<u>Temporary waiver of 15-minute</u> <u>observation period after COVID-19 mRNA</u> <u>vaccines</u>

Press release

A statement on the temporary waiver of 15-minute observation period after COVID-19 mRNA vaccines



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 <u>Coronavirus Yellow Card website</u>. 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."

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