WHO lists 9th COVID-19 vaccine for emergency use with aim to increase access to vaccination in lower-income countries

17 December 2021 GENEVA - Today, the World Health Organization issued an emergency use listing (EUL) for NVX-CoV2373, expanding the basket of WHO-validated vaccines against the SARS-CoV-2 virus. The vaccine, named CovovaxTM, is produced by the Serum Institute of India under licence from Novavax and is part of the COVAX facility portfolio, giving a much-needed boost to ongoing efforts to vaccinate more people in lower-income countries.

WHO's EUL procedure assesses the quality, safety and efficacy of COVID-19 vaccines and is a prerequisite for COVAX vaccine supply. It also allows countries to expedite their own regulatory approval to import and administer COVID-19 vaccines.

"Even with new variants emerging, vaccines remain one of the most effective tools to protect people against serious illness and death from SARS-COV-2," said Dr Mariângela Simão, WHO Assistant-Director General for Access to Medicines and Health Products. 'This listing aims to increase access particularly in lower-income countries, 41 of which have still not been able to vaccinate 10% of their populations, while 98 countries have not reached 40%."

CovovaxTM was assessed under the WHO EUL procedure based on the review of data on quality, safety and efficacy, a risk management plan, programmatic suitability, and manufacturing site inspections carried out by the Drugs Controller General of India. The Technical Advisory Group for Emergency Use Listing (TAG-EUL), convened by WHO and made up of experts from around the world, has determined that the vaccine meets WHO standards for protection against COVID-19, that the benefit of the vaccine far outweighs any risks, and that the vaccine can be used globally.

CovovaxTM is a subunit of the vaccine developed by Novavax and the Coalition for Epidemic Preparedness Innovations (CEPI). It requires two doses and is stable at 2 to 8 °C refrigerated temperatures. The vaccine uses a novel platform and is produced by creating an engineered baculovirus containing a gene for a modified SARS-CoV-2 spike protein.

The originator product produced by Novavax, named NuvaxovidTM, is currently under assessment by the European Medicines Agency (EMA). WHO will complete its own assessment of this vaccine once the EMA has issued its recommendation.

A meeting of WHO's Strategic Advisory Group of Experts on Immunization (SAGE) this week also reviewed the vaccine. SAGE formulates specific policies and recommendations for vaccines' use in populations (i.e.

recommended age groups, intervals between doses, specific groups such as pregnant and lactating women) and will issue recommendations for NuvaxovidTM/CovovaxTM in the coming days.

WHO emergency use listing

The emergency use listing (EUL) procedure assesses the suitability of novel health products during public health emergencies. The objective is to make medicines, vaccines and diagnostics available as rapidly as possible to address the emergency while adhering to stringent criteria of safety, efficacy and quality. The assessment weighs the threat posed by the emergency as well as the benefit that would accrue from the use of the product against any potential risks.

The EUL pathway involves a rigorous assessment of late phase II and phase III clinical trial data, as well as substantial additional data on safety, efficacy, quality and a risk management plan. These data are reviewed by independent experts and WHO teams who consider the current body of evidence on the vaccine under consideration, the plans for monitoring its use, and plans for further studies.

As part of the EUL process, the company producing the vaccine must commit to continue to generate data to enable full licensure and WHO prequalification of the vaccine. The WHO prequalification process will assess additional clinical data generated from vaccine trials and deployment on a rolling basis to ensure the vaccine meets the necessary standards of quality, safety and efficacy for broader availability.

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