

UK probes whether COVID-19 vaccine caused allergic reactions

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Paula McMahon prepares a shot of the Pfizer-BioNTech COVID-19 vaccine, as the mass public vaccination program gets underway, at the NHS Louisa Jordan Hospital in Glasgow, Scotland, Tuesday Dec. 8, 2020. The United Kingdom is beginning its vaccination campaign to inoculate people against the COVID-19 virus. (Jeff J Mitchell/Pool via AP)

Britain's medical regulator warned Wednesday that people with a history of serious allergic reactions shouldn't get the COVID-19 vaccine from Pfizer and BioNTech, and investigators looked into whether two reactions on the first day of the U.K.'s vaccination program were linked to the shot.

The advice was issued on a "precautionary basis," and the people who had the reactions had recovered, said professor Stephen Powis, medical director for National Health Service in England.

Pfizer and BioNTech said they were working with investigators "to better understand each case and its causes."

Also on Wednesday, Canada's health regulator approved the vaccine, with Dr. Supriya Sharma, chief medical adviser at Health Canada, calling it "a momentous occasion."

Canada is set to receive up to 249,000 doses this month and Canadian officials expect to start administering them next week as soon after they are shipped from Belgium on Friday.

Britain's Medical and Healthcare Products Regulatory Agency has said people should not receive the shot if they have had a significant allergic reaction to a vaccine, medicine or food, such as those who have been told to carry an adrenaline shot—such as an EpiPen or other similar devices—or others who have had potentially fatal allergic reactions. The medical regulator also said vaccinations should be carried out only in facilities that have resuscitation equipment.



In this file photo dated Wednesday, July 22, 2020, a Pfizer sign is seen on a podium at the Pfizer Research & Development Laboratories, in Groton, USA. The U.K. health authorities rolled out a national mass vaccination program Tuesday Dec. 8, 2020, using the Pfizer-BioNTech COVID-19 vaccine. U.K. regulators said Wednesday Dec. 9, 2020, that people who have a "significant history" of allergic reactions shouldn't receive the new Pfizer/BioNTech vaccine while they investigate two adverse reactions that occurred on the first day of the country's mass vaccination program. (AP Photo/Stew Milne)

Such advice isn't uncommon; several vaccines already on the market carry warnings about allergic reactions, and doctors know to watch for them when people who've had reactions to drugs or vaccines in the past are given new products.

The two people who reported reactions were NHS staff members who had a history of significant allergies and carried adrenaline shots. Both had serious reactions but recovered after treatment, the NHS said.

Stephen Evans, a professor of pharmacoepidemiology at the London School of Hygiene & Tropical Medicine, said the regulator had done the right thing, but the general public shouldn't be worried about getting the vaccine.

"For the general population, this does not mean that they would need to be anxious about receiving the vaccination. One has to remember that even things like Marmite can cause unexpected severe allergic reactions," he said, referring to the food spread that is made from brewer's yeast.



A nurse holds a phial of the Pfizer-BioNTech COVID-19 vaccine at Guy's Hospital in London, Tuesday, Dec. 8, 2020, as the U.K. health authorities rolled out a national mass vaccination program. U.K. regulators said Wednesday Dec. 9, 2020, that people who have a "significant history" of allergic reactions shouldn't receive the new Pfizer/BioNTech vaccine while they investigate two adverse reactions that occurred on the first day of the country's mass vaccination program. (AP Photo/Frank Augstein, Pool)

Dr. Ashish Jha, dean of the school of public health at Brown University, said he would advise patients who have had severe allergic reactions to other medicines or foods to delay vaccination if they can while the two cases in the U.K. are investigated. He would extend that advice to people who carry EpiPens.

"The cautionary approach is to say to people who have had severe reactions to other things, 'just hold,'" Jha said, adding: "There is going to be a deep dive into these two people who got an allergic reaction" to the vaccine.

He added that because the vaccine is so high-profile, "every little thing that happens all the time is going to get magnified. We should talk about it, we should be honest with people, but we should put it into context and help people understand ... there is a small proportion of people who have an allergic reaction to almost any medicine."

The comments came a day after Britain rolled out its mass vaccination program amid efforts to control a pandemic that has killed more than 62,000 people across the country. The MHRA gave an emergency authorization to the Pfizer-BioNtech vaccine last week, making Britain the first country to approve its widespread use.



Health Canada's Chief Medical advisor Supriya Sharma, right, and Deputy Chief Public Health Officer Howard Njoo, center, look on as Maj. Gen. Dany Fortin holds up a device used in the transportation a vaccine during a COVID-19 vaccine-related news conference in Ottawa, Wednesday, Dec. 9, 2020. (/Adrian Wyld/The Canadian Press via AP)

Even in nonemergency situations, health authorities must closely monitor new vaccines and medications because studies in tens of thousands of people can't detect a rare risk that would affect 1 in 1 million. Authorities have not said how many people have received the shot in Britain so far, but they plan to give 800,000 doses in the first phase, which will target people over 80, nursing home staff and some NHS

workers.

Late-stage trials of the vaccine found "no serious safety concerns," Pfizer and BioNTech said. More than 42,000 people have received two doses of the shot during those trials.

Detailed data from the vaccine's trials showed potential allergic reactions in 0.63% of those who received the vaccine, compared with 0.51% of those who received the placebo. Reviewers from the U.S. Food and Drug Administration called this a "slight numerical imbalance."

Documents published by the two companies showed that people with a history of severe allergic reactions were excluded from the trials, and doctors were advised to look out for such reactions in trial participants who weren't previously known to have severe allergies.



A nurse administers the Pfizer-BioNTech COVID-19 vaccine at Guy's Hospital in London, Tuesday, Dec. 8, 2020. U.K. health authorities rolled out the first doses of a widely tested and independently reviewed COVID-19 vaccine Tuesday, starting a global immunization program that is expected to gain momentum as more serums win approval. (AP Photo/Frank Augstein, Pool)

As part of its emergency authorization for the vaccine, the MHRA required health care workers to report any adverse reactions to help regulators gather more information about safety and effectiveness.

The agency is monitoring the vaccine rollout closely and "will now investigate these cases in more detail to understand if the allergic reactions were linked to the vaccine or were incidental," Powis said. "The fact that we know so soon about these two allergic reactions and that the regulator has acted on this to issue precautionary advice shows that this monitoring system is working well."

Dr. June Raine, head of the medical regulatory agency, informed a parliamentary committee about the reactions during previously scheduled testimony on the pandemic.

"We know from the very extensive clinical trials that this wasn't a feature" of the vaccine, she said. "But if we need to strengthen our advice, now that we have had this experience in the vulnerable populations, the groups who have been selected as a priority, we get that advice to the field immediately."



The Pfizer-BioNTech COVID-19 vaccine bottles, as the mass public vaccination program gets underway at Southmead Hospital in Bristol, England, Tuesday Dec. 8, 2020. The United Kingdom, one of the countries hardest hit by the coronavirus, is beginning its vaccination campaign to inoculate people against the COVID-19 virus. (Graeme Robertson/Pool via AP)

Margaret Keenan, the first person to get the vaccine in the U.K., was discharged Wednesday from University Hospital Coventry, where she had been undergoing a heart checkup when she was given the shot.

"I feel great and I'm so pleased to be able to go home and to spend some quality time with my family," the 90-year-old former shop clerk said in a statement released by the NHS.

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