Regulatory Provisions for Approval of Vaccines in India

Why in news?

Three vaccine developers in India have sought emergency use approval from Central Drug Standard Control Organisation (CDSCO) for their candidate Covid-19 vaccines under trials.

What are these vaccine candidates?

- **COVISHIELD** - Pune-based Serum Institute of India (SII) has sought approval for its version of the vaccine developed by Oxford University and AstraZeneca.
- It has been testing this in India for the last few months.
- The candidate is currently in phase-III trials in India.
- In its application, SII has submitted the safety data from phase I and phase II trials.
- The effectiveness data has been sourced from phase-III trials of the same vaccine in the UK and Brazil.
- **COVAXIN** - Bharat Biotech, a Hyderabad-based company is developing a vaccine, Covaxin.
- It is developing it in collaboration with National Institute of Virology, an ICMR institute in Pune.
- It has started phase-III trials only recently, and is yet to enrol all the participants as per its design.
- Its application is based mainly on the safety data from phase-I and phase-II trials.
- **BNT162b2** - US pharmaceutical major Pfizer has not carried out clinical trials in India of its vaccine developed in collaboration with BioNTech.
- But it has still sought an approval to use it in India based on the results of the trials conducted in the US.
- The Pfizer-BioNTech vaccine is the first one to receive regulator's approval anywhere in the world.
- It was granted emergency use authorisation in the UK recently.
- Notably, none of the three vaccine candidates has yet generated data about

the effectiveness of their vaccine from phase-III trials conducted in India.

What are the regulatory provisions for approval of vaccines in India?

- Clinical trials of new drugs and vaccines, and their approvals, are governed by the **New Drugs and Clinical Trials Rules, 2019**.
  - These Rules do not use the term “emergency use authorisation”.
  - This term is used mainly by the regulatory agencies in the US and some other countries.
  - It has become popular in the context of the current epidemic.
  - However, Indian regulatory system does have provisions for “special situations” like the current one.
- The 2019 rules provide for “accelerated approval process” in several situations.

What is the accelerated approval process?

- The accelerated approval process would include situations like the current pandemic.
- In such situations, there is a provision for granting approval to a drug that is still in clinical trials.
- However, this is applicable “provided there is a prima facie case of the product being of meaningful therapeutic benefit”.
- Accelerated approval may also be granted to a new drug if it is intended for the treatment of -
  i. a serious, or life-threatening condition, (or)
  ii. disease of special relevance to the country, and addresses unmet medical needs
- The definition of new drug in the 2019 Rules includes a vaccine.
- Further, it makes it clear that a new drug, or a vaccine, can be considered for approval if “remarkable” effectiveness is reported even from phase-II trials.
- In such cases, additional post licensure studies may be required to be conducted after approval to generate the data on larger population.
- Accordingly, the approval granted to drugs or vaccines that are still in clinical trials is temporary and valid only for one year.

How different are Indian regulations?

- Some provisions in the 2019 Rules are different compared to what has been prescribed by the US Food and Drugs Administration (FDA).
- The US FDA had issued very specific guidelines for approval of vaccines for Covid-19.

- According to it, an emergency use authorisation can be considered only after sufficient data from phase-3 trials are generated.
- An application cannot be made on the basis of data only from phase-1 or phase-2 trials.
- It has also said that preliminary phase-3 data should show at least 50% effectiveness in preventing the disease.
- Also, this data has to be generated from “well over” 3,000 trial participants.

What about trials made outside India?

- The 2019 Rules do not specify if data from a trial conducted in another country could be considered for accelerated approval to a drug or vaccine to be used in India.
- But the Indian health authorities seem to be open about it.
- It would all depend on what scientists and experts make of the data that are presented to them.
- They will carefully weigh the risks with the potential benefits of the vaccine.
- In this line, the expert committee in India would be willing to look at data generated during trials conducted in other countries as well.
- This is the case with the applications made by Serum Institute and Pfizer.
- The subject expert committees can reject an application or ask for more data if not satisfied.

Source: The Indian Express