Emergency Use Listing (EUL)

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In news- Bharat Biotech International will hold a preliminary meeting with the World Health Organization (WHO) before applying for an emergency-use listing (EUL) for its covid vaccine, Covaxin.

About emergency-use listing (EUL)-

- The World Health Organization (WHO) developed the **Emergency Use Assessment and Listing (EUAL) mechanism** in response to the **2014 – 2016 Ebola Virus Disease (EVD) outbreak.**
- The EUAL is a risk-based procedure for assessing and listing unlicensed vaccines, therapeutics and in vitro diagnostics (IVDs) for use primarily during **public health emergencies of international concern (PHEIC)**.
- Later the **EUL procedure replaced** the Emergency Use Assessment and Listing (**EUAL**) procedure.
- The **EUL** is a special procedure intended to **provide a time-limited listing for unlicensed products in an emergency context** when limited data are available and the products are not yet ready for application for prequalification.
- The manufacturer will complete the development of the product and submit for licensure and WHO prequalification.
- The **EUL is not intended to interfere with ongoing clinical trials.**
- Bharat Biotech officials, on 19 April, 2021 had submitted an expression of interest for EUL with WHO.
- After the company submits its final proposal for Covaxin's EUL, **WHO's product evaluation group** comprising regulatory experts from around the world and a technical advisory group will conduct a review.
- The process may include **on-site inspections of the**

company's facilities.

- The company had recently issued a statement saying that the second interim data from its **phase 3 trial** of nearly 26,000 participants showed that the vaccine has an **efficacy of 78% in preventing covid-19.**
- This efficacy is partially lower than the 80.6% found in the first interim data in March, 2021.
- **WHO's cutoff for efficacy of covid-19 vaccines is 50%,** the same as the lower limit set by regulators in India, the US and other countries.
- A WHO EUL will **make those inoculated with Covaxin eligible to enter regions such as the European Union.**
- While WHO and European Medicines Agency (EMA) have authorized vaccines from Pfizer, Moderna, AstraZeneca and Johnson & Johnson, WHO has also included jabs from China's Sinopharm in its list.