Hasty approval of COVID-19 vaccines

Why in news?

Recently drug regulator granted approval to two COVID-19 vaccines — Covishield & Covaxin —manufactured in India by the Pune-based Serum Institute & Hyderabad-based Bharat Biotech respectively.

How was the clinical trial carried out?

- The phase-2/3 trial of Covishield was carried out on 1,600 participants which intended to study only safety (1,200 participants) and immunogenicity (400 individuals).
- In the case of Covaxin, the phase-3 trial began in mid-November 2020 & the second dose was administered 28 days after the first one.
- The second dose was administered for few days and that too for a very small number of participants.
- Both the trials did not study the efficacy of the vaccine.

What were the issues in these trails?

- The regulator did not wait for sufficient safety and efficacy of the data & has hastily approved the vaccines.
- There is lack of transparency in this process because no information was shared about the clinical trials before granting approval.
- Information w.r.t the level of protection offered by the vaccine, protection against severe disease and & its efficacy in preventing infection and transmission were not known.
- Explicit permission was approved to administer the vaccine in a “clinical trial mode”-large-scale phase-3 clinical trial carried out on consenting people belonging to the four priority groups.
- However the following information is unknown:

    1. How informed the informed consent will be;

    2. Who is going to inform the recipients about the intricacies of

the trail;

3. How well the “participants” are going to be monitored;
4. How the efficacy will be determined in the absence of a control arm;

- Earlier global vaccine manufactures pledged that they would not seek premature approval from regulatory authorities.
- This is in contrast with Bharat Biotech’s haste in seeking approval.

How was the clinical trial at the global level?

- U.S. Food and Drug Administration (FDA) had a live telecast of the advisory committee’s examination of Pfizer’s and Moderna’s vaccine data before granting EUA.
- It made the detailed briefing document of the clinical trial of each vaccine and its assessment public.
- Despite pressure from U.S. President to make vaccines available before election date, FDA said that EUA will be granted based on data from a phase-3 trial which reflects the vaccine’s efficacy.
- The U.K. regulator also made the assessment of the two vaccines — by Pfizer and AstraZeneca — publicly available.

What are the consequences of this hasty approval?

- By giving approval to Covaxin without data on its efficacy, the Indian regulator has joined the ranks of China and Russia.
- Chinese CanSino Biologics’s vaccine had not undergone a phase-3 trial &Russia’s claim of 92% efficacy for Sputnik V was based on a review of just 20 COVID-19 cases.
- It set the stage to reverse decades of hard work in building vaccine confidence.
- This haste can lead to loss of trust in COVID-19 vaccines which can lead to vaccine hesitancy.
- In 2019, a single mistake in preparing the measles, mumps & rubella injection led to the deaths of two infants in Samoa which reduced vaccine uptake steadily.
- A study of 121 districts in India which had higher rates of unimmunised children found that 24% of children did not get vaccinated due to apprehension about adverse effects.

What can be done now?

- Transparency is vital for gaining people's trust so that they don't hesitate to take the vaccine.
- If there is apprehension about the safety and efficacy of COVID-19 vaccines, steps should be undertaken to mitigate such concerns.
- Approving Covishield is sufficient for emergency use but it is imperative that Serum Institute collects efficacy data from the Indian trial before seeking full approval.

Source: The Hindu