



PFIZER BIONTECH COVID-19 VACCINE - UPDATED GUIDANCE ON MANAGING ALLERGIC REACTIONS

Since the immunisation campaign commenced on Tuesday 8 December, the MHRA has been notified of two reports of anaphylaxis, and a further possible allergic reaction, shortly after receiving the Pfizer BioNtech COVID-19 vaccine. The individuals received prompt treatment and are recovering well.

Further to preliminary advice issued on 8 December, the MHRA is now issuing the following updated guidance:

1. Any person with a history of immediate-onset anaphylaxis to a vaccine, medicine or food should not receive the Pfizer BioNtech vaccine. A second dose of the Pfizer BioNtech vaccine should not be given to those who have experienced anaphylaxis to the first dose of Pfizer BioNtech vaccination.
2. Vaccine recipients should be monitored for 15 mins after vaccination, with a longer observation period when indicated after clinical assessment
3. A protocol for the management of anaphylaxis and an anaphylaxis pack must always be available whenever the Pfizer BioNtech vaccine is given. Immediate treatment should include early treatment with 0.5mg intramuscular adrenaline (0.5ml of 1:1000 or 1mg/ml adrenaline), with an early call for help and further IM adrenaline every 5 minutes. The health professionals overseeing the immunisation service must be trained to recognise an anaphylactic reaction and be familiar with techniques for resuscitation of a patient with anaphylaxis.

An Expert Group, chaired by Professor Sir Munir Pirmohamed, and attended by experts in Allergy & Clinical Immunology, met today to review the cases and advised on action to mitigate the rare risk of anaphylaxis.

Anaphylaxis can be a rare risk of most vaccines and it is important that health professionals are vigilant in watching for the early signs and initiate prompt treatment, as occurred in these cases. The vast majority of people will not be at risk of anaphylaxis after being administered the Pfizer BioNtech vaccine and the benefits in preventing the serious complications of COVID outweigh the risks.

Anyone due to receive their vaccine should continue with their appointment and discuss any concerns or medical history of serious allergies with the healthcare professional prior to administration.

Please report any suspected adverse reactions via the Yellow Card scheme. To make a report or find out more about the Yellow Card COVID-19 reporting site please visit: [Coronavirus Yellow Card reporting site](#)

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