Emergency Use Authorisation - COVID-19 Vaccines

Why in news?

- 'Emergency Use Authorisation' (EUA) has drawn attention around the world in line with vaccines that can help fight COVID-19.
- In India, too, the drug regulator has given Emergency Use Authorisation to three anti-Covid vaccines, the latest one being Russian Sputnik V.

What is Emergency Use Authorisation?

- A drug regulator would normally require some evidence for approving a drug, vaccine, device or a test.
- In the current pandemic situation, it may not be possible to have all such evidences.
- When there is a declared emergency, the regulator can decide whether it is worth releasing a drug or vaccine that is not fully tested for efficacy and safety.
    - In India's case, it is the DCGI (Drugs Controller General of India).
- If there is evidence to suggest it may benefit patients, then the regulator is well within its rights to issue an EUA to a medical product.
- It will then be made widely available for use.

Why is it important?

- In a pandemic situation, it is very important to restrain the spread of the pathogen in the quickest possible time.
- Typically, developing vaccines or drugs takes several years.
- A good part of this goes in carrying out trials to establish the vaccine's safety and efficacy.
- So the longer the wait, more people are likely to die.
- So, drug regulators in many countries follow a basic thumb rule.
    - This is to approve a drug or a vaccine if the known and potential benefits outweigh the known potential risks.

How does it work?

- An EUA does not mean that a vaccine has skipped essential safety trials.
- The regulators need to satisfy themselves that the product meets reasonable thresholds for safety and effectiveness before granting approval.

- In the US, for instance, the Food and Drug Administration grants EUA for Covid vaccines only after -
    i. a vaccine-maker has undertaken Phase 1 and Phase 2 trials
    ii. it is able to provide safety and efficacy data for Phase 3 trials as well, using data generated from over 3,000 participants
- In Phase 1 trials, a vaccine is given to a limited sample set of healthy people to assess its safety at higher doses.
- If Phase 1 does not throw up safety concerns, Phase 2 is undertaken on hundreds of people with different health conditions and from different population strata.
- This helps assess both the effectiveness and the side-effects.
- Phase 3 involves much larger sample, representative of the actual population, to assess both safety and efficacy.

How is it carried out in India?

- The process for using the EUA is less clearly spelt out in India.
- But the DGCI has also been issuing EUAs based on clinical trial data.
- In January 2021, the DCGI approved the first two vaccines:

1. Covishield, produced by Pune-based Serum Institute of India under licensing agreement from AstraZeneca
2. Covaxin, manufactured by Bharat Biotech

- The emergency approvals given to the three vaccines in India have helped in rolling out the largest vaccination drive in the world.
- But with the second wave proving quicker to spread than the first, capacity constraints are hitting the ramping up of vaccine supplies.
- Thus, granting EUA to new vaccines that have already been approved for emergency use in other countries becomes essential.

Source: Business Line