Covishield: 2nd – 3rd Phase trails

Recently, the Drugs Controller General of India (DCGI) has given approval to the Serum Institute of India (SII), Pune to conduct Phase II/III clinical trials of Covishield in India. SII is the world’s largest maker of vaccines and it has a tie-up with AstraZeneca, the Swedish-British pharma giant, to manufacture the Covid-19 vaccine for low- and middle-income countries.

- **Covishield:**
  It is the name given to an Oxford-AstraZeneca Covid-19 vaccine candidate which is technically referred to as AZD1222 or ChAdOx 1 nCoV-19.
  - It is already being tested in the UK, South Africa and Brazil, where participants are being administered two doses nearly a month apart.
  - It had triggered an immune response in humans against the novel coronavirus in early trials and is considered to be one of the global frontrunners for the Covid-19 vaccine.

**Background:** The Subject Expert Committee (SEC) for Covid-19 related therapies of the Central Drugs Standard Control Organisation (CDSCO) felt that the SII needed to take a ‘pan India’ approach while considering trial sites.

- It recommended that authorisation to market Covishield should be granted after considering clinical data generated from both the India and international trials.
- Trials: SII can now start its larger phase II/III trials, ahead of other vaccine candidates like Bharat Biotech’s Covaxin and Zydus Cadila’s ZyCoV-D which are still in phase I/II trials.
- However, the exact timings of trial beginning are not clear yet. It would take at least a week to get the ethics committee’s approval before starting the trials. If everything goes well, the vaccine could be out by the end of 2020.
- The trials for Covishield will have around 1,600 participants at 18-odd sites across the country including those identified by the National Biopharma Mission and Grand Challenges India Programme.

**Current Trend in India:** India continues to improve the Case Fatality Rate (CFR-number of deaths per positive case) and maintain its global position of having one of the lowest Covid-19 fatalities rates. The current CFR is 2.11%.

**Grand Challenges India Programm**

- It is a partnership framework for the Department of Biotechnology (DBT) in India, its Biotechnology Industry Research Assistance Council (BIRAC) and the Bill and
Melinda Gates Foundation. BIRAC is a Public Sector Enterprise, set up by the DBT.

- **Aim:** To launch joint initiatives aimed at catalyzing innovative health and development research within India.

**National Biopharma Mission**

- It is an industry-academia collaborative mission for accelerating biopharmaceutical development in the country.
- It was launched in 2017 at a total cost of Rs. 1500 crore and is 50% co-funded by World Bank loan.
- It is being implemented by the BIRAC.