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REGULATORY APPROVAL PROCESS FOR SPUTNIK VACCINE APPROVAL IN INDIA

Mohamad Ali Ahamad[1*], Gottipati Meghana[2], Sampathi Mahi Varshini[3], M. V. Nagabhushanam[4], Y. Ratna Sindhu[5], Brahmaiah Bonthagarala[6], G. Ramakrishna[7], Santosh Kumar Ch[8]

[1]Department of Pharmaceutical Regulatory Affairs, Hindu College of Pharmacy Amaravathi Road, Guntur, Andhra Pradesh, India-522002.

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Abstract:

The human world and man lifestyle was completely shaken and changed with the outbreak of novel corona virus (Covid-19) which begun in Wuhan, China in Dec 2019 was declared a pandemic by World Health Organization on 11 March 2020. To stop this uncontrollable and life-threatening virus scientists from all over the world started research to find a solution or cure to this evil virus and to protect mankind. In this process vaccine was proved to be a better solution to put a check to this pandemic virus. In this article we wanted to brush up your knowledge on covid-19 and various vaccines in market and to educate the regulatory process for approval of sputnik V in India.

Keywords: *Sputnik V, pandemic virus, Vaccines, World Health Organization, covid-19, Regulatory Approval Process.*

Corresponding author:

Mohamad Ali Ahamad,

IV/IV B.Pharmacy, Department of Pharmaceutical Regulatory Affairs, Hindu College of Pharmacy, Amaravathi Road, Guntur, Andhra Pradesh, India-522002.

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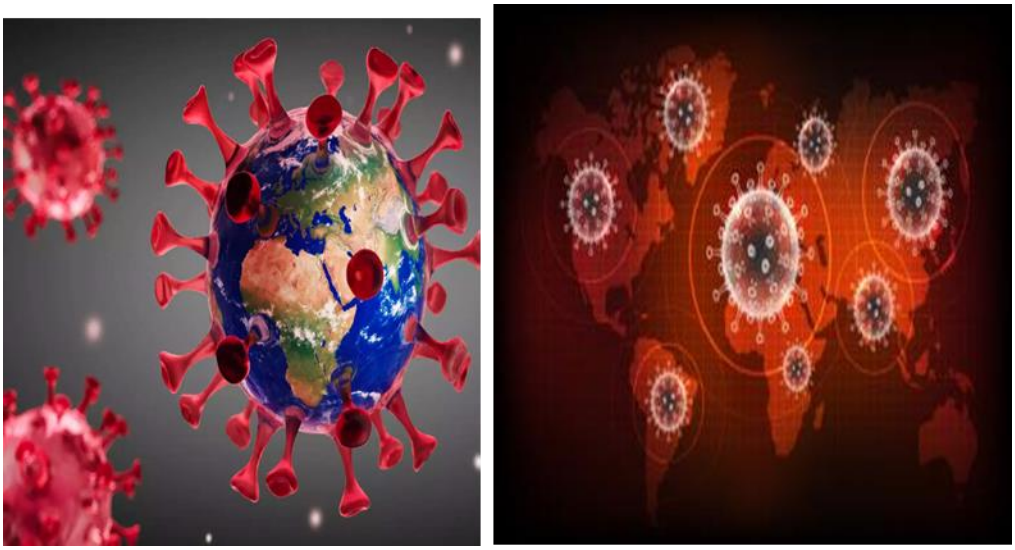
INTRODUCTION:

The year 2020 began with a rapidly spreading illness with initial flu-like symptoms, which worsen respiratory distress, pneumonia and lead to death in severe cases. The disease is identified as being caused by a "novel corona virus". Patients with this disease were first reported in Wuhan city, Hubei province in China, probably around the end of October 2019. The disease is now globally known as COVID19 (corona virus disease for the year 2019). Based on the phylogenetic analysis of related corona viruses, the Coronavirus Study Group of the International Committee on Taxonomy of Viruses named the causative virus SARSCoV2.

Initially, China and the World Health Organization (WHO) considered it as a non-communicable disease. However, it would soon proved wrong, as the virus was spreading it got worse in Wuhan and some other provinces in China and then imported via travelers to other countries, making it global in a very short time.



The disease landed in India on January 30, 2020, when the first patient traveled from Wuhan city to Kerala. Considering the worsening of the scenario on January 30, 2020, the WHO declared the disease a "public health emergency of international concern" (USPPI) and in a short time, on March 11, 2020, it was declared as pandemic importance (status report 24, February 13, 2020.WHO, Geneva, 2020).

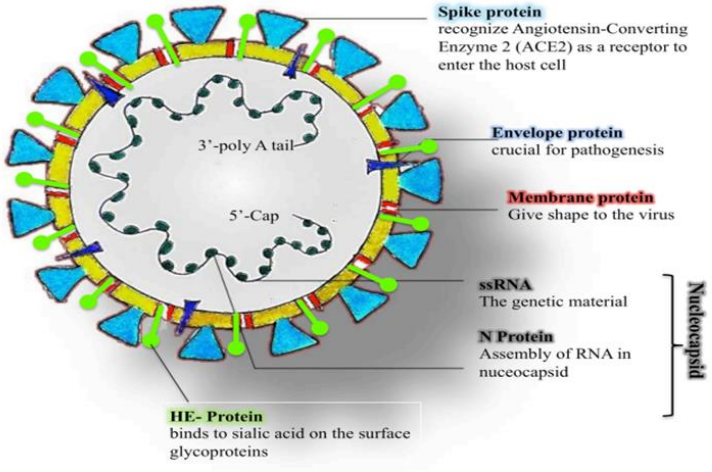


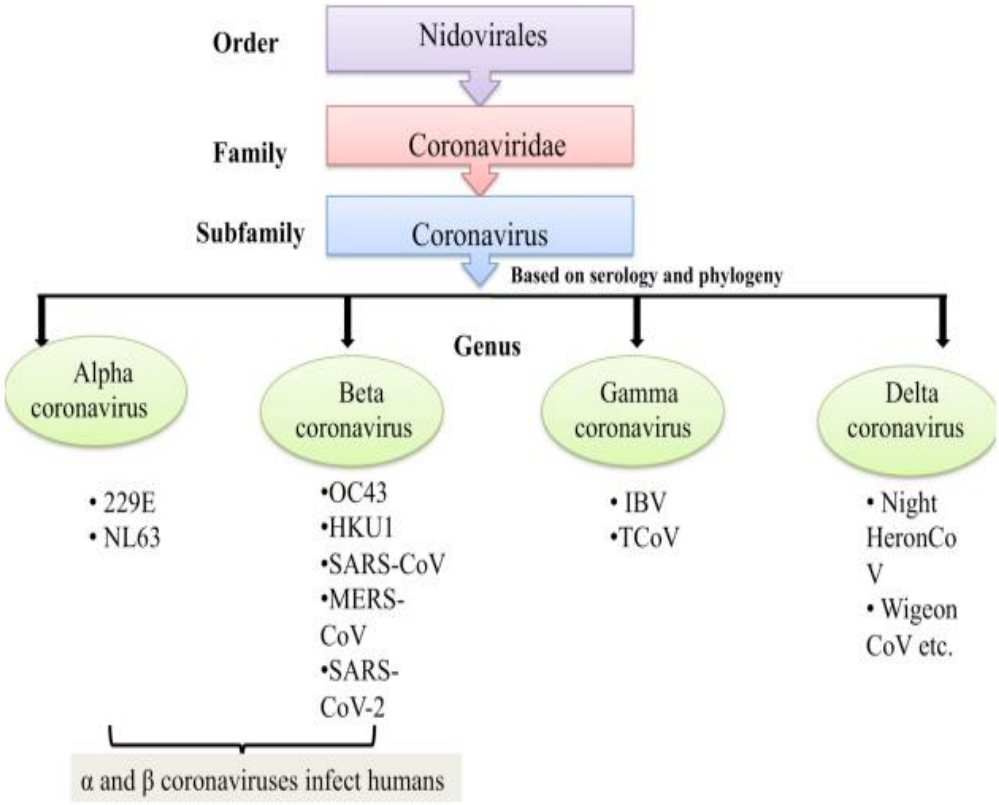
Fig-1- Structure of COVID19 Virus

The virus has infected 35, 57,235 people and caused 2, 45,150 deaths worldwide with a global mortality rate of 34% as of May 6, 2020, which continues to rise. COVID19 falls into the category of rare diseases where the infectious agent undergoes zoonotic transmission and passes from animals to humans. Ebola, SARS, MERS, are other examples of such diseases.

COVID19 is a respiratory disease and infected patients experience high fever, wheezing (difficulty breathing or wheezing) and acute invasive lesions in both lungs. Most reported fatalities are due to respiratory failure, but the virus also affects the heart and liver

Structural Description Of Covid 19 [7,8]:
The virion belongs to a broad category of enveloped viruses and has projections of glycoprotein's, which facilitate its entry into the host cell. The complete corona virion is spherical and has a diameter of approximately 125 nm. The outer body of the virion contains structural proteins, namely spike (S), envelope (E), membrane proteins (M) .the club-shaped spears on the surface give the virion the appearance of a solar corona seen during an eclipse, the class is called corona virus. The SARSCoV2 genome contains 29,891 nucleotides, coding for 9,860 amino acids and it looks more like SARS than MERSCoV. Moreover, there are also several accessory proteins that facilitate viral replication in the host cell.

DID CORONA VIRUS ATTACKED BEFORE [9,10]:
Yes, the family of covid 19was not new and had shown up before the details of its various types and classification are as following



The causative agent of the disease COVID19, the SARSCoV2 virus, is not the only corona virus that has infected humans. It belongs to a large family of corona viruses, known since 1931. Interestingly, the first corona virus that infected humans was isolated in 1965. Based on serology and phylogeny, corona viruses are classified into four genera, of which Alpha and beta corona viruses are known to infect humans (Fig. 1). Interestingly, corona viruses tend to cross species barriers by acquiring new mutations.

Human corona viruses (hCoV) 229E and OC43 cause the common cold as endemic; they have likely crossed species over the past 200 years. Corona virus outbreaks, deadly to the human race, were reported before COVID19. In 2002, Guangdong province in southern China reported severe acute respiratory syndrome (SARS), caused by the βSARS corona virus (SARSCoV). Most recently, in 2012, Middle East Respiratory Syndrome (MERS).) was triggered by the β corona virus MERSCoV in Saudi Arabia and zoonotically transmitted by Arabian camels (Camelus dromedarius) to humans. A detailed comparison of SARSCoV, MERS, and SARSCoV2 is shown in Table 1. Therefore, corona viruses have long been known to infect humans, but before the SARS outbreak, they were known only for respiratory infections benign. It is important to note that the death rate in COVID-19 is although lower than that in case of the SARS and MERS, yet it is far more contagious and widespread.

Table 1 : Comparative of SARS-CoV, MERS-CoV and SARS-CoV-2.The data is presented here is from WHO.

	SARS (Source-WHO SARS)	**MERS (Source-WHO MERS)**	**SARS-COV-2 (CSSE)**
Origin	Guangdong,China 2002	Saudi Arabia, 2012	Wuhan, China 2019
Naturalreservoir	Bat	Bat	Bat
Intermediate host	Palm civet	Camel	Unknown
Last case reported	5th July 2003	13th Jan 2003	Ongoing
Incubation time	2-7days	6 days	2-14 days
Reproductive no.	1.5-3.5	<1	2.2-2.6
Cellular receptor	ACE2	DPP(also known as CD26)	ACE2
Countries infected	29	27	209
Causalities	809, 10% of total reported cases	861, 34.4% of total reported cases	30,105, 3.4% of total reported cases
Transmission	• Close contact with infected patients (droplets, aerosol) • Fomites	• Limited human to human transmission • Mainly by close contact with infected camels or consuming their meat/milk.	• Close contact with infected patients (droplets, aerosol) • Fomites

Mechanism of action of covid 19:

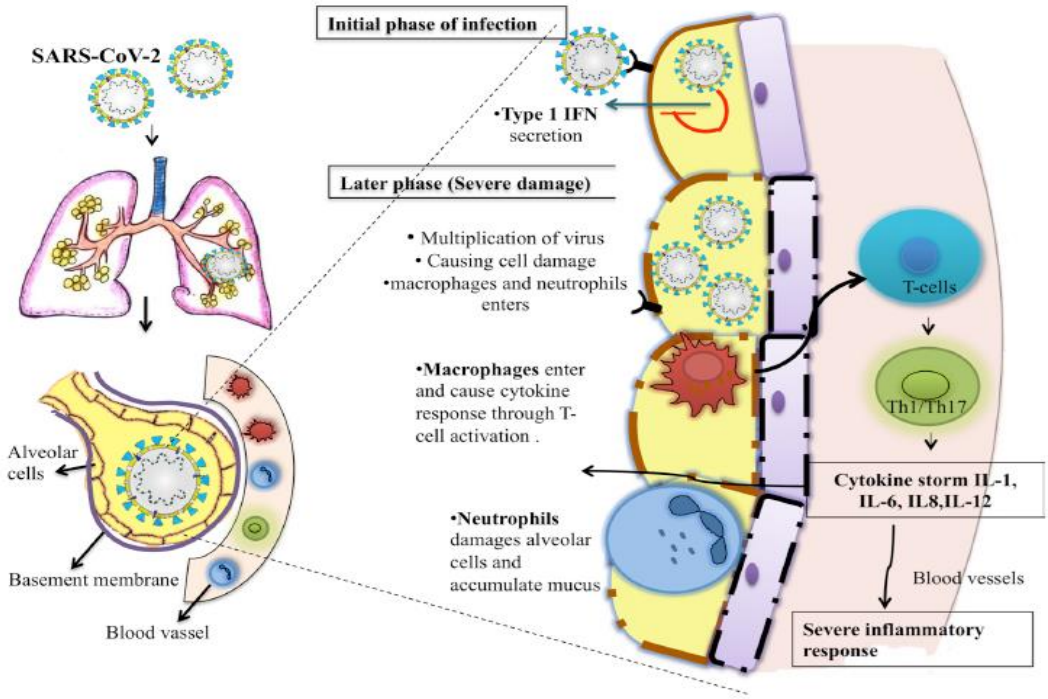


Fig-2- Mechanism of action of covid 19

INTRODUCTION OF VACCINES IN TREATMENT OF COVID 19 [10-14]:

Definition:

A substance used to stimulate the production of antibodies and provide immunity against one or several diseases, prepared from the causative agent of a disease, its products, or a synthetic substitute, treated to act as an antigen without inducing the disease.

Need of vaccination against covid-19:

What You Need to Know

- Getting vaccinated against COVID-19 can lower your risk of getting and spreading the virus that causes COVID-19. Vaccines can also help prevent serious illness and death.
- All steps have been taken to ensure that vaccines are safe and effective for people ages 5 years and older.
- If you already had COVID-19, you should still get a COVID-19 vaccine for added protection.
- When you are up to date on COVID-19 vaccination, you can resume many activities with proper precautions (e.g., mask wearing in indoor public spaces).

COVID-19 Vaccination Is a Safer Way to Build Protection

Getting a COVID-19 vaccination is a safer way to build protection than getting sick with COVID-19. COVID-19 vaccination helps protect you by creating an antibody response without you having to experience sickness.

Getting sick with COVID-19 can have serious consequences.

- Getting sick with COVID-19 can cause severe illness or death, even in children, and we can't reliably predict who will have mild or severe illness.
- You may have long-term health issues after COVID-19 infection. Even people who do not have symptoms when they are initially infected can have these ongoing health problems.
- People who are sick with COVID-19 may spread COVID-19 to others including friends and family who are not eligible for vaccination and people at increased risk for severe illness from COVID-19

COVID-19 Vaccines Are Safe for Children and Adults

While COVID-19 vaccines were developed quickly, all steps have been taken to ensure their safety and effectiveness.

- Hundreds of millions of people in the United States have received COVID-19 vaccines under the most intensive safety monitoring program in U.S. history.
- A growing body of evidence shows that the benefits of COVID-19 vaccination outweigh the known and potential risks. CDC recommends an mRNA COVID-19 vaccine (Pfizer-Biotech or Moderna) in most circumstances based on an updated risk-benefit analysis.

Before recommending COVID-19 vaccines, including for children ages 5 years and older, scientists conducted clinical trials with thousands of adults and children and found no serious safety concerns. Learn more about the benefits of COVID-19 vaccination for children and teens.

Everyone who receives a COVID-19 vaccine can participate in safety monitoring by enrolling themselves and their children ages 5 years and older in **v-safe** and completing health check-ins after their COVID-19 vaccination. Parents and caregivers can create or use their own account to enter their children's information.

COVID-19 vaccines are effective:

COVID 19-vaccines are effective and can lower your risk of getting and spreading the virus that causes COVID-19. COVID-19 vaccines also help prevent serious illness and death in children and adults even if they do get COVID-19. Vaccines become less effective at preventing infection or severe illness over time, especially for people ages 65 years and older. This is why booster shots are recommended for people ages 12 years and older who have completed their primary vaccination series. However, even as the vaccine's ability to prevent infection decreases with time, COVID-19 vaccination continues to reduce the risk of hospitalization and death when people become infected with COVID-19. People who have certain medical conditions or who are taking medications that weaken their immune system may not be completely protected even if they completed the primary vaccination series. Some people who are moderately or severely immuno compromised should get an additional primary dose of COVID-19 vaccine and a booster shot.

About Variants:

Viruses are constantly changing, including the virus that causes COVID-19. These changes occur over time and can lead to the emergence of variants that may have new characteristics. Vaccines continue to reduce a person's risk of contracting the virus that causes COVID-19. Vaccines are highly effective against severe illness.

COVID-19 vaccination is a more reliable way to build protection:

The level of protection people get from having COVID-19 (sometimes called natural immunity) may vary depending on how mild or severe their illness was, the time since their infection, and their age; and there is still not an antibody test available that can reliably determine if a person is protected from further infection. All COVID-19 vaccines currently available in the world are effective at preventing COVID-19. Staying up to date with COVID-19 vaccination gives most people a high level of protection against COVID-19.You should get a COVID-19 vaccine, even if you already had COVID-19. Emerging evidence shows that getting a COVID-19 vaccine after you recover from COVID-19 illness provides added protection to your immune system.

DIFFERENT VACCINES AVAILABLE IN WORLD [15-17]:

Sl. No.	Name of Vaccines	Developer of the Vaccines	Country of Origin	Dose	Efficacy	Stability (Temperature °C)	Technological Platforms	Clinical Trials No	References
1.	Ad5-nCoV	Beijing Institute of Biotechnology, CanSino Biologics	China	Single dose	66%	2–8	Modified adenovirus vector vaccines	NCT04380701, NCT04523571, NCT04368728, NCT04368728	[45]
2.	BBIBP-CorV (Sinopharm)	China National Pharmaceutical Group Corporation, Beijing Institute of Biological Products, Wuhan Institute of Biological Product	China	Double doses (four to three weeks interval)	79.3%	2–8	Conventional inactivated vaccines	NCT04560881	[46]
3.	Sputnik V (Gamaleya)	Gamaleya Research Institute of Epidemiology and Microbiology	Russia	Double doses (three weeks interval)	91.6%	18	Viral vector vaccines	NCT04436471, NCT04437875, NCT04530396	[47]
4.	ZF2001 (RBD-Dimer)	Chinese Academy of Sciences, Anhui ZhifeiLongcom Biologic Pharmacy Co. Ltd.	China	Triple doses (30 days interval)	72%	-	Protein subunit vaccines	NCT04646590	[48]
5.	CoronaVac	Sinovac Biotech Ltd.	China	Double doses (two weeks interval)	78%	2–8	Conventional inactivated vaccines	NCT04551547, NCT04383574, NCT04352608, NCT04617483, NCT04582344, NCT04508075	[49]
6.	EpiVacCorona	State Research Center of Virology and Biotechnology VECTOR	Russia	Double doses (four weeks interval)	-	2–8	Protein subunit vaccines	NCT04527575, NCT04780035	[50]
7.	BBV152 (Covaxin)	Indian Council of Medical Research (ICMR), and Bharat Biotech Ltd.	India	Double doses (four weeks interval)	81%	2–8	Conventional inactivated vaccines	NCT04641481, NCT04471519	[51]
8.	CoviVac	Russian Academy of Sciences	Russia	Double doses (two weeks interval)	-	2.8	Conventional inactivated vaccines	NCT04619628	[52]

Sputnik the first savior [18]:

Sputnik V is the world's first registered vaccine based on a well-studied human adenovirus vector platform. It has been approved for use in 71 countries with a total population of 4 billion people. The vaccine is named after the first Soviet space satellite. The launch of Sputnik-1 in 1957 reinvigorated space research around the world, creating a so called "Sputnik moment" for the global community. The vaccine's efficacy is 91.6%, based on the analysis of data on the incidence of corona virus among Russians vaccinated with both vaccine components between December 5, 2020 and March 31, 2021. Phase 1 and 2 clinical trials for the vaccine were completed on August 1, 2020. The Phase 3 clinical trial results were published in Russia in the Lancet magazine on February 2, 2021. Phase 3 clinical trials of Sputnik V have also been successful in the UAE, India, Venezuela and Belarus.

The Sputnik V vaccine is based on a proven well-studied human adenovirus vector platform; these vectors cause the common cold and have plagued humanity for millennia.

Sputnik V was the first corona virus vaccine to use a heterogeneous boosting approach based on 2 different vectors for 2 vaccine shots. This approach generates a more sustainable immunity compared to vaccines that use the same delivery mechanism for both shots.

The safety, efficacy and lack of long-term adverse effects of adenovirus vaccines have been proven in more than 250 clinical trials over two decades.

Sputnik V does not cause severe allergies:

A storage temperature of +2…+8 °C allows the vaccine to be stored in a regular refrigerator without the need to invest in additional cold chain infrastructure.

Sputnik V is effective against new strains of corona virus, according to a study by the Gamaleya Research Institute for Epidemiology and Microbiology published in the leading international magazine Vaccines.

The vaccine produces protective neutralizing antibody titres against new strains, including Alpha B.1.1.7 (first identified in the UK), Beta B.1.351 (first identified in South Africa), Gamma P.1 (first identified in Brazil), Delta B.1.617.2 and B.1.617.3 (first identified in India) and variants B.1.1.141 and B.1.1.317 with mutations in the receptor-binding domain (RBD) identified in Moscow.

Preliminary laboratory study by the Gamaleya Center shows that Sputnik V demonstrates high virus neutralizing activity against Omicron variant and is expected to protect against severe cases and hospitalizations.

Sputnik V has demonstrated 3-7x less of a reduction in virus neutralizing activity against Omicron as compared to data from other leading vaccines.

How adenoviral vector-based vaccines work [19-22]:
"Vectors" are vehicles, which can induce a genetic material from another virus into a cell. The gene from adenovirus, which causes the infection, is removed while a gene with the code of a protein from another virus spike is inserted. This inserted element is safe for the body but still helps the immune system to react and produce antibodies, which protect us from the infection.

The technological platform of adenovirus-based vectors makes it easier and faster to create new vaccines through modifying the initial carrier vector with genetic material from new emerging viruses that helps to create new vaccines in relatively short time. Such vaccines provoke a strong response from a human immune system.

Human adenoviruses are considered as some of the easiest to engineer in this way and therefore they have become very popular as vectors.

Safety and efficacy [24]:
After the start of the COVID-19 pandemic Russian researchers extracted a fragment of genetic material from novel corona virus SARS-COV-2, which codes information about the structure of the spike S-protein, which forms the virus' "crown" and is responsible for connection with human cells. They inserted it into a familiar adenovirus vector for delivery into a human cell creating the world's first COVID-19 vaccine.

In order to ensure lasting immunity Russian scientists came up with a breakthrough idea to use two different types of adenovirus vectors (rAd26 and rAd5) for the first and second vaccination, boosting the effect of the vaccine.
The use of human adenoviruses as vectors is safe because these viruses, which cause the common cold, are not novel and have been around for thousands of years.

Efficacy of Sputnik V against COVID-19 was reported at 91.6%. The figure is based on the analysis of data on 19,866 volunteers, who received both the first and second doses of the Sputnik V vaccine or placebo at the final control point of 78 confirmed COVID-19 cases. Sputnik V's efficacy was validated by internationally peer reviewed data published in The Lancet.

Efficacy against new strains [25]:
On 12.07.2021, a study on the efficacy of Sputnik V against new strains of corona virus was published in the leading international magazine Vaccines by the Gamaleya Research Institute for Epidemiology and Microbiology.

The vaccine produces protective neutralizing antibody titres against new strains including Alpha B.1.1.7 (first identified in the UK), Beta B.1.351 (first identified in South Africa), Gamma P.1 (first identified in Brazil), Delta B.1.617.2 and B.1.617.3 (first identified in India) and variants B.1.1.141 and B.1.1.317 with mutations in the receptor-binding domain (RBD) identified in Moscow.

The study methodology was based on assessing the viral neutralizing activity (VNA) using live virus, which provides the most reliable data and is the accepted standard. The study compared the VNA of human serum after vaccination with Sputnik V on global strain samples with the VNA against the original strain B.1.1.1. Serum was sampled from individuals immunized with both components of Sputnik V.

The data obtained demonstrate that Sputnik V retains its protective properties against new strains. The reduction in viral neutralizing activity of Sputnik V against a number of strains was significantly lower compared to data published by manufacturers of other vaccines that earlier confirmed their efficacy against new corona virus mutations.

SPUTNIK V APPROVAL IN INDIA [26-30]:
India's drug regulatory body (CDSCO) had given approval to Russia's Sputnik V vaccine for restricted use in the country; sources within the drug regulator's office had confirmed the development on April 12 2021.

Sputnik V demonstrated a 91.6% efficacy rate in the interim analysis of the Phase 3 clinical trial, which included data on 19,866 volunteers in Russia. In February 2021, Dr Reddy had requested emergency use of the Sputnik V vaccine.

India now has a set of three vaccines, Covishield from Serum Institute, Covaxin from Bharat Biotech, and Russian Sputnik V for vaccination against infection in the country which has recently seen a record spike in virus cases.
The approval of the Russian Sputnik V vaccine in India is also of significance as several states have

reported that the stock of vaccine doses has run out, requesting an urgent supply.

In February, Hyderabad-based pharmaceutical manufacturer Dr. Reddy's Laboratories had launched the Emergency Use Authorization (EUA) application process in India for the Russian Covid19 vaccine candidate Sputnik V. It then completed the trial on 1,300 participants in India as part of its bridging studies.

The CDSCO expert committee then met to discuss the limited use request and requested more data on the Sputnik V vaccine from Dr. Reddy.

Here is what Dr. Reddy was asked [31-36]:

1. Data for all immunogenicity endpoints, including GMT titers for virus neutralizing antibody and SARS-specific glycoprotein COV2 antibody COV2 at day 42, as per to the protocol.
2. Data of all serious adverse events and RTPCR positive cases along with analysis of casualties reported to date.
3. Correlation of immunogenicity data including cellular response between phase 2 and 3 studies.
4. Comparative analysis of phase 3 data generated on Indian and Russian studies at different time points.
5. Leaflets, information sheets, summary of product characteristics including indication, Contradictions on dosage schedule, warning of precautions and storage conditions.
6. Consistency data regarding clinical outcomes. Vaccine in India.

The central government has said it is trying to develop at least seven vaccines to protect its citizen from the pandemic virus COVID-19

CONCLUSION:

The pandemic has completely affected human life and there is no better cure than vaccine at present so every citizen and individual must take vaccine to ensure safety of oneself, one's own family society and to protect the country from the pandemic.

Sputnik V is an effective vaccine with 91.7% efficiency and it is approved all over the world and India regulatory gave it license as an emergency drug after undergoing a series of safety and efficacy tests. It provides us surety that the vaccines are safe to use and ensure public safety thus now it's over duty to join the battle and fight against covid -19 by getting ourselves vaccinated.

CAUTION:

This article is only meant for education purpose it has nothing to deal with copyrights or advertisement of any particular company. The main object behind this article is to create awareness about covid-19 its vaccines and safety measures taken by Indian regulatory body before giving permission to any covid-19vacccine or medicine.

REFERENCES:

1. Sohrabi, C.; Alsafi, Z.; O'Neill, N.; Khan, M.; Kerwan, A.; Al-Jabir, A.; Iosifidis, C.; Agha, R. World Health Organization declares global emergency: A review of the 2019 novel corona virus (COVID-19). Int. J. Surg. 2020, 76, 71–76. [CrossRef]
2. Li, R.; Pei, S.; Chen, B. Substantial undocumented infection facilitates the rapid dissemination of novel corona virus (SARS-CoV2). Science 2020, 368, 489–493. [CrossRef] [PubMed]
3. Elbek, O. COVID-19 Outbreak and Turkey. Turk. Thorac. J. 2020, 21, 215. [PubMed]
4. Kumar, S.U.; Kumar, D.T.; Christopher, B.P.; Doss, C. The rise and impact of COVID-19 in India. Front. Med. 2020, 7, 250. [CrossRef] [PubMed]
5. Susanto, A.P.; Findyartini, A.; Taher, A.; Susilaradeya, D.P.; Ariawan, I.; Dartanto, T.; Takwin, B.; Prasodjo, I.B.; Yusuf, P.A.; Sudarmono, P.P.; et al. COVID-19 in Indonesia: Challenges and Multidisciplinary Perspectives for a Safe and Productive New Normal. Acta Med. Indones. 2020, 52, 423–430.
6. Kafieh, R.; Arian, R.; Saeedizadeh, N.; Amini, Z.; Serej, N.D.; Minaee, S.; Yadav, S.K.; Vaezi, A.; Rezaei, N.; Javanmard, S.H. COVID-19 in Iran: Forecasting Pandemic Using Deep Learning. Comput. Math. Methods Med. 2021, 2021, 6927985. [CrossRef]
7. OECD/WHO. The impact of the COVID-19 outbreak on Asia-Pacific health systems. In Health at a Glance: Asia/Pacific 2020: Measuring Progress Towards Universal Health Coverage; OECD Publishing: Paris, France, 2020. [CrossRef]
8. 8. Triggle, C.R.; Bansal, D.; Farag, E.A.B.A.; Ding, H.; Sultan, A.A. COVID-19: Learning from Lessons To Guide Treatment and Prevention Interventions. mSphere 2020, 5, 5. [CrossRef]
9. Cheng, H.-Y.; Huang, A.S.-E. Proactive and blended approach for COVID-19 control in Taiwan. Biochem. Biophys. Res. Commun. 2021, 538, 238–243. [CrossRef] [PubMed]

10. Chang, I.W.J. Taiwan's Model for Combating COVID-19: A Small Island with Big Data. In COVID-19 in the Middle East and Asia: Impacts and Responses; Ministry of Health and Welfare: Taipei, Taiwan, 2020.
11. Agoramoorthy, G.; Shieh, P. Control of the COVID-19: A Successful Model of a Small Island. Interciencia 2020, 45, 174. Vaccines 2021, 9, 600 25 of 27
12. Yamamoto, N.; Bauer, G. Apparent difference in fatalities between Central Europe and East Asia due to SARS-COV-2 and COVID-19: Four hypotheses for possible explanation. Med. Hypotheses 2020, 144, 110160. [CrossRef] [PubMed]
13. Omer, S.B.; Malani, P.; Del Rio, C. The COVID-19 pandemic in the US: A clinical update. JAMA 2020, 323, 1767–1768. [CrossRef] [PubMed]
14. Haug, N.; Geyrhofer, L.; Londei, A.; Dervic, E.; Desvars-Larrive, A.; Loreto, V.; Pinior, B.; Thurner, S.; Klimek, P. Ranking the effectiveness of worldwide COVID-19 government interventions. Nat. Hum. Behav. 2020, 4, 1303–1312. [CrossRef]
15. Forni, G.; Mantovani, A. COVID-19 vaccines: Where we stand and challenges ahead. Cell Death Differ. 2021, 28, 626–639. [CrossRef]
16. Chakraborty, C.; Agoramoorthy, G. India's cost-effective COVID-19 vaccine development initiatives. Vaccine 2020, 38, 7883–7884. [CrossRef]
17. Vaidyanathan, G. India will supply corona virus vaccines to the world—Will its people benefit? Nat. Cell Biol. 2020, 585, 167–168. [CrossRef] [PubMed]
18. Thiagarajan, K. Covid-19: India is at centre of global vaccine manufacturing, but opacity threatens public trust. BMJ 2021, 372, n196. [CrossRef] [PubMed]
19. Cyranoski, D. China's corona virus vaccines are leaping ahead-but face challenges as virus wanes. Nature 2020, 584, 17–18. [CrossRef] [PubMed]
20. Xiong, C.; Jiang, L.; Chen, Y.; Jiang, Q. Evolution and variation of 2019-novel corona virus. Biorxiv 2020. [CrossRef]
21. Bhattacharya, M.; Sharma, A.R.; Patra, P.; Ghosh, P.; Sharma, G.; Patra, B.C.; Lee, S.S.; Chakraborty, C. Development of epitopebased peptide vaccine against novel corona virus 2019 (SARS-COV-2): Immunoinformatics approach. J. Med. Virol. 2020, 92, 618–631. [CrossRef] [PubMed]
22. Chakraborty, C.; Sharma, A.R.; Bhattacharya, M.; Sharma, G.; Saha, R.P.; Lee, S.-S. Ongoing Clinical Trials of Vaccines to Fight against COVID-19 Pandemic. Immune Netw. 2021, 21, e5. [CrossRef] [PubMed]
23. Cohen, J. With record-setting speed, vaccinemakers take their first shots at the new corona virus. Science 2020, 31. [CrossRef]
24. Thanh Le, T.; Andreadakis, Z.; Kumar, A.; Gómez Román, R.; Tollefsen, S.; Saville, M.; Mayhew, S. The COVID-19 vaccine development landscape. Nat. Rev. Drug Discov. 2020, 19, 305–306. [CrossRef] [PubMed]
25. Le, T.T.; Cramer, J.P.; Chen, R.; Mayhew, S. Evolution of the COVID-19 vaccine development landscape. Nat. Rev. Drug Discov. 2020, 19, 667–668. [CrossRef]
26. Gates, B. Responding to Covid-19—A once-in-a-century pandemic? N. Engl. J. Med. 2020, 382, 1677–1679. [CrossRef] [PubMed]
27. Nuismer, S.L.; May, R.; Basinski, A.; Remien, C.H. Controlling epidemics with transmissible vaccines. PLoS ONE 2018, 13, e0196978. [CrossRef] [PubMed]
28. Greenwood, B. The contribution of vaccination to global health: Past, present and future. Philos. Trans. R. Soc. B Biol. Sci. 2014, 369, 20130433. [CrossRef] [PubMed]
29. Lahariya, C. A brief history of vaccines & vaccination in India. Indian J. Med. Res. 2014, 139, 491–511. [PubMed]
30. Shearer, F.M.; Moyes, C.; Pigott, D.M.; Brady, O.J.; Marinho, F.; Deshpande, A.; Longbottom, J.; Browne, A.J.; Kraemer, M.U.G.; O'Reilly, K.; et al. Global yellow fever vaccination coverage from 1970 to 2016: An adjusted retrospective analysis. Lancet Infect. Dis. 2017, 17, 1209–1217. [CrossRef]
31. Ruck, D.J.; Bentley, R.A.; Borycz, J. Early warning of vulnerable counties in a pandemic using socio-economic variables. Econ. Hum. Biol. 2021, 41, 100988. [CrossRef] [PubMed]
32. Painter, E.M.; Ussery, E.N.; Patel, A.; Hughes, M.M.; Zell, E.R.; Moulia, D.L.; Scharf, L.G.; Lynch, M.; Ritchey, M.D.; Toblin, R.L. Demographic characteristics of persons vaccinated during the first month of the COVID-19 vaccination program—United States, 14 December 2020–14 January 2021. Morb. Mortal. Wkly. Rep. 2021, 70, 174. [CrossRef]
33. 33.Brahmaiah Bonthagarala, Regulatory Requirements for Registration of Generic Drugs in "BRICS" Countries, International Journal of Pharmaceutical Science and Health Care, ISSN 2249 – 5738, Issue 6, Vol. 6 (November-December 2016), 20-39.
34. 34.Brahmaiah Bonthagarala, Current Regulatory Requirements for Registration of Medicines,

Compilation and Submission of Dossier in Australian Therapeutic Goods Administration, International Journal of Advanced Scientific and Technical Research, ISSN 2249-9954, Issue 6 volume 6, November-December 2016, 144-157.

35. 35.Brahmaiah Bonthagarala, Comparison of Regulatory Requirements for Generic Drugs Dossier Submission in United States and Canada, International Journal of Pharmaceutical Science and Health Care, ISSN 2249 – 5738, Issue 6, Vol. 6 (November-December 2016), 1-19.
36. 36.Brahmaiah Bonthagarala, Nanomedicine Clinical Use, Regulatory And Toxicology Issues In Europe, Journal of Drug Delivery and Therapeutics, 2019; 9(4-s):846-848.