Covishield shot

January 2, 2021

In news

A panel under India's top drug regulator clears Covidshield shot

Key highlights

- The Subject Expert Committee (SEC) recommended that the Indian version of the Covid-19 vaccine **developed by the University of Oxford and AstraZeneca**, should be approved with certain conditions. Outside India it is known as AZD1222
- AZD1222, on which Covishield is based, received the approval of the UK MHRA for "emergency" use on people aged 18 years and above
- The current recommendation is significant, as it paves the way for India to get its first vaccine against the novel coronavirus
- This recommendation has come two days after regulators in the United Kingdom approved the use of the Oxford-AstraZeneca vaccine among the British public
- Meanwhile, an expert body in India was considering an application for clearance for Covishield, which is being tested and manufactured under licence by Serum Institute of India (SII).
- The Subject Expert Committee had on Wednesday sought additional information from the Pune-headquartered firm, including a fact sheet of information about the vaccine for the general public.
- Now, Subject Expert Committee (SEC) recommended that the Central Drugs Standard Control Organisation (CDSCO) should grant approval to Covishield despite the candidate not having completed phase 2/3 clinical trials in India

- The panel has recommended the approval of two full doses of the vaccine that should be administered around 4-6 weeks apart
- If the Drug Controller General of India (DCGI) greenlights this, SII will be able to supply Covishield to the government for mass vaccination before it completes these trials.

What is Emergency Use Approval/Authorization (EUA)of a Vaccine?

- It is a mechanism to facilitate the availability and use of medical countermeasures, including vaccines, during public health emergencies, such as the current COVID-19 pandemic
- In India, such authorization is given by the Central Drugs Standard Control Organisation (CDSCO).

Regulatory provisions for the approval of vaccines in India:

- In India, Clinical trials of new drugs and vaccines, and their approvals, are governed by the New Drugs and Clinical Trials Rules(NDCT), 2019.
- But, these Rules do not use the term “emergency use authorization”.
- This term is used mainly by the regulatory agencies in the US and some other countries and has become popular in the context of the current epidemic.
- However, that does not mean that the Indian regulatory system does not have provisions for “special situations” like the current one.
- The NDCT rules 2019 provide for an “accelerated approval process” in several situations that would include the one like the current pandemic.
- In such situations, there is a provision for granting approval to a drug that is still in clinical trials, “provided there is a prima facie case of the product being of meaningful therapeutic benefit”.

- Provisions of these rules says that “Accelerated approval may also be granted to a new drug if it is intended for the treatment of a serious, or life-threatening condition, or disease of special relevance to the country, and addresses unmet medical needs,”. The definition of new drug in the 2019 Rules includes a vaccine.
- Further,the new rules make it clear that a new drug, or a vaccine, can be considered for approval if “remarkable” effectiveness is reported even from phase-II trials.
- Provided, the remarkable efficacy is observed with a defined dose in the phase-II clinical trials of the investigational new drug for the unmet medical needs of serious and life threatening disease in the country, it may be considered for grant of marketing approval by the central licensing authority based on phase-II clinical trial data.
- In such cases, additional post licensure studies may be required to be conducted after approval to generate the data on larger population
- Therefore, the approval granted to drugs or vaccines that are still in clinical trials is temporary, and valid only for one year.