Pfizer's Covid-19 Vaccine Candidate

Why in News

Recently, **American pharma company Pfizer** has claimed that its **vaccine candidate BNT162b2 is more than 90% effective** in preventing **Covid-19** in participants without evidence of prior **SARS-CoV-2** infection.

Key Points

- **BNT162b2:**
    - It is a **single nucleoside-modified messenger RNA** (modRNA) vaccine, which is made of a short segment of genetic material (the messenger RNA/mRNA) which **provides instructions for a human cell to make a harmless version of a target protein,** in this case the spike protein of SARS-CoV-2, in order **to activate an immune response.**
        - The mRNA vaccine is a new approach to protecting against viral infection.
        - Unlike traditional vaccines, which work by training the body to recognise and kill proteins produced by pathogens, mRNA tricks the patient's immune system to **produce viral proteins itself.**
        - The proteins are harmless, but sufficient to provoke a robust immune response.
    - Its **phase 3 clinical trial began in July** with 43,538 participants, 38,955 of whom had received a second dose by November. The case split between vaccinated individuals and those who received the placebo indicates a **vaccine efficacy rate above 90%,** at 7 days after the second dose.
    - It means that **protection is achieved 28 days after the initiation of the vaccination,** which consists of a **2-dose schedule.**
    - Pfizer has become the **first firm to release promising late-stage trial data of a potential vaccine** for Covid-19, even though the announcement **does not have scientifically conclusive evidence** on the safety and efficacy of the vaccine candidate.
    - However, the **analysis o**f the vaccine candidate by an **external independent Data Monitoring Committee** (DMC) has **not reported any serious safety concerns.**
    - The announcement comes days before the company plans to submit safety and efficacy data from the trial to the American regulator, the **United States Food and Drug Administration** (USFDA) seeking emergency use authorisation.
- **Vaccines Worldwide:**
    - As of mid-October 2020, the **World Health Organization** (WHO) has identified **42 candidate vaccines** at the stage of clinical trials, up from 11 in mid-June.
    - **Ten of them** were at the most advanced **phase 3 stage,** in **which a vaccine's effectiveness is tested on a large scale,** generally tens of thousands of people across several continents.
    - The **USA biotech firm Moderna,** several **state-run Chinese labs,** and a **European project led by the University of Oxford** and **AstraZeneca** are also closing in on potentially viable vaccines.
    - **Two Russian Covid-19 vaccines** have been registered for use even before clinical trials were completed, but have not been widely accepted outside of Russia.

India’s Progress

- India is **preparing to administer a vaccine against Covid-19 to its population early in 2021** and for that, it is **working with neighbouring countries** on possible collaborative clinical trials of vaccine candidates in the future.
- A specialist team of scientists and researchers from the **Indian Council of Medical Research** (ICMR) and the **Department of Biotechnology** (DBT) under the Union Ministry of Science and Technology, has **imparted training to doctors and regulators** in **Sri Lanka, Myanmar, Bangladesh, Bhutan, Nepal, and Afghanistan.**
- The Indian team has focused its training on conducting crucial **phase II and III** human clinical trials of the potential vaccine candidate along lines of India’s regulatory mechanism.
    - In **phases II/III,** reactogenicity (ability to produce common, adverse reactions), immunogenicity (ability to provoke an immune response), and safety of the vaccine candidate are assessed in a larger population.
- The **current aim is to facilitate a future collaborative clinical trial** but in **future, it will allow India to explore the option of buying** the potential Covid-19 vaccine from these neighbouring countries.
- **Indigenously Developed Vaccines:**
    - **ZyCoV-D**: Designed and developed by Zydus (a pharmaceutical company) with support from the DBT.
    - **Covaxin**: Developed by Bharat Biotech in collaboration with the ICMR.
- **Assistance in Global Trails:**
    - **Covishield**: Name given to an Oxford-AstraZeneca Covid-19 vaccine candidate which is technically referred to as AZD1222 or ChAdOx 1 nCoV-19.
    - **Sputnik V**: The first vaccine to be officially registered and has been developed by Moscow’s Gamaleya Institute in collaboration with the Russia’s defence ministry.

Source: IE