Russian Covid Vaccine: Sputnik V

Why in News

Recently, Russia became the first country to officially register a **Covid-19** vaccine and declare it ready for use.

Key Points

- The vaccine has been called **Sputnik V,** named after the **first artificial Earth satellite, Sputnik-I** launched by the Soviet Union.
- It is the **first Covid-19 vaccine to be approved.**
  - However, a Chinese vaccine had been cleared for 'limited use' before this. It is an **adenovirus vector vaccine** approved to be administered only on soldiers of the **People's Liberation Army.**
- The russian vaccine has outrun other Covid-19 vaccines like **Oxford-AstraZeneca, Moderna and Pfizer** which are still in trials.
  - India's **Covaxin** has been approved for human clinical trials. Another Indian vaccine **ZyCoV-D** has entered phase I/II of clinical trials.
- This vaccine has been developed by Moscow's **Gamaleya Institute** in collaboration with the Russia's defence ministry.
- The vaccine is based on the **DNA** of a **SARS-CoV-2** type **adenovirus,** a common cold virus.
  - The vaccine uses the weakened virus to deliver small parts of a pathogen and stimulate an immune response.
  - The vaccine is administered in two doses and consists of two types of a human adenovirus, each carrying an **S-antigen of the new coronavirus,** which enter human cells and produce an **immune response.**
- Russian officials have said that large-scale production of the vaccine will start in September, and mass vaccination may begin as early as October.

- **Adenovirus Vector Vaccine :**
    - In this vaccine, adenovirus is used as a tool to deliver genes or vaccine antigens to the target host tissue.
    - **Adenovirus:** Adenoviruses (ADVs) are **DNA viruses** ranging from 70-90 nanometre in size, which induce many illnesses in humans like cold, respiratory infection etc.
    - Adenoviruses are preferred for vaccines because their DNA is **double stranded** which makes them **genetically more stable** and the chances of them changing after injection are lower.
    - **Rabies vaccine** is an adenovirus vaccine.
    - However, there are drawbacks of adenovirus vector vaccines like **pre-existing immunity in humans, inflammatory responses etc.**

        Just as human bodies develop immune responses to most real viral infections, they also develop immunity to adenoviral vectors. Since adenoviral vectors are based on natural viruses that some humans might already have been exposed to, these vaccines **might not work for everyone.**
- **Concerns Regarding the Vaccine:**
    - Experts expressed concerns over the safety and efficacy of the vaccine due to its **extremely fast production and lack of published data** on the vaccine.
    - Russia has only made **public** the **results of phase-I** of the clinical trials, which it claimed were successful and produced the desired immune response.
    - The human trials, which take several years in normal circumstances, have been completed in less than two months for Sputnik V. The late-phase human trials are important because the vaccine's efficacy can differ on different population groups.

        Russia, however, has claimed that this was made possible due to the fact that its Covid-19 vaccine candidate closely resembled a vaccine for **Middle East Respiratory Syndrome (MERS)** disease, caused by another coronavirus, that had already been tested extensively.

- **Use in India:**
    - Russia has claimed that around 20 countries have shown interest in the Sputnik V vaccine, including India.

        India has also **partnered with the USA** for development of Covid-19 vaccine.
    - The approval for a vaccine is given by the Central Drugs Standard Control Organisation (CDSCO).
        - **The Central Drugs Standard Control Organisation (CDSCO),** under Directorate General of Health Services ,Ministry of Health & Family Welfare, is the National Regulatory Authority (NRA) of India.
        - Under the Drugs and Cosmetics Act, 1940, CDSCO is responsible for **approval of Drugs, Conduct of Clinical Trials, laying down the standards for Drugs, control over the quality of imported Drugs in the country and coordination of the activities of State Drug Control Organizations by providing expert advice.**
    - CDSCO can ask Russia **to conduct late-phase human trials,** usually both phase-2 and phase-3, on an **Indian population.**

        This is the usual requirement for all vaccines developed outside of India.
    - CDSCO can also give **emergency authorisation** without late-phase trials, considering the extraordinary situation.

        The drug **remdesivir** was recently granted similar emergency approval to be used as a therapeutic on novel coronavirus patients.
    - However, this is unlikely as vaccines are given to a large number of people, and the risks involved are much higher.
    - There are also issues in manufacturing the vaccine as there is **no agreement for its production in India right now.**

        Pune-based Serum Institute of India, **the world's largest manufacturer of vaccines by volume,** has already entered into tie-ups with developers to mass-produce their vaccines. Other Indian companies have also done similar agreements but there is none with Russia.

Development of a vaccine

- The general stages of the development cycle of a vaccine are:
    - Exploratory stage
    - Pre-clinical stage
    - Clinical development
    - Regulatory review and approval
    - Manufacturing and
    - Quality control.

- The Clinical development is a three-phase process:
    - Clinical trials in humans are classified into **three phases: phase I, phase II and phase III** and in certain countries formal regulatory approval is required to undertake any of these studies.
    - The **phase I** clinical studies carry out initial testing of a vaccine in small numbers (e.g. 20) of healthy adults, to test the properties of a vaccine, its tolerability, and, if appropriate, clinical laboratory and pharmacological parameters. Phase I studies are primarily **concerned with safety.**
    - **Phase II** studies involve larger numbers of subjects and are intended to provide preliminary information about a vaccine's ability to produce its desired effect (usually immunogenicity) in the target population and its general safety.
    - Extensive **phase III** trials are required to fully assess the protective efficacy and safety of a vaccine. The phase III clinical trial is the pivotal study on which the **decision on whether to grant the licence is based** and sufficient data have to be obtained to demonstrate that a new product is safe and effective for the purpose intended.
    - Many vaccines undergo **Phase IV** formal ongoing studies after the vaccine is approved and licensed.

Way Forward

The Russian Vaccine, although, is a welcome step, concerns regarding its efficacy and safety must be addressed by the developers on a priority basis. Also, the manufacturing and distribution procedures need to be clearly laid down so that they can be administered to everyone in a quick and efficient manner.

Source: IE