



COVID-19 VACCINES INDIA

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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 and platforms. These include viral-vectored, protein subunit, nucleic acid (DNA, RNA), live attenuated, and inactivated vaccines.

Comparative Sheet for different Covid-19 vaccines, under Indian Government supply

INDICATOR	COVISHIELD	COVAXIN	SputnikV
Type of Vaccine	Recombinant COVID-19 Vaccine based on Viral Vector Technology	Whole-Virion Inactivated Corona Virus vaccine	Gam-COVID-Vac combined vector vaccine
Price	As per media communication- INR- 700 to 900 per dose per person for private Sector. Vaccination shall continue as before in Govt. of India vaccination centers, provided free of cost to the eligible population as defined earlier i.e., Health Care Workers (HCWs), Front Line Workers (FLWs) and all people above 45 years of age.	As per media communication- INR- 1250 to 1500 per dose per person for private sector. Vaccination shall continue as before in Govt. of India vaccination centers, provided free of cost to the eligible population as defined earlier i.e., Health Care Workers (HCWs), Front Line Workers (FLWs) and all people above 45 years of age.	The vaccine is currently being imported at a price of Rs 948 a dose, and with a 5 per cent GST, the cost of the vaccine for every dose comes to Rs 995.40 . (Operational charges extra)
No. of doses in each vial	10	20	single dose
Shelf life	6 months	6 months	6 months
Expiry date available on vial	Yes	Yes	Yes
Vaccine Vial Monitor (VVM)	Not Available	Not Available)	Not Available
Route	Intramuscular (IM) Injectable	Intramuscular (IM) Injectable	Intramuscular (IM) Injectable
Physical Appearance of Vaccine	Clear to slightly opaque, colourless to slightly brown	Whitish translucent	freeze dry powder vaccine which makes it easy to store.
Dose	0.5 ml each dose	0.5 ml each dose	0.5 ml each dose
Course	2-doses	2-doses	2-doses
Schedule	12-16 weeks apart	3-4 weeks apart	21 days
Vaccination during Pregnancy	Not recommended	Not recommended	Not recommended
Vaccination < 18 years of age	Not recommended	Not recommended	Not recommended
Vaccination to Lactating mother	Recommended	Recommended	Not recommended

INDICATOR	COVISHIELD	COVAXIN	SputnikV
Storage and transportation	+2°C to +8°C at all levels	+2°C to +8°C at all levels	+2°C to +8°C at all levels
Cold chain storage space in secondary packaging	2.109 cm ³	1.7187 cm ³	–
Shake test	Not applicable	Not applicable	Not applicable
Open Vial Policy	Not applicable	Not applicable	Not applicable
Freeze Sensitive	Yes	Yes	Freeze dry powder
Discard the vaccine vial, if found	'frozen' or 'frozen and thawed'	'frozen' or 'frozen and thawed'	–
Discard the vial, if	The solution is discoloured, or visible particles are observed	Presence of particulate matter or other coloration	The solution is discoloured, or visible particles are observed
AEFI (Adverse event following Immunization)	Some mild AEFIs may occur like injection site tenderness, injection site pain, headache, fatigue, myalgia, malaise, pyrexia, chills arthralgia, nausea.	Some mild AEFIs may occur like injection site pain, headache, fatigue, fever, body ache, abdominal pain, nausea and vomiting, dizziness-giddiness, tremor, sweating, cold, cough, and injection site swelling.	The most common adverse events were flu-like illness, injection site reactions, headache, and asthenia.
AEFI Other	Paracetamol may be used to provide symptomatic relief from post-vaccination adverse reactions Very rare events of demyelinating disorders have been reported following vaccination with this Vaccine without the causal relationship establishment. As with other intramuscular injections, COVISHIELD should be given with caution to individuals with thrombocytopenia	–	–
Any other instruction	–	Shake well, before use. Use of Chloroquine and Corticosteroids may impair antibody response.	–

CONCERNS



Information on the new COVID-19 vaccine

Provide prompt, simple, and focused communication on the COVID-19 vaccine(s) and vaccination processes.



Vaccine Eagerness

Ensure understanding and acceptance of the phased and prioritized approach to overcome concerns of the population waiting for vaccination.



Vaccine Hesitancy

Build public confidence in the safety and efficacy of the new vaccine.



COVID Appropriate Behaviour

Maintain and sustain key preventive behaviour - wearing masks, maintaining physical distance, and handwashing with soap.

GOVERNMENT POLICY

Government Task Force

The main job of this task force will be to work as a bridge between academia, research institutions, and international collaborations in the field of drug testing and vaccine development. The members will be from the Indian Council of Medical Research (ICMR), department of science and technology (DST), Department of Biotechnology (DBT), the council of scientific and industrial research (CSIR), defence research and development organisation (DRDO), directorate general of health services (DGHS) and drug controller general of India (DCGI). This task force will monitor the progress, not just in India but globally, happening in the field of vaccine development and drug trials. They will create a clinical cohort for long-term follow-up of people for achieving a better understanding of disease management.

Eligibility

Authorized beneficiary Group:

All Health Care Workers and Frontline Workers as specified by the MoHFW *

All such citizens that are aged, or will attain the age of, 45 years as on 1st January 2022 (free in central government centers)

Anyone above 18 years to receive anti-Covid shots from May 1 vaccines procured by the state government or open market

Vaccination during Pregnancy



Not recommended

Vaccination below 18 years of age



Not recommended

Vaccination to Lactating mother



Recommended

Rates

Vaccination shall continue as before in Govt. of India vaccination centers, provided free of cost to the eligible population as defined earlier i.e., Health Care Workers (HCWs), Front Line Workers (FLWs) and all people above 45 years of age.

Manufacturers would transparently make an advance declaration of the price for 50% supply that would be available to State Govts. and in open market, before 1st May 2021. Currently, the Serum Institute of India (SII) will charge state governments INR. 300/- per dose and private hospitals INR.600/- per dose for the vaccine. Bharath Biotech will charge state governments INR. 400/- per dose and private hospitals INR.1250/- per dose for the vaccine. Dr Reddy's Laboratories in association with Apollo Hospitals have priced the Sputnik V vaccine at Rs 1,250 (including the administration charges). However, the vaccine is currently being imported at a price of Rs 948 a dose, and with a 5 per cent GST, the cost of the vaccine for every dose comes to Rs 995.40. These doses will then be made available to the public at slightly higher costs, as private players will mark up the prices to include the cost of administering the vaccine and a certain amount of profit.

Distribution Strategy

All Health Care Workers and Frontline Workers as specified by the MoHFW *

All such citizens that are aged, or will attain the age of, 45 years as on 1st January 2022 (free in central government centers)

Anyone above 18 years to receive anti-Covid shots from May 1 vaccines procured by the state government or open market

Contraindications

On persons with history of

- Anaphylactic or allergic reaction to a previous dose of COVID-19 vaccine
- Immediate or delayed-onset anaphylaxis or allergic reaction to vaccines or injectable therapies, pharmaceutical products, food-items etc.

Pregnancy & Lactation

Pregnant women have not been part of any COVID-19 vaccine clinical trial so far. As per recent MOHFW guidelines lactating women should be the part of COVID-19 vaccine at this time.

Provisional/temporary contraindications

Deferring the Covid 19 vaccination in the following scenario..

- In case of individuals having lab test proven SARS-2 Covid 19 illness, Covid 19 vaccination to be deferred by 3 months after recovery.
- In case of SARS-2 Covid 19 patients who have been given Anti SARS-2 monoclonal antibodies or Convalescent plasma, Covid 19 vaccination to be deferred by 3 months from discharge from the hospital.
- In case of individuals who have received at least the first dose and got Covid 19 infection before completion of dosing schedule, the second dose should be deferred by 3 months from clinical recovery from Covid 19 illness.
- Person with any other serious general illness requiring hospitalization or ICU care should also wait for 4 to 8 weeks before getting the Covid 19 vaccine.
- An individual can donate blood after 14 days of either receipt of Covid 19 vaccine or testing RTPCR negative, if suffering from Covid 19 disease.
- Covid 19 Vaccination is recommended for all lactating women.
- There is no requirement for screening of vaccine recipients by rapid antigen test prior to Covid 19 vaccination..

Directives to Institutions/ Corporates

- Do not be anxious about the availability of the vaccine - wait for your turn.
- Make sure that you always follow COVID Appropriate Behaviors, even after vaccination.
- Attend community meetings on the COVID-19 vaccination process organized in your locality while maintaining social distancing.
- You may volunteer to support the implementation of vaccination sessions in your areas.
- If feeling unwell, get tested for COVID-19 at the nearest facility; you won't need a doctor's prescription. If tested positive, self-isolate immediately and seek medical support.
- If you have any questions, call 24x7 National Helpline No.1075; +91- 11-23978046.

Indication of Market Availability

The vaccines have started to be available in the market. This is largely a function of the supply of vaccines by the manufacturers

Vaccination Phases

Open for all except below 18 & Pregnant women.

Miscellaneous

- COVID-19 vaccine is safe and effective and will be available.
- COVID-19 vaccine along with CAB effectively protect individuals from COVID-19 infection.
- COVID-appropriate behaviors are to be strictly followed at all times even after vaccination.
- Pre-registration is a must for the eligible beneficiaries.
- The vaccine will not be given to individuals who are not registered.
- The registration process will be guided by the mobilisers/volunteers as and when available.
- If you are unwell at the time of your second dose of vaccine appointment, it is advisable to wait until you have recovered. You should try to get the second dose as soon as possible after recovery.
- You should not attend a vaccination appointment if you are self-isolating or waiting for a COVID-19 test or unsure if you are not well.
- A complete schedule of vaccination will reduce the chances of a person becoming seriously ill.

EMPLOYER SPACE

Government/corporate partnership: No information yet

Direct corporate purchase: Not allowed by Government.

Covered in non-insurance benefit: NO

Incentives: NO

View on liability:

Employers are exploring their options for mandating or encouraging workers to get COVID-19 vaccinations. They may even want to facilitate vaccination onsite as and when these options are available. So, can an employer be held liable if a worker has an adverse reaction to the vaccine?

Since Employers have an obligation to protect the health and safety of their employees, they could implement a variety of safety COVID protocols and measures to do this. At this stage, it is advisable for Employers to encourage and even facilitate Employees to get the vaccine, making the vaccination mandatory could open Employers up to potential employment practices violation claims as some employees may have genuine health or disability related objections. In addition, it is important to ensure that consistent communication to employees detailing potential risks and legal consent to the vaccination process.

Communication:

- Managing and mitigating any potential disappointment expressed by unmet demand for the vaccine or 'eagerness' amongst people.
- Addressing vaccine 'hesitancy' that could arise because of apprehensions around vaccine safety, efficacy; and any other myths and misconceptions.
- Provide information on potential risks and mitigate unintended crisis (e.g. AEFI clusters, delay in vaccine rollout for certain population categories) during the introduction and rollout.
- The strategy also seeks to build trust and enable greater confidence in the COVID-19 vaccine amongst all people by employing transparency in communication, while also managing any mis/disinformation and rumors around it.

Concerns:

- Ensure that all eligible groups receive the vaccine with confidence.
- All people get the correct information and are not influenced by mis/disinformation, myths, or misconceptions.
- The hesitancy of the public is addressed on the COVID-19 vaccination process.
- Provide correct, consistent, and timely information on the new COVID-19 vaccine(s) (availability, safety, and timelines) and vaccination processes.
- Generate awareness and understanding of the phased approach of prioritizing target groups.
- Address low-risk perception of the infection amongst people and build an enabling environment to adopt and maintain COVID appropriate behavior to reduce any risks of infection.

Miscellaneous:

- There is significant keenness amongst the public as people have been waiting for the COVID-19 vaccine so that they can get back to their normal life. It is therefore important to:
- Acknowledge that there might be a degree of vaccine eagerness, but people will have to wait to get vaccine access, based on the defined prioritization criteria.
- Refer to key message's communication package addressing the potential for vaccine eagerness and engaging people to support the vaccination rollout.
- Share accurate information, consistently with the public and those waiting for the vaccine to address any knowledge gaps.
- Advocate for and refer to reliable sources of information (MoHFW website and official social media handles), and proactively manage any mis/disinformation or fake news.

VENDOR MANAGEMENT

Available vendors: Health Aggregators, TPA's, Insurers

Manufacturer or provider: Bharat Biotech, SII , Dr. Reddy's till date

Amenable to direct negotiation: Allowed by Government.

Concerns:

- **The unprecedented scale and speed of delivery -**
30 Cr envisioned to be vaccinated by Aug 2021 (20x scale of UIP)
- **Shortage of trained paramedics to administer doses -**
1.7 per 1000 population vs WHO norm of 3)
- **Medical supervision required in initial cohorts -**
Guidelines of 1 doctor and 4 paramedics per "squad" in initial camps.
- **Supply-demand mismatch -**
Manufacturing expected to rest with a maximum of 3-4 players in the early months.

Miscellaneous:



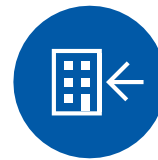
Prewrite



Appointment
Scheduling



Beneficiary
Registration



Site Identification
(Onsite Delivery)



Sign up of Staff - Doctor,
Paramedics, Ambulance.



Beneficiary Identification
and Prioritisation;
Blueprinting



Contracting and
Alignment with the
Delivery Partner

Insurance:

C19 vaccine covered & adverse effect covered:

Insurer & Insured both are checking the feasibility at both ends. with a maximum of 3-4 players in the early months.

QUICK FACTS YOU SHOULD KNOW ABOUT COVID-19 VACCINATION

- Vaccines have been made available only after they have passed rigorous scientific and regulatory parameters through vaccine trials.
- The various stakeholder including policymakers are alive to the supply and demand situation and efforts are being made to bridge those to ensure that there is a fair and equitable distribution of vaccines.
- India has had the experience of running large scale grassroots based immunization program every year and vaccinating nearly 2.7 crores new-born annually.
- This is the first time that vaccines for COVID-19 has been developed and launched globally to protect you, your family, and communities from COVID-19
- The government is committed to covering all population groups.
- These are safe and immunogenic vaccines, have been developed after due scientific research & trials.
- The vaccines will provide immunity against COVID-19 and reduce the risk of contracting the infection.
- These are injectable vaccines & all vaccinators are trained in vaccine safety protocols.
- While vaccine efficacy is a factor reported for clinical and research purposes, irrespective of that, all attempts should be made to get vaccinated with whichever vaccine is available (First Dose) instead of trying to wait for a particular brand.

COVID APPROPRIATE BEHAVIOUR DURING & AFTER VACCINATION



Wear double mask/face cover.



Practise frequent handwashing or use hand sanitiser.



Maintain 6 feet physical distance.



If any symptoms develop, promptly self-isolate or seek medical assistance.

FAQS ON COVID-19 VACCINE

Will COVID-19 vaccine be given to everyone simultaneously?

All Health Care Workers and Frontline Workers as specified by the MoHFW

All such citizens that are aged, or will attain the age of, 45 years as on 1st January 2022 (free in central government centers)

Anyone above 18 years to receive anti-Covid shots from May 1 vaccines procured by the state government or open market

Will the vaccine be safe as it is being introduced in a short span of time?

Vaccines will be introduced in the country only after regulatory bodies clear it based on its safety and efficiency.

Is it mandatory to take the vaccine?

Vaccination for COVID-19 is voluntary. However, it is advisable to receive the complete schedule of COVID-19 vaccine for protecting oneself and limiting the spread of the disease.

It necessary for a COVID recovered person to take the vaccine?

It is advisable to receive a complete schedule of the vaccine irrespective of the past history of infection as it will help in developing a strong immune response.

Can a person having COVID-19 (confirmed/suspected) infection be vaccinated?

Infected individual should defer vaccination for 3 months after symptoms resolution as they may increase the risk of spreading the virus to others at the vaccination site.

Out of the multiple vaccines available how is one or more vaccine chosen for administration?

The safety and efficiency data from clinical trials of vaccine candidates are examined by the Drug Regulator before granting the license. Hence, all the license COVID-19 vaccines will have comparable safety and efficiency. However, it must be ensured that the entire schedule of vaccination is completed by only one type of vaccine different COVID-19 vaccines are not interchangeable.

Does India have the capacity to store COVID vaccines at +2 to + 8 degree Celsius and transport them at required temperature?

India runs one of the largest immunisation programmes in the world, catering to the vaccination needs of over 26,000,000 new-borns and 29,000,000 pregnant women. The program mechanisms are being strengthened to effectively cater to the countries larger and diverse population.

Will the vaccine introduced in India be as effective as the ones introduced in other countries?

Yes, the COVID-19 vaccine introduced in India will be effective as any vaccine developed by other countries as various phases of action trials are undertaken to ensure safety and efficiency.

How will I know if I am eligible for vaccination?

Eligible beneficiaries will be informed through the registered mobile number regarding the Health Facility for vaccination and its schedule time.

What documents are required for registration of eligible beneficiary?

Any of the below mentioned ID with photo may be produced at time of registration:



Aadhar/ driving licence/
voter ID/ PAN card/
passport/ job card/
pension document



Health insurance smart
card issued under the
scheme of Ministry of
Labour



Mahatma Gandhi
National Rural Employment
Guarantee Act (MGNREGA)



Official identity cards
issued to MPs/ MLAs/
MLCs



Passbooks issued by
bank or post office



Service ID card issued by central
or state government/ public
limited companies

Can a person get the COVID-19 vaccine without registration?

No, registration is mandatory for COVID-19 vaccination. Only after registration, the information on the session site and time will be shared.

If a person is unable to produce photo ID at the session site, will s/he be vaccinated?

Photo ID is a must for both registration verification at sessions site to ensure that the intended person is vaccinated.

How will the beneficiary receive information about the due date of the vaccination?

Following online registration, the beneficiary will receive SMS on their mobile about the due date, place, and time of vaccination.

Will beneficiaries receive information on their vaccination status after completion?

Yes. On getting due doses of COVID-19 vaccine, the beneficiary will receive SMS on the mobile number. After all doses out of vaccine administered, a QR code-based certificate will also be sent to their number.

Are there any preventive measures and precautions that one needs to follow at the session site?

You must rest at the vaccination centre for at least half an hour after taking the COVID-19 vaccine.



Inform the nearest health authorities/ANM/ASHA in case you subsequently feel any discomfort or uneasiness.



Remember to continue following COVID appropriate behavior like wearing double mask, maintaining hand sanitization, and physical distancing of 6 feet.

What about the possible side effects from COVID-19 vaccine?

COVID vaccine will be introduced only when the safety is proven.

As is true for other vaccines, the common side effects in some individuals could be mild fever, pain, etc. at the site of infection.

States have been asked to start making arrangements to deal with any COVID-19 vaccine-related side-effects.

If one is taking medicines for illnesses like cancer, diabetes, hypertension, etc., can he or she take the COVID-19 vaccine?

Yes. Persons with one or more of these comorbid conditions are considered high risk category. They need to get COVID-19 vaccination.

How many doses of vaccine would have to be taken and at what interval?

Two doses of vaccine, 12-16 for Covishield, 3-4 week for Covaxin, 21 days for Sputnik v.

When would antibodies develop after taking the dose?

Protective levels of antibodies are generally developed 2 weeks after receiving the second dose of COVID-19 vaccine.

ANVITI'S SUGGESTION

The national COVID-19 vaccination strategy will continue to evolve. At present, the task of vaccination is primarily on the following stakeholders;

- **Central Government** – Continues to provide for vaccines above 45 years through its infrastructure
- **State Governments** – Vaccinate all groups above 18 years
- **Work Establishments** – In coordination with PCVCs

We are beginning to see private organizations beginning to vaccinate employees through both onsite and offsite models. However the supply of doses continue to be a challenge. We are going to see a similar trend in the short to medium term. Leading PCVCs will continue to balance the allocation of vaccines between corporates and general public. We are also seeing different dynamics play out in different cities vis a vis supply and demand. Hence our advice to clients will be to continue a '**mixed-hybrid**' approach. Employees be constantly encouraged to get their respective vaccine shots on their own and organizations playing a supplementary role of facilitating vaccination camps wherever possible. As your trusted advisors, we continue to track all regulatory development on this front and we assure you that those would continue to be shared with you on a timely basis. And as a final piece of advise, while we all continue to wait for more widespread access to COVID-19 vaccines, we do not let up on practicing and preaching the importance of social distancing, masking, and hand hygiene.

