

15-minute observation period after vaccine temporarily suspended to speed up booster rollout

- Temporary suspension of short observation period for Pfizer and Moderna vaccines
- Advice from four UK Chief Medical Officers includes first, second and booster jabs and will be kept under review
- The risk of a serious allergic reaction after vaccination with the mRNA vaccines is low – around 1 report per 100,000 vaccine doses

The 15 minute observation period following a vaccination with Pfizer or Moderna will be temporarily suspended as part of new measures to speed up the booster rollout as part of our emergency response to the rapid spread of the Omicron variant.

Following advice from the four UK Chief Medical Officers and the independent regulator Medicines and Healthcare products Regulatory Agency's Commission on Human Medicines, the government has agreed to implement the temporary measure to help accelerate the rollout of vaccinations as quickly as possible.

The temporary suspension is being made on the basis of clinical advice that maintaining the 15 minute rule would cause more harm than it can avert because removing it will significantly increase the number of people who can be vaccinated over a short period of time.

Each devolved administration will determine how operationally the advice recommending the suspension will be implemented when safe and appropriate to do so.

The risk of a serious allergic reaction after vaccination with the mRNA vaccines is low – around 1 report per 100,000 vaccine doses – and we now have much more experience with giving these vaccines to millions of people. People are not normally observed for 15 minutes after other vaccinations.

MHRA Chief Executive, Dr June Raine said:

In light of the rapid spread of the new Omicron variant and the proven effectiveness of booster doses against Omicron, the 15-minute observation period following mRNA vaccines (Pfizer and Moderna) can be waived during the emergency response to the Omicron variant. This advice includes first and second vaccine doses as well as boosters.

The 15-minute observation period after vaccination will remain in place for the small number of people who may have previously suffered anaphylaxis or other allergic reactions to a food, insect sting and most medicines or vaccines.

Anaphylaxis and other severe allergic reactions are very rare side effects with the COVID-19 vaccines. During this time when the Omicron variant is spreading rapidly, the benefits of vaccinating as many people as possible, which will be gained from waiving the 15-minute wait, far outweigh the very small risks of anaphylaxis.

We are continuing to closely monitor both UK and international data and would ask anyone who suspects they have experienced a side effect linked with their COVID-19 vaccine to report it to the Coronavirus Yellow Card website. Anyone who experiences symptoms of an allergic reaction such as difficulty breathing, rapid heartbeat or faintness should seek urgent medical attention

Chair of Commission on Human Medicines, Professor Sir Munir Pirmohamed said:

The decision to temporarily waive the post mRNA observation period in specific circumstances comes after the Commission on Human Medicines (CHM) considered and reviewed the available Yellow Card data on anaphylaxis after the primary course and after boosters. The data show that anaphylaxis and other severe allergic reactions are an extremely rare side effect with the COVID-19 vaccine.

Swift action is needed to tackle the rapid increase in cases of the Omicron variant of COVID-19 and the increasing risk to the public and healthcare services.

This temporary measure will assist in the major task of vaccinating the nation ahead of the end of the year.

We would encourage all individuals who have not yet had their first, second or third dose of a COVID-19 vaccine to please come forward as soon as they are able to.

Dr Mary Ramsay, Head of Immunisation at the UKHSA, said:

With Omicron growing at such a fast rate, and with early data suggesting two doses of the vaccine is not enough to protect against symptomatic infection, it is vital we do everything we can to get more jabs in more arms as quickly as possible.

The removal of the 15-minute wait, as agreed by the CHM, will help streamline the process at vaccine centres, and we have updated our guidance to facilitate this.

Nikki Kanani, GP and deputy for the NHS vaccination programme, said:

The updated CMO advice to temporarily suspend the 15 minute wait – where safe and appropriate – will be particularly helpful for

smaller vaccination sites, helping get more people protected as quickly as possible.

As part of the national mission to protect the public against the new Omicron variant, the NHS has set out action to accelerate its COVID-19 booster programme with more pop up vaccination centres planned and extended opening hours.

Those who have a history of allergies, particularly to other vaccines, or have had an immediate reaction after a previous doses may be advised to stay for the 15 minutes. People are advised to tell the vaccine centre if that is the case and to tell them if they have previously fainted following vaccination.

The UK Health Security Agency has updated the Green Book to reflect the change from today [Tuesday December 14]. The updated Patient Group Direction and Protocol will be published shortly.

The change will be able to be implemented following the Green Book update at sites such as hospitals and GP practices and for housebound visits and the NHS will implement the guidance as soon as possible to wider vaccination sites once necessary clinical guidance is in place.

NOTES TO EDITORS:

- [Link to four UK CMO's statement](#)
- The need for the suspension will be kept under review by the Commission of Human Medicines, the MHRA and the JCVI based on the need of urgency for the vaccination and booster programme and monitoring of anaphylaxis reports.
- Instead of waiting for 15 minutes after their vaccine, anyone coming forward for the jab is now asked to adhere to the following guidance:
 - Avoid leaving the centre if you feel unwell
 - Let the centre know if you have a history of allergies
 - Do not drive for 15 minutes after receiving the vaccine
 - If you are vaccinated at home, you may need to arrange to have someone with you
 - Make sure the person you are with has a 'phone available
 - If you get tingling or throat tightness, get person you are with to dial 999 or call for help if you are near the vaccine centre