Public Health Link

From the Chief Medical Officer for Wales

Distribution: As Appendix 1

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Category: Immediate (cascade within 24 hours)

Title: COVID-19 Vaccine Moderna and Pfizer/BioNTech COVID-19 vaccine: myocarditis and pericarditis– revisions to the product information

Dear colleagues,

The Medicines and Healthcare products Regulatory Agency (MHRA) and the Government's independent expert advisory body, the Commission on Human Medicines (CHM), has conducted a thorough review of suspected adverse reaction reports of myocarditis and pericarditis following COVID-19 vaccination.

The CHM has carefully considered the available data and has advised that healthcare professionals should be alert to the signs and symptoms of myocarditis and pericarditis. Vaccinated individuals should be advised to seek immediate medical attention should they experience new onset of chest pain, shortness of breath or symptoms of arrhythmia.

This notification informs you of revisions to the product information for COVID-19 Vaccine Moderna and Pfizer/BioNTech COVID-19 vaccine.

The information for healthcare professionals now reads as follows:

Section 4.4: Special warnings and precautions for use

Myocarditis and pericarditis

There have been very rare reports of myocarditis and pericarditis occurring after vaccination with COVID-19 mRNA Vaccine BNT162b2, often in younger men and shortly after the second dose of the vaccine. These are typically mild cases and individuals tend to recover within a short time following standard treatment and rest.

Healthcare professionals should be alert to the signs and symptoms of myocarditis and pericarditis. Vaccinated individuals should also seek immediate medical attention should they experience new onset of chest pain, shortness of breath, palpitations or arrhythmias.

Section 4.8: Undesirable effects

Cardiac disorders:

Myocarditis, pericarditis (frequency unknown)

The information for UK vaccine recipients has also been updated in line with these revisions.

Further information

As of 16 June 2021, the MHRA has received 87 Yellow Card reports of myocarditis and pericarditis as suspected side effects after administration of the Pfizer/BioNTech COVID-19 vaccine and 4 reports after the Moderna COVID-19 vaccine. Up to the same date an estimated 16.8 million first doses and 10.9 million second doses of the Pfizer/BioNTech vaccine had been administered, and an approximate 0.73 million first doses of the COVID-19 Vaccine Moderna have also now been administered. There has also been reporting of similar cases internationally following receipt of the Pfizer/BioNTech and Moderna vaccines. These have occurred most frequently in younger males aged 40 years and younger and within 10 days after the second dose. Most of these cases were mild and individuals typically recovered within a short time and with symptomatic treatment and rest. While reports of myocarditis and pericarditis after vaccination with COVID-19 vaccine AstraZeneca have also been received, there is insufficient evidence to recommend similar warnings for this vaccine.

Healthcare professionals should be alert to the signs and symptoms of myocarditis and pericarditis. Confirmation of diagnosis of these conditions typically requires targeted diagnostic procedures, such as electrocardiograms, cardiac imaging, and biomarker analysis, and it is also important to exclude other potential causes for the symptoms. Treatment of more symptomatic patients will occasionally require relevant expert follow up that might need detailed cardiac imaging to determine the nature of the condition.

Healthcare professionals working with the public should ensure they receive both doses of the vaccine, in line with their professional responsibilities.

Advice for the public

Vaccinated individuals should be advised to seek immediate medical attention should they experience new onset of chest pain, shortness of breath, or symptoms of disturbance of cardia rhythm.

The COVID-19 vaccines remain highly effective in protecting people from COVID-19 and have already saved thousands of lives. These events are extremely rare and tend to be mild when they do occur. Our advice remains that the benefits of getting vaccinated outweigh the risks in the majority of people. It is still vitally important that people come forward for their first and second vaccination when invited to do so, unless advised otherwise.

Reporting advice for healthcare professionals

Suspected adverse reactions associated with COVID-19 vaccines should be reported to the MHRA through the MHRA's Coronavirus Yellow Card reporting site https://coronavirus-yellowcard.mhra.gov.uk/ or via the Yellow Card app.

As these products are under additional monitoring this includes all suspected ADRs associated with these vaccines. This will allow quick identification of new safety information.

When reporting please provide as much information as possible, including information about medical history, any concomitant medications, onset, treatment dates, and vaccine product brand name and batch number.
You may be contacted following submission of a Yellow Card report so that the MHRA can gather additional relevant information for the assessment of the report. These contributions form an important part of our understanding of suspected adverse events.

Yours sincerely

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Appendix 1

To: Health Boards and NHS Trusts:

Chief Executives

Medical Directors

Nurse Directors

Hospital Principals and Chief Pharmacists

To: NHS Wales Shared Services Partnership to cascade to:

- GPs
- Community Pharmacists
- Independent hospitals

Cc: Public Health Wales
Directors of Public Health