What is Emergency Use Approval of a Vaccine?

December 9, 2020
In news

Recently, the USA's drug maker Moderna said it was applying for emergency use authorization for its COVID vaccine.

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).

Is approval necessary & what is the process?

- Vaccines and medicines, and even diagnostic tests and medical devices, require the approval of a regulatory authority before they can be administered.
- With respect to vaccines and medicines, approval is granted after an assessment of their safety and effectiveness, based on data from trials.
- The approval from the regulator is required at every stage of these trials.
- It's a long process, designed to ensure that a medicine or vaccine is absolutely safe and effective.
- The fastest approval for any vaccine until now – the mumps vaccine in the 1960s – took about four-and-a-half years after it was developed.
- During the emergency situations, like the current one, regulatory authorities around the world have developed mechanisms to grant interim approvals if there is

sufficient evidence to suggest a medical product is safe and effective.
- Final approval is granted only after completion of the trials and analysis of full data; until then, emergency use authorization allows the medicine or the vaccine to be used on the public.

When can emergency use authorization be granted?

- In the USA, the Food and Drug Administration (FDA) grants an EUA only after it has been determined that the "known and potential benefits outweigh the known and potential risks of the vaccine" (or medicine).
- It means that an EUA application can be considered only after sufficient efficacy data from phase 3 trials had been generated

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 authorisation".
- 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**.