

# COVID-19 Vaccine News: U.S. FDA Says Four Persons In Pfizer's Vaccine Trials Develop Facial Paralysis. UK Officials Says Vaccine Not For Those With Allergies

**COVID-19 Vaccine News:** The U.S. FDA has warned that four participants in Pfizer's COVID-19 vaccine trials had developed facial paralysis while UK regulators have issued yet another warning that individuals with allergies should avoid the COVID-19 vaccine.



The U.S. FDA commenting on the incident of the 4 individuals developing facial paralysis after having the Pfizer's COVID-19 vaccine said that the issue should be monitored as the vaccine jab becomes more widely available.

Interestingly these incidences along with others cases were only revealed after the US drug regulator published an analysis of the Pfizer-BioNTech vaccine ahead of a meeting to consider emergency use authorization for the jab in the United States.

These official documents revealed that Bell's palsy, a form of temporary facial paralysis, was reported by four participants during phase 3 trials. The individuals had been administered the jab, and no members of the placebo group experienced similar adverse effects. <https://www.fda.gov/media/144245/download>

This condition typically resembles a stroke, with most sufferers watching helplessly as one side of their face droops and their muscles go limp. In some rare situations, both sides of the face may become paralyzed. It is unclear what causes Bell's palsy, although the temporary paralysis usually goes away on its own.

Bell's palsy is a type of facial paralysis that results in a temporary inability to control the facial muscles on the affected side of the face. Symptoms can vary from mild to severe. They may include muscle twitching, weakness, or total loss of the ability to move one, and in rare cases, both sides of the face. Other symptoms include drooping of the eyelid, a change in taste, and pain around the ear. Typically symptoms come on over 48 hours. Bell's palsy can trigger an increased sensitivity to sound known as hyperacusis. Many believe that this is due to a viral infection that results in swelling.

However the U.S.FDA claimed that the frequency of the health issue is "consistent with the expected background rate in the general population," and added that there was no clear evidence linking the COVID-19 vaccine to the unpleasant medical condition. Still, the federal regulator recommended "surveillance for cases of Bell's palsy with deployment of the vaccine into larger populations."

The U.S.FDA claimed the "numerical imbalance" of Bell's palsy cases among the vaccine and placebo groups, but said there were no other "non-serious adverse events" that showed a similar pattern.

The U.S. FDA document state that side effects are common but appear to be minor. Out of the trial participants, 84 percent experienced some kind of reaction. After receiving the jab, 63 percent of trial subjects reported fatigue and 55 percent said they suffered from headaches. Chills were reported by 32 percent of participants, 24 percent complained of joint pain and 14 percent developed a fever.

Strangely, the COVID-19 vaccine jab appears to have received good marks from the FDA. In its report, the regulator said that the two-dose vaccine is about 50 percent effective even after just the first injection. The vaccine is believed to be 95 percent effective after the second dose, administered three weeks later.

The U.S. FDA also claimed that the jab reduced the risk of severe Covid-19 symptoms after the first dose.

Meanwhile on Tuesday, while the United Kingdom became the first country in the world to begin administering the Pfizer-BioNTech vaccine to the general population, its health regulator warned that those with a 'significant history of allergic reactions,' are not to take these vaccines.

The UK regulator issued the warning after two NHS medics, vaccinated on Tuesday, experienced severe reactions.

The national medical director for the NHS in Britain, Professor Dr Stephen Powis, said on Wednesday that the Medicines & Healthcare Products Regulatory Agency (MHRA) had issued a warning about the administering of Pfizer's COVID-19 vaccine.

The MHRA have advised, on a precautionary basis, that individuals with a significant history of allergic reactions to not receive this vaccination.

The warning comes after two NHS staff members, who were vaccinated on Tuesday as part of the UK's first day of vaccine roll-out, experienced adverse reactions to the jab.

Professor Powis said that "two people with a history of significant allergic reactions responded adversely yesterday. Both are recovering well."

The British NHS said that all hospitals had been informed and would be asking everyone scheduled to receive the vaccine whether they have a history of such reactions.

The head of the MHRA, Dr June Raine, told a joint select committee hearing on Wednesday that "real-time vigilance" would continue as the vaccine is rolled out.

December 8th Tuesday marked the first day of the UK's mass vaccination programme, in what has been touted as a watershed moment in the battle against the COVID-19 pandemic.

A British grandmother has become the first person in the world to be given the Pfizer COVID-19 jab as part of a mass vaccination programme.

91 year old Margaret Keenan said the injection she received at 06:31 GMT was the "best early birthday present".

This was the first of 800,000 doses of the Pfizer/BioNTech COVID-19 vaccine that will be dispensed in the coming days in Britain.

Another four million doses more are expected by the end of the month.

Inoculation hubs in the UK are starting the rollout by vaccinating the over-80s and some health and care staff.

To date the British regulator has only approved the US's Pfizer jab, but Health Minister Matt Hancock suggested on Tuesday that the UK's AstraZeneca vaccine may receive approval this year.

Update (10th December), 0800 hrs Bangkok Time), More Adverse Reactions From Pfizer's COVID-19 Vaccines

The British Medicines and Healthcare Products Regulatory Agency (MHRA) said there had been two reports of anaphylaxis and one report of a possible allergic reaction since rollout began.

MHRA Chief Executive June Raine said in a statement, "Any person with a history of anaphylaxis to a vaccine, medicine or food should not receive the Pfizer BioNTech vaccine."

She added, "Most individuals will not get anaphylaxis and the benefits in protecting people against COVID-19 outweigh the risks ... You can be completely confident that this vaccine has met the MHRA's robust standards of safety, quality and effectiveness."

Typically anaphylaxis is an overreaction of the body's immune system, which the National Health Service describes as severe and sometimes life-threatening.

A detailed guidance, clarifying that the main risk was from anaphylaxis specifically, was issued after consulting experts on allergies. The MHRA had initially advised anyone with a history of a "significant allergic reaction" not to take the shot.

Both Pfizer and BioNTech said they were supporting the MHRA's investigation.

MHRA chief Raine told lawmakers such allergic reactions had not been a feature of the Pfizer's clinical trials.

Pfizer has said individuals with a history of severe adverse allergic reactions to vaccines or the candidate's ingredients were excluded from their late-stage trials, which is reflected in the MHRA's emergency approval protocol.

However, the allergic reactions may have been caused by a component of Pfizer's vaccine called polyethylene glycol, or PEG, which helps stabilise the shot and is not in other types of vaccines.

Notes: The Pharmaceutical giants and the American Government along with the support of social media platforms like twitter, facebook and even search engines like google are now trying to suppress any reporting of real facts and data concerning adverse reactions or issues that arise from any COVID-19 vaccines or drugs such as remdesivir and regeneron's monoclonal antibodies etc that were financially aided by the U.S. government, to make sure that the general American population has no access to such news or data by lowering the feed or such websites or even trying to find ways to make sure that the American population are not able to find such websites or information. Our website has been affected by the latest Google algorithm core update such that all COVID-19 and coronavirus news to the American people will only be supplied by certain American media that abide by not reporting too much details or developments about the disease. To those concerned Americans with intelligence and interested in what we do on our site and also interested in COVID-19 factual reporting with science based reporting, please help share more of our articles and our site to your loved ones, friends etc.