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Injection of urgency

Britain to be first to license a fully tested covid-19 vaccine

Inoculations with the Pfizer-BioNTech jab could start in less than a week

THE FIRST fully-tested covid-19 vaccine is expected to be approved imminently in Britain. The drug regulator, the Medicines and Healthcare products Regulatory Agency (MHRA), is believed to be about to grant emergency authorisation to the vaccine made by Pfizer, an American pharmaceutical giant, and BioNTech, a smaller German firm. Trials have shown that the vaccine has an efficacy of 95%, a response consistently found in people of different ages, sexes and ethnicities.

Britain has ordered 40m doses of the mRNA vaccine, known as BNT162b2. The regulator's decision will trigger the release of supplies. These are expected to come from a manufacturing site in Puurs, Belgium, and will be delivered in stages this year and throughout 2021. Britain has also told hospitals to be ready to distribute the vaccine as soon as December 7th. In the interim, Britain's Joint Committee on Vaccination and Immunisation will have to make a final decision on the priority groups for vaccination—such as health-care workers and those at high-risk from covid-19.

The speed with which the vaccine is moving through regulatory systems is due to the rolling reviews that have been under way for some time. Instead of waiting for pharmaceutical firms to collate and submit a full data and safety package, regulators have been reviewing results as they become available. In a statement a week ago, the MHRA said that “no covid-19 vaccine would be authorised until it has demonstrated safety, quality and efficacy through a robust clinical trial programme”.

Even so, Britain has moved remarkably quickly. Earlier today, the head of America's Food and Drug Administration (FDA) was summoned to the White House to answer questions on why his agency has not moved faster to approve BNT162b2. The move will also fuel concern that Britain's rapid movement is political, and might even be an example of “regulatory nationalism”—ie, countries moving quickly to approve vaccines in order to jump ahead of the queue for deliveries.

Britain is home to a small, but well-regarded, medicines agency. Nevertheless, both the FDA and the European Medicines Agency have arranged public meetings in the coming weeks at which covid-19 vaccines will be discussed—ahead of regulatory

approval. Melanie Ivarsson, chief development officer at Moderna, which announced highly encouraging results for its own mRNA vaccine a week after Pfizer and BioNTech, said these were important, as they allow independent experts to look at the safety and the analysis, and for the public to ask questions, something that will build confidence in these vaccines. “We want people to feel really comfortable,” says Dr Ivarsson.

Vaccine experts are optimistic about the general safety of the mRNA vaccine platform. Although this is the first time an mRNA vaccine has been authorised for human use, mRNA vaccines have been tested for various applications in cancer for over a decade. The BNT162b2 vaccine, as well as Moderna’s, have now been in trials comprising 73,000 volunteers. Half of these would have been given active vaccine. In clinical-trial terms, this is a hefty dataset. Both vaccines have been well tolerated with no serious adverse events.

Although a large number of patients have been tested, health authorities have already constructed safety follow-up plans, says Penny Ward, chair of the education and standards committee of the Faculty of Pharmaceutical Medicine, a charity. These include a system for following up adverse reactions, and using anonymised healthcare records to see how the incidence of disease varies between those who have been vaccinated and those who have not. One hypothetical concern with any new vaccine is that it may make the risk of infection worse in some groups. Another is that in rare cases vaccines can trigger autoimmune reactions. Viral infections can do this too.

There are, though, also hypothetical reasons to think that mRNA vaccines might actually be safer than some other kinds of vaccine. Live vaccines, for example, are weakened versions of the virus itself, but there is a risk that the virus will revert to a more dangerous form. With covid-19 vaccines being delivered to hundreds of millions, and then billions, of people, a great deal of surveillance will be needed.

The Pfizer vaccine delivers a strand of genetic material—mRNA—encapsulated in tiny spheres of fat. This mRNA directs human cells to produce a piece of the virus, the spike protein, inside the human body. From here the body mounts an immune response. Because the protein is manufactured in situ, the body sees this protein in exactly the same way that it would see the virus itself.

And mRNA is a natural component of living cells, which is made and destroyed regularly every day. Its turnover is measured in days. Once the mRNA from the vaccine is delivered into the body it will prime the immune system and then be broken down. The inherent instability of mRNA is why the Pfizer vaccine needs to be kept frozen at less than -70°C . Misinformation has also been spread about the vaccine. One falsehood is that it will alter DNA. This is more than a little unlikely. The “central dogma” of molecular biology is that genetic information flows from DNA,

through to RNA, and then to make proteins. For RNA to alter DNA it would have to break this biological axiom.

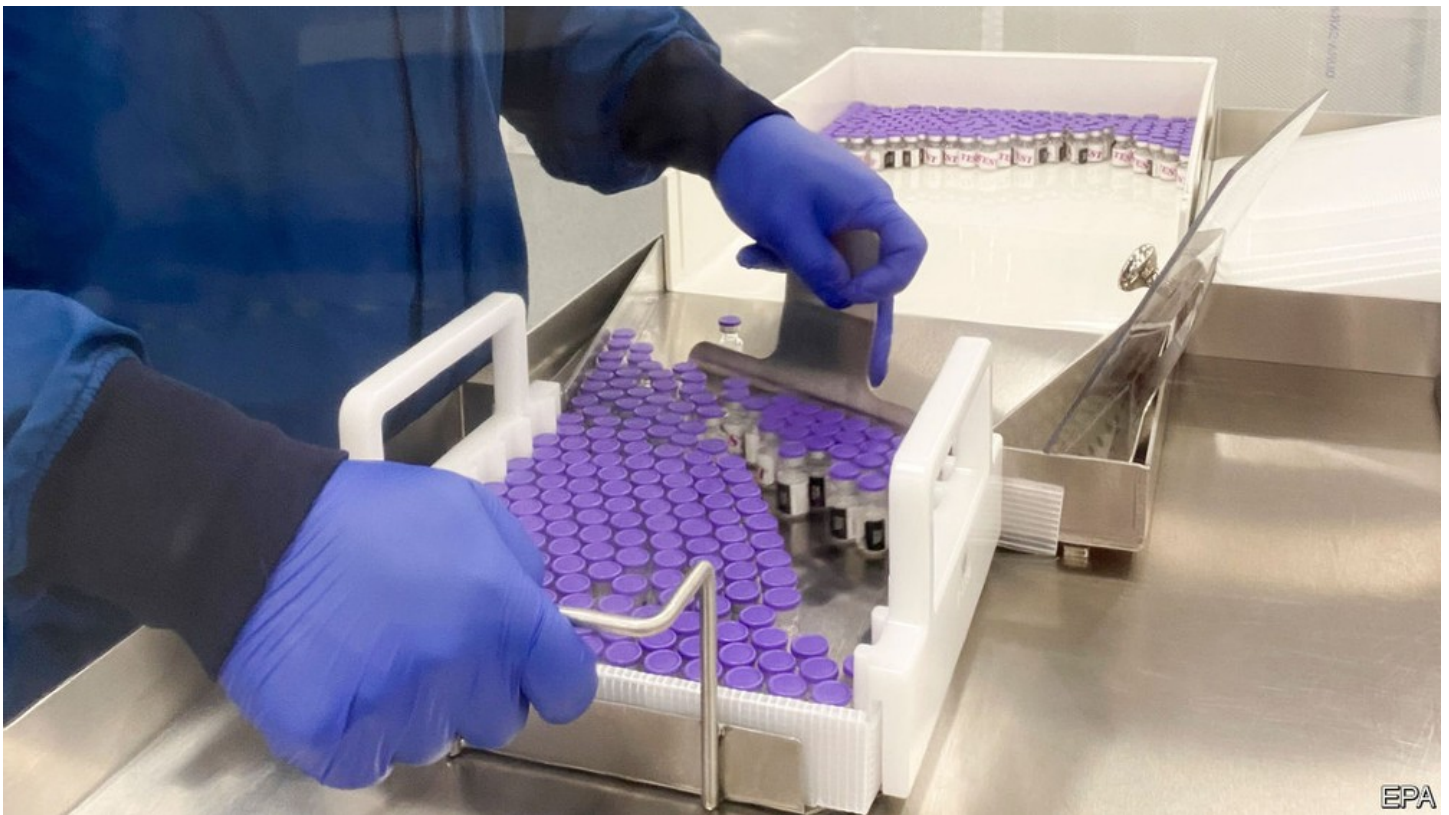
Having moved so quickly, the MHRA, and the British government, will be under pressure to convince the public that the regulator has made a good decision. That may be easier in Britain where polls say 79% of people intend to take a covid-19 vaccine, above the international average. In America, by contrast, only 64% say the same. Ultimately all decisions to approve medicines are taken on the balance of risks versus benefits. For vaccines the benefits always have to vastly outweigh the possible risks, simply because, unlike drugs, they are given to healthy people. Although it would have been useful to know what factors the MHRA took when weighing the decision to grant emergency authorisation, one brutal calculation may have been foremost in regulators' minds: each day of waiting is measured in lost lives.

Science & technology

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Britain becomes the first country to license a fully tested covid-19 vaccine

Inoculations with the Pfizer-BioNTech jab could start in less than a week



Dec 1st 2020



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pharmaceutical giant, and BioNTech, a smaller German firm. Trials have shown that the vaccine has an efficacy of 95%. Ugur Sahin, head of BioNTech, said the decision would reduce people in the high-risk population being hospitalised. The

firms anticipate further such decisions in the coming days and weeks, and say it marks an historic milestone in the fight against covid-19.

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Editor’s note: This piece has been updated following authorisation for the vaccine being granted

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