Pact for Sputnik V Availability in India

Why in News

The **Russia Direct Investment Fund (RDIF),** which is piloting **Russia's** Sputnik V **vaccine,** has partnered with the **Hyderabad-based Dr. Reddy's Laboratories** to supply 100 million doses of the vaccine.

Key Points

- **Sputnik V:**
    - The Russian vaccine has been named after the **first artificial Earth satellite, Sputnik-I** launched by the Soviet Union.
    - It is the **first Covid-19 vaccine** to be approved by any government for common people.
    - The Russian vaccine **has outrun other Covid-19 vaccines** like **Oxford-Astra Zeneca, 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.
    - It has been developed by Moscow's **Gamaleya National Research Institute of Epidemiology and Microbiology** in collaboration with the Russia's defence ministry.
    - It is based on the **DNA** of a **SARS-CoV-2** type **adenovirus,** a common cold virus.
        - It uses the **weakened virus** to deliver small parts of a pathogen and stimulate an immune response.
        - It is administered in **two doses** and consists of two types of a human adenovirus.
    - The **Phase 1 and 2 results have shown promise.**
        - The results of Phase I and Phase II clinical trials of the vaccine were published in The Lancet, demonstrating no serious adverse effects and a stable immune response in 100% of the participants.
    - **Phase 3 trials will be conducted in India** to meet the requirements of the Indian regulators.
        - Sputnik V vaccine could provide a credible option in India's fight against Covid-19.
        - India has also **partnered with the USA** for development of Covid-19 vaccine.
- **Regulatory Requirements in India:**
    - The **approval** for a vaccine is given by the **Central Drugs Standard Control Organisation (CDSCO).**
        - A vaccine, developed outside India, needs to be **tested with late-phase human trials,** usually both phase-2 and phase-3, on an **Indian population** as a part of general requirement.
        - CDSCO can also give **emergency authorisation** without late-phase trials, considering the extraordinary situation.
- **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 and phase II** of the clinical trials, which it claimed were successful and produced the desired immune response.
    - The late-phase human trials are important because the vaccine's efficacy can differ on different population groups. After trials, vaccines are given to a large number of people, and the risks involved are much higher if trials are not comprehensive.
        - 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.
    - There are also issues in manufacturing the vaccine in India as there is **no agreement for its production in India.**
        - 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.
- **Vaccine Base in India:**
    - Besides a big domestic market, India is a strong player globally in the field of vaccines. In FY20, vaccine exports accounted for 4.27% of total pharma exports.
    - Its manufacturing skill is evident from the fact that about 70% WHO vaccines and 90% of measles shots are sourced from India.

Adenovirus Vector Vaccine

- In this vaccine, adenovirus is used as a tool to deliver genes or vaccine antigens to the target host tissue.
- 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.
- However, there are drawbacks of adenovirus vector vaccines like **pre-existing immunity in humans and inflammatory responses** which may make vaccines less effective.

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.**

Source: TH