Pfizer-BioNTech's Covid-19 vaccine: path ahead in UK

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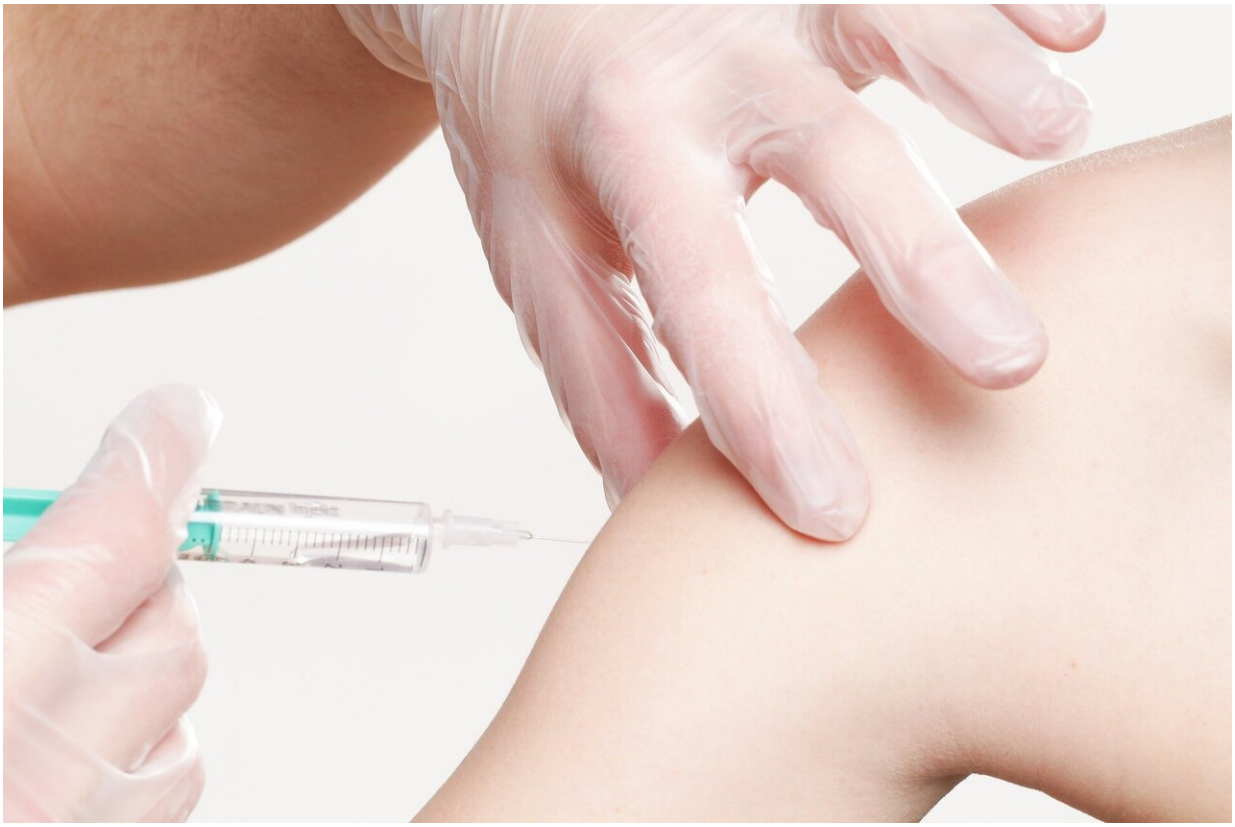

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The British government has accepted a recommendation by the country's independent medicines regulator to approve Pfizer-BioNTech's COVID-19 vaccine for general use.

Here are some of the next steps.

When will it be available?

Pfizer said Wednesday it will begin delivering the vaccine to Britain within days.

UK Health Secretary Matt Hancock has announced the rollout will then begin "early next week" for the most vulnerable.

The country's state-run National Health Service (NHS) will be charged with conducting the mass vaccination programme over the subsequent weeks and months.

How many doses are on order?

The vaccine, which proved 95 percent effective in global trials, requires two doses 21 days apart.

BioNTech and Pfizer have said they expect to supply up to 50 million doses globally in 2020, and up to 1.3 billion in 2021.

Britain has pre-ordered 40 million in total, and expects to receive an initial batch of 800,000 to begin next week's rollout.

Regulators are still to grant approval for the vaccine in the United States, which has ordered 100 million doses, and in the European Union, where 300 million are on order.

Who will get it first?

UK health officials have drawn up criteria to decide when people will receive any approved COVID-19 vaccines.

Preventing further deaths and protecting health and social care staff and systems are the top priority.

Elderly care home residents and their carers will be the very first to get inoculated, then those aged 80 and over and frontline health and care staff.

Other elderly people and the clinically extremely vulnerable will be next, with the rest of the population then prioritised by age.

In the US, a high-level panel of experts voted Tuesday for a similar plan that will see health care workers and residents of long-term care facilities get the jabs first.

What are the challenges?

Pfizer-BioNTech's vaccine poses significant obstacles when it comes to transport and storage.

It must be stored at -70 degrees Celsius (-94 degrees Fahrenheit), temperatures much colder than those of a standard freezer.

The vaccine will be manufactured at BioNTech's sites in Germany and Pfizer's plant in Puurs, Belgium, and transported in temperature-controlled thermal shippers that use dry ice.

Professor Munir Pirmohamed, of the UK's Commission on Human Medicines which advises on the safety of medicinal products, said it is stable for "a short period of time" at 2-8 Celsius.

This will allow for transportation and regular fridge storage for up to five days at distribution centres, according to the government.

It said last month it was "confident that the cold supply chain needed... will not cause any problems and will make no difference to the speed at which the UK will receive its doses".

How did the UK approve it first?

Britain's independent Medicines and Healthcare products Regulatory Agency (MHRA) used a "rolling review" process to assess the vaccine in record time since June.

"We have carried out a rigorous scientific assessment of all the available evidence of quality, safety and effectiveness," MHRA chief executive June Raine said Wednesday.

"Our expert scientists and clinicians worked tirelessly, around the clock, carefully, scientifically, robustly and rigorously poring over hundreds of pages and tables of data, methodically reviewing the data."

Penny Ward, professor in pharmaceutical medicine at King's College London, said the MHRA was less constrained by having to consult more widely, as is the case with the European Medicines Agency (EMA) and the US Food and Drug Administration.

The MHRA had been "permitted to take unilateral decisions" on the same available data as part of Britain's divorce deal with the 27-member European Union, she added.

"Unlike the EMA (European Medicines Agency), they can ask questions as they go and obtain responses faster as a single agency," she said.