

WHO prequalifies first Ebola vaccine

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The World Health Organization (WHO) on Tuesday said it had prequalified an Ebola vaccine for the first time, hailing a "critical step" towards its licensing, access and roll-out in countries most at risk of



outbreaks.

"This is the fastest vaccine prequalification process ever conducted by WHO," it said in a statement, explaining that "prequalification means that the vaccine meets WHO standards for quality, safety and efficacy."

The announcement comes hot on the heels of a decision last Monday by the European Commission to allow the release to market of the injectable vaccine, Ervebo, made by US laboratory Merck Sharpe and Dohme (MSD) after the European Medicines Agency gave the product its green light on October 18.

"This is a historic step towards ensuring the people who most need it are able to access this life-saving vaccine," said WHO Director-General Tedros Adhanom Ghebreyesus.

"Five years ago, we had no vaccine and no therapeutics for Ebola. With a prequalified vaccine and experimental therapeutics, Ebola is now preventable and treatable," he added.

WHO said Ervebo has been shown to be effective in protecting people from the Ebola Zaire virus and added it is recommended by the organisation's Strategic Advisory Group of Experts (SAGE) for vaccines as part of a broader set of Ebola response tools.

The WHO said licensed doses will only be available from the middle of next year.

WHO said it had "accelerated prequalification by reviewing safety and efficacy data as the information became available" and said it was engaged in facilitating licensing for use in countries at risk of Ebola outbreaks.



"WHO, with the support of EMA, has worked closely with many African regulators who have indicated they will quickly license the vaccine following the WHO recommendation," the world body said.

Since the current epidemic, which has cost some 2,190 lives out of 3,290 declared cases since it began in DR Congo, more than 236,000 people have been treated, according to the WHO, including 60,000 health professionals, with the vaccine, known in the lab as rVSV-ZEBOV-GP.

Merck's vaccine was administered to them under an exceptional procedure, granting permission to use non-licensed drugs in emergency cases.

A second vaccine still at the experimental stage and developed by Johnson & Johnson for administration in two doses at 56-day intervals, is due to be introduced in the coming days in zones where the virus is as yet absent.

The current epidemic in DR Congo is the tenth in the country since the first in 1976. It is the second most deadly to date after a 2014-2016 outbreak which cost some 11,000 lives and underscored the urgency to bring a <u>vaccine</u> to market.

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