

UK approves Pfizer/BioNTech Covid vaccine for rollout next week

'Historic moment' allows mass immunisation, with 800,000 doses expected to be available next week

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The UK has become the first western country to license a vaccine against Covid, opening the way for mass immunisation with the Pfizer/BioNTech vaccine to begin next week for those most at risk.

The vaccine has been authorised for emergency use by the Medicines and Healthcare products Regulatory Authority (MHRA), before decisions by the US and Europe. The MHRA was given power to approve the vaccine by the government under special regulations before 1 January, when it will become fully responsible for medicines authorisation in the UK after Brexit.

The first doses of the vaccine would arrive in the coming days, said the company. The UK has bought 40m doses of the vaccine, which has been shown to have 95% efficacy in its final trials.

A Department of <u>Health</u> and Social Care spokesman said: "The government has today accepted the recommendation from the MHRA to approve Pfizer/BioNTech's Covid-19 vaccine for use.

"This follows months of rigorous clinical trials and a thorough analysis of the data by experts at the MHRA who have concluded that the vaccine has met its strict standards of safety, quality and effectiveness.

"The Joint Committee on Vaccination and Immunisation will shortly also publish its latest advice for the priority groups to receive the vaccine, including care home residents, health and care staff, the elderly and the clinically extremely vulnerable. The vaccine will be made available across the UK from next week."

The health secretary, Matt Hancock, said the first doses would be issued to the most vulnerable people. The UK would have 800,000 doses available next week, he said.

Older people and those in care homes, including staff, would be first in line for immunisation "and then it essentially comes down the age range", Hancock said. NHS staff were also high on that priority list and also the clinically extremely vulnerable, he said.

He added: "The goal will be to vaccinate through the NHS right across the UK as rapidly as the company can manufacture. It will help save lives. Once we've protected the most vulnerable it will help us all get back to normal and back to some of the things that we love."

Hancock told BBC News that from Easter next year, the country could return to some normality and indicated that no restrictions would be needed by summer 2021.

He said: "So many families have suffered, including my own. I'm just so, so pleased ... 2020 has been just awful and 2021 is going to be better. Help is on its way. Help is on its way with this vaccine – and we can now say that with certainty rather than with all the caveats that we normally have to put around that.

"I'm confident now, with the news today, that from spring – from Easter onwards – things are going to be better. We're going to have a summer next year that everybody can enjoy. Between now and then we've got to hold our resolve."

The JCVI is expected to set out later on Wednesday morning which groups of people will be eligible from next week.

Albert Bourla, the chairman and chief executive officer of Pfizer added: "Today's emergency use authorisation in the UK marks a historic moment in the fight against Covid-19. This authorisation is a goal we have been working toward since we first declared that science will win, and we applaud the MHRA for their ability to conduct a careful assessment and take timely action to help protect the people of the UK."

Although the vaccine has to be kept at -70C, the companies say it can be stored for up to five days in a fridge, at 2-8°C. The first priority groups for vaccination are care home residents, who may not be able to come to a vaccination centre, together with the staff who look after them. At fridge temperatures, it may be possible for the vaccine to be brought to them. Next in line will be the over-80s and NHS staff.

The trial data showed the vaccine had equal efficacy among younger volunteers and those over 65 who are most at risk from Covid. Gender, race and ethnicity also made no difference.

Pfizer and BioNTech say their combined manufacturing network has the potential to supply globally up to 50m vaccine doses in 2020 and up to 1.3bn doses by the end of 2021.

The delivery of the UK's 40m doses will start immediately. Delivery will continue throughout 2020 and 2021 in stages "to ensure an equitable allocation of vaccines across the geographies with executed contracts", say the companies.

The US, which has ordered 100m doses, and Europe, which has bought 200m, are expected to approve the vaccine within weeks.

The MHRA has moved with unprecedented speed to grant emergency use authorisation, having received the final data from the companies on 23 November. It has been carrying out a rolling approval process, scrutinising data from early trials as they came in.

"The emergency use authorisation in the UK will mark the first time citizens outside of the trials will have the opportunity to be immunised against Covid-19," said Uğur Şahin, the CEO and co-founder of BioNTech.

"We believe that the rollout of the vaccination programme in the UK will reduce the number of people in the high-risk population being hospitalised. Our aim is to bring a safe and effective vaccine upon approval to the people who need it. The data submitted to regulatory agencies around the world are the result of a scientifically rigorous and highly ethical research and development programme."

Link to the original source (the Guardian):

https://www.theguardian.com/society/2020/dec/02/pfizer-biontech-covid-vaccine-wins-licence-for-use-in-the-uk