2. Two More Vaccines and a Drug join India's Fight against COVID

Prelims Syllabus: Medicine and Pharmaceuticals

Mains Syllabus: GS-II Issues relating to development and management of Social Sector or Services relating to Health, Education, Human Resources.

Why in News?

- India has recently approved two more vaccines under emergency use authorisation and an antiviral drug, Molnupiravir.

About the News:

- Currently, India uses Covishield, Covaxin and Sputnik V in its vaccination programme.
- Corbevax is co-developed by Biological E, Baylor College of Medicine in Houston, United States, and American company Dynavax Technologies.
- Covovax is produced by the Serum Institute of India under licence from Novavax, a U.S.-based biotechnology company.
- Covovax has been approved by the World Health Organisation (WHO) under its Emergency Use Listing and, therefore, will also be available globally as part of the COVAX initiative to ensure that at least 40% of world is vaccinated on priority.

Regular procedure for Drug Approval:

- Vaccines and medicines, and even diagnostic tests and medical devices, require the approval of a regulatory authority before they can be administered.
- In India, the regulatory authority is the Central Drugs Standard Control Organisation (CDSCO).
- For vaccines and medicines, approval is granted after an assessment of their safety and Effectiveness, based on data from Trials.

About CDSCO:

- The Central Drugs Standard Control Organisation (CDSCO) under Directorate General of Health Services, Ministry of Health & Family Welfare, Government of India is the National Regulatory Authority (NRA) of India.
- Under the Drugs and Cosmetics Act, CDSCO is responsible for
  - ✓ Approval of New 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 with a view to bring about the uniformity in the enforcement of the Drugs and Cosmetics Act.

- CDSCO along with state regulators is jointly responsible for grant of licenses of certain specialized categories of critical Drugs such as blood and blood products, Vaccine and Sera.

When can Emergency use Authorisation (EUA) be Granted?

- In the US, the Food and Drug Administration (FDA) grants EUA only after it has been determined that the "known and potential benefits outweigh the known and potential risks of the vaccine" (or medicine).
- This means that a EUA application can be considered only after sufficient efficacy data from phase 3 trials had been generated.
- A EUA cannot be granted solely on the basis of data from phase 1 or phase 2 trials.

What is the process of getting an Emergency use Authorisation in India?

- Experts and activists say India's drug regulations do not have provisions for a EUA, and the process for receiving one is not clearly defined or consistent.
- Despite this, CDSCO has been granting emergency or restricted emergency approvals to COVID-19 drugs during this pandemic for Remdesivir and favipiravir.
- Already it has granted permission for Covaxin, Covishield and Sputnik V.

Is there a risk in using a Product that has only been Granted a EUA?

- Now the public has to be informed that a product has only been granted an EUA and not Full Approval.
- In the case of a Covid-19 vaccine, for example, people have to be informed about the known and potential benefits and risks, and the "extent to which such benefits or risks are unknown", and that they have a right to refuse the Vaccine.