Vaccinating the UK: how the covid vaccine was approved, and other questions answered

The momentous news that the first covid-19 vaccine had been approved in the UK has prompted questions about how it was authorised and will be delivered. The BMJ spoke to experts to find out the answers

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How was the MHRA able to approve the vaccine so quickly?

The Medicines and Healthcare Products Regulatory Agency gave temporary authorisation to the supply of specific batches of Pfizer and BioNTech’s vaccine on 2 December,1 on the basis of efficacy data submitted between 1 October and 2 December 2020. The regulator credits the rapid turnaround to its “rolling review” process, which allowed it to analyse the data as they were submitted.

The MHRA has not published specific details about the approval process, but a spokesperson told The BMJ that scientists and clinicians had “carefully and scientifically reviewed the safety, quality, and effectiveness data—how [the vaccine] protects people from covid-19 and the level of protection it provides.”

The agency added, “The data included results from the lab and clinical trials in humans, manufacturing and quality controls, product sampling, and testing of the final product. This process is designed to make sure that any vaccine approved meets the expected high standards of safety, quality, and effectiveness.”

Phase III data from the Pfizer and BioNTech vaccine trial have not yet been published.

Why was the vaccine given temporary authorisation?

Usually, the UK would wait for the European Medicines Agency to approve a vaccine before looking to distribute it, but in an emergency EU countries are allowed to use their own regulator to issue temporary authorisation. In October the government made changes to the Human Medicines Regulations 2012 to allow the MHRA to grant temporary authorisation of a covid-19 vaccine without needing to wait for the EMA.2

A temporary use authorisation is valid for one year only and requires the pharmaceutical companies to complete specific obligations, such as ongoing or new studies, says the law firm Brodies.3 Once comprehensive data on the product have been obtained, standard marketing authorisation can be granted. This initially lasts five years but can be renewed and is not subject to specific obligations.

Have only certain batches of the vaccine been approved?

Yes, but this is the standard procedure for all new vaccines, says David Salisbury, David director of immunisation at the Department of Health for England until the end of 2013 and now an associate fellow for the global health programme at the think tank Chatham House.

He explained, “Each batch of vaccine that gets released for use will have gone through both the manufacturer’s own testing and independent external testing from an agency such as the NIBSC [National Institute for Biological Standards and Control]. And until NIBSC is satisfied, and the manufacturer is able to provide the evidence and the regulator is satisfied, all batches get tested.”

What about other European countries?

Most European Union countries are waiting for the EMA to grant approval. The EMA has said it will decide by 29 December whether to provisionally authorise the Pfizer and BioNTech vaccine. Unlike the UK’s temporary authorisation, the EMA is hoping to grant the vaccine “conditional marketing authorisation” for its use in any EU country.

The Swiss medical regulator Swissmedic has said it did not have all the data it needed to approve the vaccines, especially when it came to use in people with pre-existing illnesses. “We lack data on the effectiveness of the clinical trials and on the important subgroups that participated in these large studies,” said Claus Bolte, head of Swissmedic’s authorisation division, at a press briefing on 1 December.4

Does approval have anything to do with Brexit?

Though some MPs have suggested that this approval process has been made possible only because the UK is leaving the European Union, Salisbury said that is not true. The MHRA acted in line with EU regulations, and any other EU country could have done the same, he said.

Stephen Evans, professor of pharmacoepidemiology at the London School of Hygiene and Tropical Medicine, has said that still being in the transition period may have helped speed up the approval because UK staff have not had to assess new vaccines or drugs intended for the whole EU for the past 18 months, allowing them to focus on the UK authorisation.

However, this will change from 1 January 2021 when the MHRA will become responsible for handling all applications for new drugs and vaccines to be authorised in the UK.
And the US?

Leaders in the US seemed to have criticised the UK’s process, with US Food and Drug Administration commissioner Stephen Hahn and National Institute of Allergy and Infectious Diseases director Anthony Fauci suggesting that the US’s approval system was better.

Hahn, who was called to the White House to explain why the US would not be the first country to distribute a vaccine, said in a recent interview, “We’re not going to take a summary from a company and take their conclusions and base our decision on that . . . We’re going to crunch the numbers ourselves.”

Fauci said that the US had the “gold standard of a regulatory approach” and that “the UK did not do it as carefully” but later apologised, saying, “Our process is one that takes more time than it takes in the UK. I did not mean to imply any sloppiness even though it came out that way.”

Salisbury said he trusted the MHRA’s scrutiny. “I have full confidence that they will have undertaken due diligence. They will have scrutinised all of the information as thoroughly as was appropriate. And to my knowledge, neither Tony Fauci, for whom I have great respect and know, or the FDA commissioner were members of the MHRA.”

The MHRA defended its processes. A spokesperson told The BMJ, “Covid-19 vaccines, including this one, are being developed in a coordinated way that allows some stages of this process to happen in parallel to condense the time needed, but it does not mean steps and the expected standards of safety, quality, and effectiveness have been bypassed.”

Who will get the vaccine first?

Although care home residents were initially deemed the highest priority for vaccination, the challenge of delivering the vaccine at −70°C and the fact it comes in batches of 957 doses have meant a change to plans. From 8 December care home staff and people aged over 80 will be called in to 50 “hospital hubs” around England for their first vaccination and recalled three weeks later for their second shot. Any appointments not used will go to healthcare staff at higher risk of serious illness from covid-19. Once more vaccine becomes available, more than 1000 local vaccination centres, operated by groups of GPs, will be set up across the country, and pharmacies will also be able to deliver shots after vaccine units can be split. The health services in Wales, Scotland, and Northern Ireland will run their own vaccination programmes.

Do people who have had covid-19, including those with long covid, need to be vaccinated?

Yes, says Salisbury. “We do not know the length of immunity of the natural infection and therefore having a vaccine will not do them harm and has the probability of doing the benefit . . . I can’t think of reasons why you should not be vaccinated,” he said. “And we do know that people who’ve had covid can be reinfected. My judgment would be, if you’re offered the vaccine, to have it. But there are many questions to which as yet we don’t have evidence based answers.”

If I’m vaccinated do I still need to self-isolate?

Government sources told the Telegraph that “people who get vaccinated will have to stick to the same rules as everyone else because we don’t know if it stops people being carriers and passing the virus on to others.”

Who shouldn’t be vaccinated?

The vaccine has not been approved for use in pregnant women, and women of childbearing age should be advised to avoid pregnancy for at least two months after their second dose. The vaccine should also not be used during breastfeeding.

People receiving “anticoagulant therapy or those with a bleeding disorder that would contraindicate intramuscular injection should not be given the vaccine unless the potential benefit clearly outweighs the risk of administration,” the MHRA has said.

The Joint Committee on Vaccination and Immunisation has also specified that only children (under 16) at “very high risk of exposure and serious outcomes, such as older children with severe neuro-disabilities that require residential care, should be offered vaccination.”

Do we know anything about interactions with other drugs?

No. In guidance to healthcare professionals the MHRA said that “no interaction studies have been performed.”

2. Mahase E. Midwives and paramedics can deliver flu and covid vaccines after new laws come into force. BMJ 2020;371:m4044. doi: 10.1136/bmj.m4044 pmid: 33067245
5. Dyer O. White House demands to know how UK approved vaccine before FDA. BMJ 2020;371:m4725. doi: 10.1136/bmj.m4725 pmid: 33272918

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The mechanics of medicines regulation: shining a spotlight on the MHRA vaccine approval decision.


