergency or conditional use of AstraZeneca's COVID-19 vaccine AZD1222 (marketed as Covishield). Covishield is developed by the University of Oxford and its spin-out company, Vaccitech. It's a viral vector vaccine based on replication-deficient Adenovirus that causes cold in Chimpanzees. It can be stored, transported and handled at normal refrigerated conditions (2 to 8 °C/ 36 to 46 °F). It has a shelf-life of at least six months.

Covaxin:

Covaxin was developed by Indian pharmaceutical company Bharat Biotech in collaboration with the Indian Council of Medical Research, a government funded biomedical research institute, and its subsidiary the National Institute of Virology.

As an inactivated vaccine, Covaxin uses a more traditional technology that is similar to the inactivated polio vaccine. Initially, a sample of SARS-CoV-2 was isolated by India's National Institute of Virology and used to grow large quantities of the virus using vero cells. From then on, the viruses are soaked in beta-propiolactone, which deactivates them by binding to their genes, while leaving other viral particles intact. The resulting inactivated viruses are then mixed with an aluminium-based adjuvant [16]. Process involved in development of inactivated vaccines is depicted in Fig 2.

The ingredients of COVAXIN includes 6 µg of whole-virion inactivated SARSCoV-2 antigen (Strain: NIV-2020-770), and the other inactive ingredients such as aluminium hydroxide gel (250 µg), TLR 7/8 agonist (imidazoquinolinone) 15 µg, 2-phenoxyethanol 2.5 mg, and phosphate ® buffer saline up to 0.5 ml.

The vaccine is similar to CoronaVac (the Chinese vaccine developed by Sinovac) in that it uses a complete infective SARS-CoV-2 viral particle consisting of RNA surrounded by a protein shell, but modified so that it cannot replicate. Covaxin comes as a two-dose regimen, recommended to be taken 28 days apart [17,18].

Covaxin's phase I trial to assess safety and immunogenicity is published. All 375 subjects who

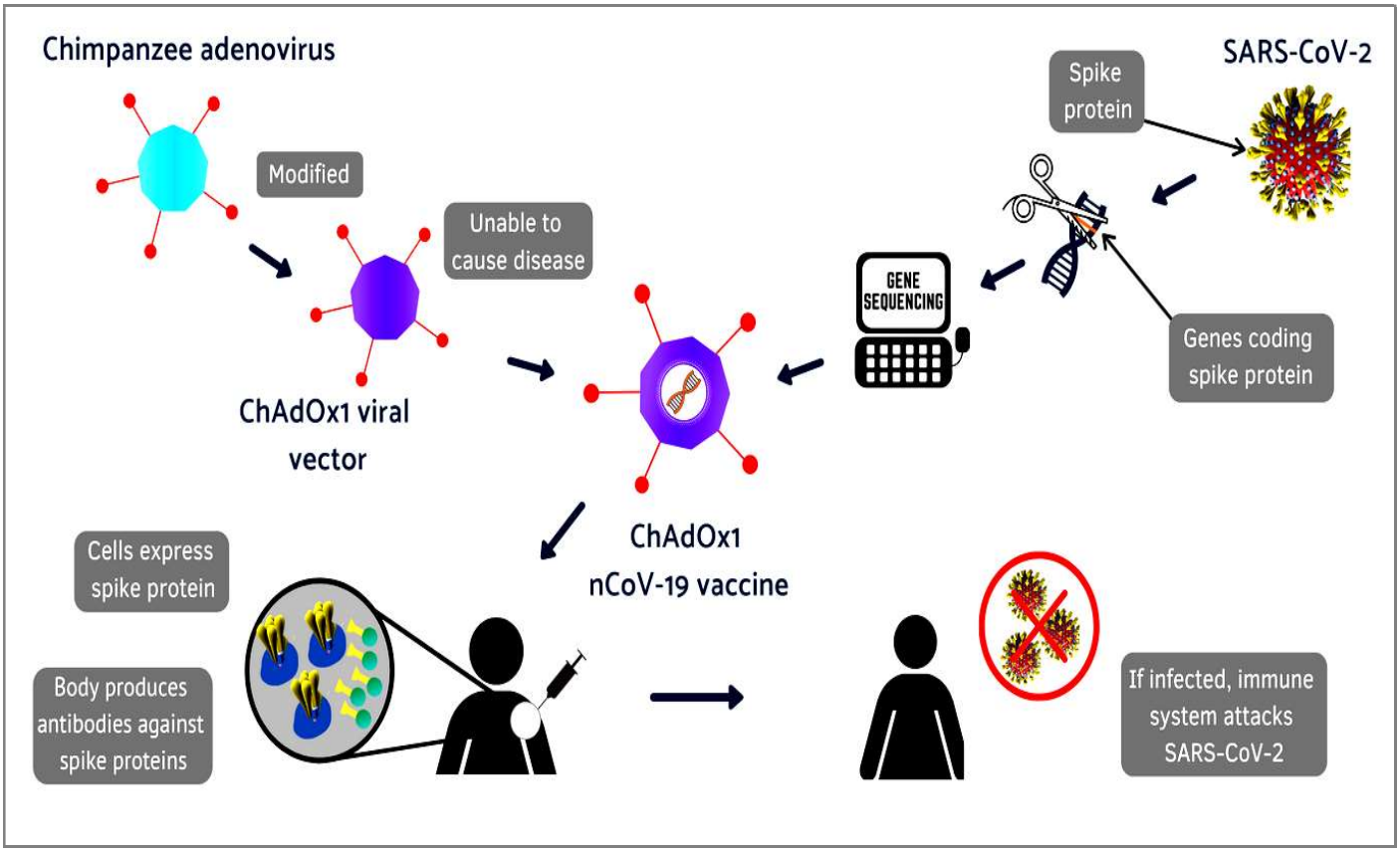

Fig 1. How Covishield works [15]?

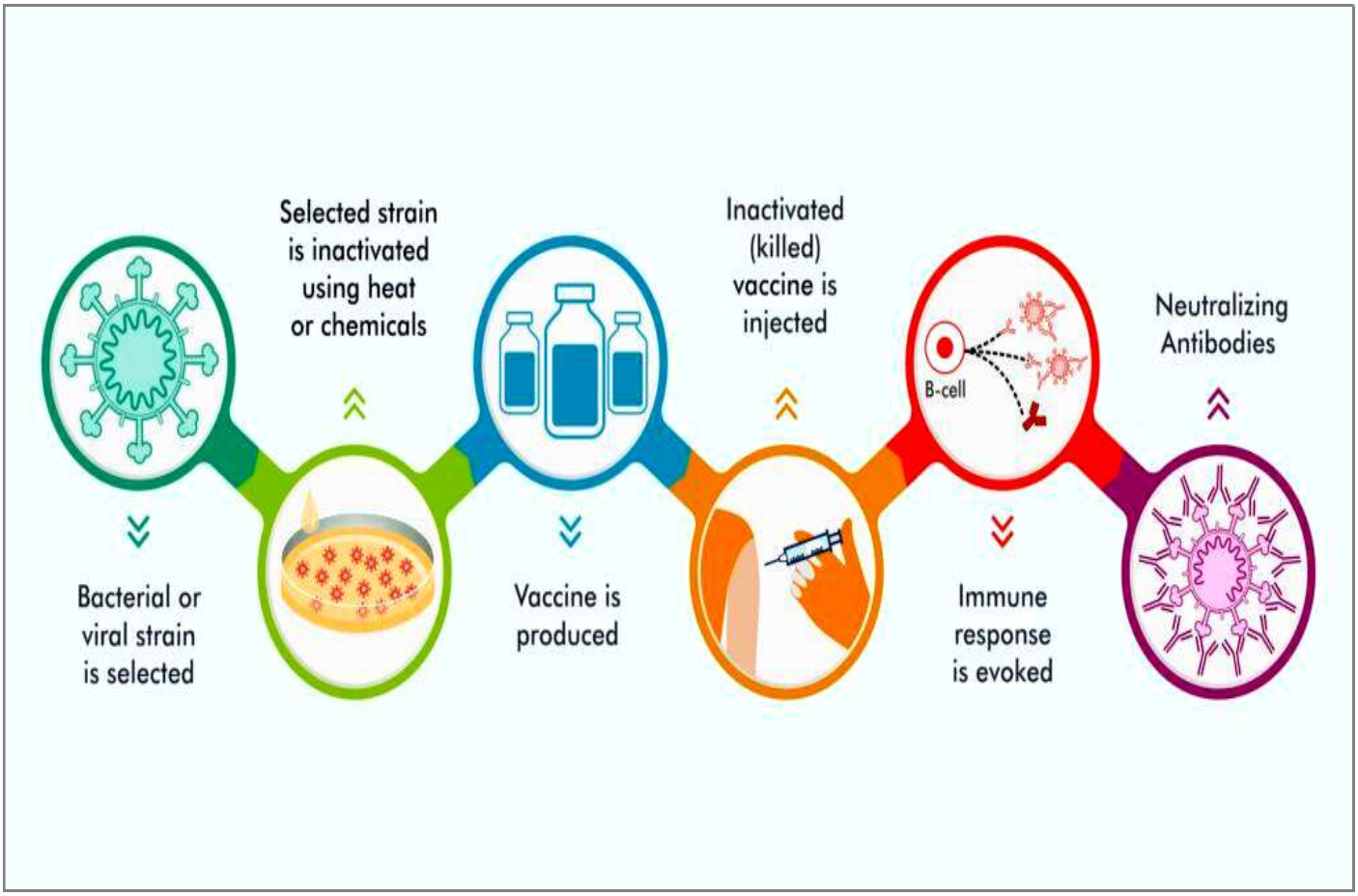

Fig 2. Development of inactivated vaccine [16].

received the vaccine had notably elevated antibody response. The phase II trial result has not yet been published in a peer reviewed journal, but a preprint has been posted on MedRxiv. The provisional data indicate enhanced immune response and tolerable safety outcomes. Since November, 25 800 participants have been enrolled in ongoing phase III trials.

Side effects that have been reported in the fact sheet of Bharat Biotech COVID-19 vaccine (COVAXIN) include Injection site pain, swelling, redness, itching, headache, fever, malaise/body ache, nausea, vomiting, and Rashes. A severe allergic reaction may very rarely occur after getting a dose of COVAXIN. These may not be all the possible side effects of COVAXIN. Serious and unexpected side effects may occur. COVAXIN is still being studied in clinical trials.

On 2nd January 2021, BBV152 (marketed as Covaxin), became the first domestically-produced vaccine to receive approval from the Drug Controller General of India for its emergency or conditional usage. This approval was met with some concern as the vaccine had not yet completed its phase 3 trials. On 3 March 2021, Bharat Biotech reported that Covaxin showed 81 % efficacy in a phase 3 trial with 25,800 participants. On 20th April 2021, Bharat Biotech announced that it had expanded its production capabilities for Covaxin to 700 million doses per-year, including facilities in Bangalore and Hyderabad. In April 2021, Haffkine Institute procured manufacturing rights via technology transfer from ICMR to produce the vaccine in India along with Bharat Biotech [19-22].

Sputnik-V:

A third coronavirus vaccine has been approved for use in India amid a deadly second wave of infections. Sputnik V is a viral vector vaccine for COVID-19 developed by the Gamaleya Research Institute of Epidemiology and Microbiology. Registered on 11 August 2020 by the Russian Ministry of Health as Gam-COVID-Vac Sputnik V is an adenovirus viral vector vaccine. The "V" in the name is the letter V, not the Roman numeral for five [23,24].

Gam-COVID-Vac was initially approved for distribution in Russia on the preliminary results of Phase I–II studies eventually published on 4th September 2020 [25].

The quick approval in early August of Gam-COVID-Vac was met with criticism in mass media and precipitated discussions in the scientific community whether this decision was justified in the absence of robust scientific research confirming the safety and efficacy of the vaccine [26].

However, on 2nd February 2021, an interim analysis from the trial was published in The Lancet, indicating 91.6 % efficacy without unusual side effects [27].

Emergency mass-distribution of the vaccine began in December 2020 in multiple countries including Russia, Argentina, Belarus, Hungary, Serbia and the United Arab Emirates. By February 2021 over a billion doses of the vaccine had been ordered for immediate distribution globally.

Gam-COVID-Vac is a viral two-vector vaccine based on two human adenoviruses – a common cold virus – containing the gene that encodes the full-length spike protein (S) of SARS-CoV-2 to stimulate an immune response. The Gam-COVID-Vac vaccine was developed by a cellular microbiologist's team of the government-backed Gamaleya Research Institute of Epidemiology and Microbiology.

The group was led by MD and RAS associate member Denis Logunov, who also worked on vaccines for the Ebolavirus and the MERS-coronavirus.

The active component for both vectors is a modified (recombinant) replication-defective adenovirus of a different serotype (Serotype 26 containing $1.0 \pm 0.5 \times 10^{11}$) particles of gene for the first vaccination and serotype 5 containing $(1.0 \pm 0.5) \times 10^{11}$ particles of gene for the second vaccination), which has been modified to include the spike protein-expressing gene of SARS-CoV-2.

As per the official datasheet, the ingredients (excipients) include Tris(hydroxymethyl)aminomethane, Sodium chloride (salt), Sucrose (sugar), Magnesium chloride hexahydrate, Disodium EDTA dihydrate (buffer), Polysorbate 80, Ethanol 95 % and Water.

The recombinant adenovirus types 26 and 5 are both used as vectors in the vaccine. They were biotechnology-derived and contain the SARS-CoV-2 S protein cDNA. Both of them are administered into the deltoid muscle: the Ad26-based vaccine is used on the first day and the Ad5 vaccine is used on the 21st day to boost immune response.

The vaccine can be formulated in two ways: as a ready-to-use solution in water that is frozen at the common home-freezer storage temperature of −18 or 0 °F or lower; and as a freeze-dried powder, "Gam-COVID-Vac-Lyo", whose storage temperature is above freezing, 2 to 8 °C or 36 to 46 °F, at the common home-

refrigerator temperature. The freeze-dried powder must be reconstituted with water before use.

The production of the frozen liquid formulation was developed for large-scale use, it is cheaper and easier to manufacture.

The production of the freeze-dried formulation takes much more time and resources, although it is more convenient for storage and transportation. It was developed with vaccine delivery to hard-to-reach regions of Russia in mind [25,27].

A single-dose version is also being developed to speed up vaccination outside Russia. It will offer less protection than the two-dose versions, but it is still expected to reach an efficacy of 85 %.

On 12th April 2021, an expert panel approved the Sputnik-V vaccine's emergency use in India. Sputnik-V conducted the phase-III clinical trial in India in September 2020, and the result of the trials showed 91.6 % efficacy.

Other vaccine candidates under development in India:

The other candidates which are in different stages of trials in India to test safety and efficacy include:

i) ZyCov-Di is developed by Ahmedabad-based Zydus-Cadila. Zydus Cadila, focused on discovering and developing NCEs, Novel Biologicals, Biosimilars and Vaccines, announced that its plasmid DNA vaccine to prevent COVID-19, ZyCoV-D. Safety in Phase I clinical trial of ZyCoV-D in healthy subjects established as endorsed by the independent Data Safety Monitoring Board (DSMB). Zydus commenced Phase II trial.

ii) A vaccine being developed by Hyderabad-based Biological E, the first Indian private vaccine-making company, in collaboration with US-based Dynavax and Baylor College of Medicine. Biological E. Limited is conducting a prospective open label randomised Phase-I seamlessly followed by Phase-II study to assess the safety, reactogenicity and immunogenicity of Biological E's novel COVID-19 vaccine containing Receptor Binding Domain of SARS-CoV-2 for protection against COVID-19 disease when administered intramuscularly in a two-dose schedule (0, 28D) to healthy volunteers.

iii) HGCO19, India's first mRNA vaccine made by Pune-based Genova in collaboration with Seattle-based HDT Biotech Corporation, using bits of genetic code to cause an immune response. mRNA based vaccine (HGCO19) is under development. Randomized, Phase I/II, Placebo-controlled, Dose-Ranging, study to evaluate the Safety, Tolerability and Immunogenicity of the candidate HGCO19 (COVID-19 vaccine) in healthy adult subjects are in progress. The trial is being conducted by Gennova Biopharmaceuticals Limited.

iv) A nasal vaccine is developed by Bharat BioTech (BBV154 - Intranasal vaccine). Bharat Biotech is conducting a Multicenter Study to Evaluate the Reactogenicity, Safety, and Immunogenicity of an Intranasal Adenoviral vector COVID-19 vaccine (BBV154) in Healthy Volunteers. BBV154 is an intranasal vaccine that stimulates a broad immune response – neutralizing IgG, mucosal IgA, and T cell responses. Immune responses at the site of infection (in the nasal mucosa) – essential for blocking both infection and transmission of COVID-19.

v) COVOVAX is a one more vaccine being developed by Serum Institute of India and American vaccine development company Novavax. Indian Council of Medical Research and Serum Institute of India jointly performing a phase 2/3, observer-blind, randomized, controlled study to determine the safety and immunogenicity of COVOVAX [SARS-CoV-2 recombinant spike protein nanoparticle vaccine (SARS-CoV-2 rS) with Matrix-M1™ adjuvant] in Indian adults [28,29].

CONCLUSION:

Vaccination is one of the most cost-effective strategies for prevention of diseases. Even if a safe and effective vaccine is available, it may not be possible to obtain the required number of doses, cold chain maintenance, cost and other logistics of mass vaccination especially in developing countries like India. With the public sector investing heavily in the development of these vaccines, there are growing calls for universal vaccine accessibility, but nationalistic, geographical, and commercial factors could stand in the way. The vaccine therefore may not be the only panacea for the prevention and stopping of the pandemic, if it continues. We might have to follow general hygienic measures including, hand washing, wearing mask, cough and sneeze etiquette and social distancing for some more time before the pandemic of COVID-19 gets over on its own.

ACKNOWLEDGEMENT:

Authors are very much thankful to Dr. Paraag Gide, Principal, Hyderabad (Sindh) National Collegiate Board's Dr. L. H. Hiranandani College of pharmacy, Ulhasnagar for his continuous support, guidance, and encouragement.

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Conflict of Interest: None
Source of Funding: Nil
Paper Citation: Pawar HA*, Pawar AH, Pawar SA, Pawar PA. COVID-19 Vaccines approved for use and under development in India: An overview. J Pharm Adv Res, 2021; 4(6): 1277-1284.