FAQs for Healthcare Workers and Front line workers

A. General

1. Which COVID-19 vaccines are licenced in India?

Two vaccines that have been granted emergency use authorization by the Central Drugs Standard Control Organization (CDSCO)in India are Covishield® (AstraZeneca's vaccine manufactured by Serum Institute of India) and Covaxin® (manufactured by Bharat Biotech Limited)

2. What is Emergency Use Authorization (EUA)/ Permission for restricted use?

Emergency Use Authorization (EUA) is a regulatory mechanism to allow the use of vaccines and medicines to prevent and or reduce the impact of life-threatening diseases or conditions as caused by Covid19. However, before grant of the EUA, there is rigorous assessments of laboratory and clinical trial data, including data on quality, safety, production of protective antibodies and efficacy. Safety is particularly critical aspect of this scrutiny and a risk-versus-benefit evaluation is done in the context of a public health emergency. Full licensure is obtained when the manufacturer submits the complete data.EUA by Indian regulators is aligned with global guidelines.

3. Is the EUA a new process introduced for COVID-19 Vaccine?

Concept of EUA always existed to save the lives of people all over the world with vaccine and medicines for life threatening diseases while companies continue to obtain additional safety and effectiveness information to enable full licensure. Previously, EUAs have been granted to vaccines for outbreaks due to anthrax, Ebola, enterovirus, H7N9 influenza, and Middle East respiratory syndrome. As of January 2021, nine COVID-19 vaccines were in emergency use in numerous countries around the globe.

4. Have the vaccines undergone the needed clinical trials before EUA?

Both the Indian COVID 19 vaccines have completed their Phase I & II trials. Covishield® has completed its Phase III trials in UK and the bridging trial in India.

5. What is Phase I, II and III of clinical trial for a vaccine?

Vaccine trail phases includes:

Phases of vaccine development/trial	**Purpose**
Pre-clinical	Vaccine development in laboratory animals
Phase 1 Clinical trial (small number of participants)	Assess vaccine safety, immune response and determine right dosage (short duration)
Phase 2 Clinical trial (few hundred participants)	Assess safety and the ability of the vaccine to generate an immune response (short duration)
Phase 3 Clinical trial (thousands of participants)	Determine vaccine effectiveness against the disease and safety in a larger group of people (duration 1-2 years)

6. Why vaccination is not provided to children who are usual target?

COVID-19 affects all age groups; however, morbidity & mortality is several times higher in adults particularly in those above the age of 50 years. Children have either asymptomatic or mild infection.

The general practice is to first evaluate any new vaccine in older population and then age reduction is done to assess the safety and effectiveness in paediatric population. The currently available vaccines have not been evaluated in children so far. There are some clinical trials now underway to test the effectiveness and safety of the COVID 19 vaccines in children.

B. Vaccine Attributes

1. **What technology has been used in development of the currently available two vaccines in India?**

   Covishield® vaccine, manufactured by the Serum Institute of India, is a Viral Vector based Technology which is also used to manufacture Ebola vaccine.
   Covaxin® vaccine, manufactured by the Bharat Biotech, is a whole-Virion Inactivated Corona Virus Vaccine which is also used to manufacture vaccines like Influenza, Rabies and Hepatitis-A.

2. **What is the composition of both the vaccines?**

   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 dihydrate (EDTA).

   Composition of **Covaxin** includes inactivated Corona Virus, Aluminum Hydroxide Gel, TLR 7/8 agonist, 2-Phenoxyethanol and Phosphate Buffered Saline[NKA1].

3. **Both vaccines require cold chain temperature. How is the cold chain been maintained during storage and transportation of vaccine?**

   Both vaccines need to be stored and transported at $+2^0$ to $+8^o$ Celsius. The cold chain for both vaccines is maintained through active and passive cold chain equipment available at approximately 29000 cold chain points across India.

4. **If I have received vaccine as a health worker, how will my family members receive the vaccine (as they are exposed as well)?**

   The people at highest risk of exposure such as health care and frontline workers will receive the vaccine on priority. These personnel are also likely source of infection of their family members. Other family members will be vaccinated according to the age specific prioritization by the Government of India.

5. **Is COVISHIELD® same as the vaccine been given in UK by Astra Zeneca?**

   Yes, Covishield® vaccine, manufactured by the Serum Institute of India, is based on the same patent technology as the Astra Zeneca vaccine.

6. **What is the dose schedule of both the vaccines?**

   As per the permission granted by the Drug Controller General (India), for Covisheild the second dose is to be administered 4-6 weeks after the first dose and Covaxin is to be administered in two doses interval of day 0 & day 28.

7. **Do I have a choice of vaccine I will receive?**

   The vaccine will be supplied to various parts of India as per availability and distribution plan, beneficiaries load and so at present the option of choice of vaccine is not available.

C. Efficacy & protection

1. **Indian regulators have given authorization to Covaxin even before its Phase 3 trial results were out. How do we explain this?**

   We are passing through Covid19 pandemic. COVID-19 has caused social disruption, economic downturn and significant number of deaths. To control this pandemic, the society as well as the system may have to take steps which may also be termed as drastic. Both pre-clinical and clinical data (complete data for Phase I and II, and partial data for Phase III of Covaxin have been thoroughly scrutinized by the regulators. This data shows that the vaccine is safe and induces a robust antibody response. However, to what extent the vaccine will protect the recipients from getting the disease is not fully known yet. Therefore, the regulators have allowed its use in trial mode.

2. **What does trial mode mean for a vaccine recipient?**

   The way we do in a clinical trial phase: first, the recipient will be asked to give a written consent. Additionally, the recipient will be followed up actively to see if the vaccine has led to any side effects. In short, it will be an extension of the Phase 3 trial. But in this, the person would know that he or she has received the vaccine, and not the placebo. It is completely voluntary.

3. **Developing a vaccine takes years. But this time our scientists have developed a vaccine against the novel corona virus in such a short time. How was this possible?**

   Developing a vaccine generally involves years of research. First, we need a vaccine candidate that is evaluated in animals for its safety and efficacy. After a vaccine candidate passes a pre-clinical trial, it enters the clinical trial phase. While scientists have worked round the clock in the laboratory, even regulatory approvals which used to take several months have been fast tracked. It helped eliminate all the time lapses between the pre-clinical and clinical trial stages. Earlier, the vaccine development involved a series of steps, but in the case of the coronavirus vaccine, the scientists and regulators worked in tandem, accelerating the whole process without compromises on any protocols and any step.

4. **What is the safety and efficacy of the vaccines used in the country?**

To ensure that a vaccine is safe, we need to try it on a large number of people. The vaccine developers have not reduced the sample size at any stage of clinical trials rather it was bigger than what we usually test a vaccine on.
When a vaccine is tested, most of the adverse events or unwanted effects, if any, occur in the first four to six weeks of its administration. So, in order to ensure that it is safe, we keep a close watch, for the first two-three months, on the people it has been given to. This data help us decide if a vaccine is safe. All concerned in the line of vaccine development, testing and evaluation have followed these procedures to the T. Both Indian vaccines are considered safe on this yardstick.

As for the efficacy of the vaccine, we need time to tell how effective a vaccine is. All the global agencies have set the benchmark that only those vaccine candidates which show and efficacy of at least 50-60% will be considered. Most of the vaccines have shown as efficacy of 70-90% within the short period of two or three months of observation. Besides when a vaccine is given an emergency use authorizations/permission for restricted use, as in the case of the COVID-19 vaccine, the trial follow-up continues for one-two years to assess the total duration of protection the vaccine will provide.

5. **Do I need to use the mask/other COVID appropriate precautions after receiving the vaccine?**

Yes, it is absolutely necessary that everyone who has received the COVID vaccine should continue to follow the COVID appropriate behaviour i.e., mask, do gaj ki doori and hand sanitization to protect themselves and those around from spreading the infection.

6. **How long I will remain protected after vaccination?**

Longevity of the immune response in vaccinated individuals is yet to be determined. Hence, continuing the use of masks, handwashing, physical distancing and other COVID-19 appropriate behaviours is strongly recommended.

7. **Does vaccination protect me against newer strains / mutated virus of SARS-CoV2?**

The body responds to vaccination by making more than one type of antibodies to virus parts including spike protein. Therefore, all vaccines are expected to provide reasonable amount of protection against the mutated virus also. Based on the available data the mutations as reported are unlikely to make the vaccine ineffective.

8. **Which vaccine is better between Covisheild and Covaxin**

   There is no head-to-head comparison done between the two vaccines being used in India so one cannot choose one over the another. Both would work fine in preventing the infection as well as prevent a person from going into severe state of the disease. As a long-term effect, it would be preventing death for elderly people or those who have co-morbidities.

9. **In how many days will the vaccination create an adequate immune response and protection?**

   Adequate immune response takes 2-3 weeks after completion of entire vaccination schedule i.e., after the second dose of COVISHIELD® and COVAXIN®.

10. **Does this vaccine provide herd immunity?**

    When an increasing number of people get vaccinated in the community, indirect protection through herd immunity develops.
    The percentage of people who need to be immune in order to achieve herd immunity varies with each disease. For example, its 95% for measles, however the proportion of the population that must be vaccinated against COVID-19 to begin inducing herd immunity is not known.

D. Side-effects

1. What are expected immediate and delayed side effects of this vaccine?

Covishield®: Some mild symptoms may occur like injection site tenderness, injection site pain, headache, fatigue, myalgia, malaise, pyrexia, chills and arthralgia, nausea. Very rare events of demyelinating disorders have been reported following vaccination with this vaccine but without the causal relationship establishment.
Covaxin®: Some mild symptoms 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. No other vaccine-related serious adverse effects have been reported.

2. What are the contraindications for this vaccine?

Contraindication

i. 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.

ii. Pregnancy & Lactation:

- Pregnant & Lactating women have not been part of any COVID-19 vaccine clinical trial so far. Therefore, women who are pregnant or not sure of their pregnancy; and lactating women should not receive COVID-19 vaccine at this time

Provisional / temporary contraindications: In these conditions, COVID vaccination is to be deferred for 4-8 weeks after recovery

- Persons having active symptoms of SARS-CoV-2 infection.
- SARS-COV-2 patients who have been given anti-SARS-CoV-2 monoclonal antibodies or convalescent plasma
- Acutely unwell and hospitalized (with or without intensive care) patients due to any illness.

3. **Which drug should be taken to minimize the adverse effects of this vaccine?**

   In case of minor adverse effects such as injection site pain, tenderness, malaise, pyrexia, etc., paracetamol may be used to alleviate the symptoms.

4. **Should you avoid alcohol after receiving the COVID19 Vaccine?**

   As per experts, there is no evidence of alcohol impairing the effectiveness of the vaccine.

5. **Claims on social media suggested that covid19 vaccine could affect female fertility. Is it true?**

   Rumours or social media posts suggesting that COVID-19 vaccines could cause infertility are not true and totally baseless. Such rumours were floated in the past against other vaccines also e.g. polio and measles. None of the available vaccines affects fertility. All vaccines and their constituents are tested first on animals and later in humans to assess if they have any such side effects. Vaccines are authorized for use only after their safety and efficacy is assured.

E. Precautions

1. **What precautions I need to take after receiving the vaccine?**

   Both the vaccines are safe but in case of any discomfort or complaint, ask the beneficiary to visit the nearest health facility and/or call the health worker whose phone number is given in the COWIN SMS received after vaccination.

2. **If I suffer from HTN/DM/CKD/heart disease/lipid disorders etc., can I safely take this vaccine?**

   Overall, the vaccine is safe and efficacious in adults with comorbidity. The maximum benefit of getting the COVID vaccine is for those who have such co-morbidities. However, if you are concerned for any specific reason, please consult your doctor.

3. **What medications should be avoided before taking COVID-19 vaccine and for how long?**

   Currently, there is no such instruction. One can take one's regular medication uninterruptedly. Just inform the vaccinator about the medicines you consume.

4. **The Health Ministry has advised caution in vaccinating persons with a history of bleeding or coagulation disorder. How does a person know if he/she has a coagulation disorder? What tests can be conducted?**

   There are a few bleeding disorders like 'haemophilia'. These persons should take the vaccine under the supervision of their treating physician. Patients who are admitted in hospital or ICU and have bleeding problems should delay the vaccination till they are discharged. However, several people with heart and brain disorders are on blood thinners like aspirin and anti-platelet drugs. They can continue with their medicines and have the vaccines. For them, vaccines are absolutely safe.

5. **The health advisory also states that those with immunity issues should be cautious about taking the vaccine. What are the markers of 'Immunity issues'?**

   Immune issues are of two types: one, immunosuppression due to any disease such as AIDS, and people on immunosuppressant drugs such as anti-cancer drugs, steroids, etc. Second, immunodeficiency in people who suffers from some defect in the body's protective system such as congenital immunodeficiency.

   Currently, available COVID vaccines do not have any live virus and therefore individuals with immune issues can have the vaccine safely. But the vaccine may not be as effective in them. One should inform the vaccinator about the medicines they consume and if they are suffering from any known immune issues. The vaccinator should have a record of one's medical condition.

6. **I had COVID infection and was treated, why should I receive vaccine?**

   Development of immunity or duration of protection after COVID-19 exposure is not established therefore it is recommended to receive vaccine even after COVID-19 infection. Wait for 4-8 weeks after recovery from COVID symptoms before getting the vaccine.

7. **Is the vaccine contraindicated in person with chronic diseases?**

   Chronic diseases and morbidities like the Cardiac, neurological, pulmonary, pulmonary, metabolic, renal and malignancies etc. are not contraindicated. In fact, the benefit of COVID vaccines to reduce the risk of severe COVID disease and death is for those who have these co-morbidities.

F. **Follow-up & Booster**

1. **Is it important for me to receive the same vaccine during second dose?**

   As the vaccines available are not interchangeable, it is important to receive the second dose of same vaccine as the first one. The COWIN app is also going to help to ensure that everyone receives the same vaccine.

2. **How long I will remain protected?**

   The duration of protection is yet to be established.

3. **Will this require any repeated vaccination or booster dose after the 2nd dose in future?**

   Requirement of booster dose is yet to be determined.

4. **Will I get any certificate that I am vaccinated?**

   Yes, a provisional certificate would be provided after the first dose. On completion of second dose, when you receive the message for completion of schedule it would include a link to download digital certificate of vaccination for your perusal. This certificate can be then be saved in the digi-locker.

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