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1. Directors of Pharmacy
2. Medical Directors NHS Boards

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Dear Healthcare Professional,

COVID-19 - MHRA ADVICE - VACCINE ASTRAZENECA AND THROMBOEMBOLIC EVENTS WITH CONCURRENT LOW PLATELETS – REVISIONS TO PRODUCT INFORMATION

Please see the attached advice from MHRA about the Astra Zeneca COVID-19 vaccine thromboembolic events with concurrent low platelet counts and the subsequent revisions to the product information. I would be grateful if you could cascade this information to relevant colleagues.

Could all Directors of Pharmacy please forward this alert to:-

- Hospital Pharmacists
- Community Pharmacists

Please could Medical Directors forward this alert to:-

- Accident & Emergency Departments
- Directors of Public Health
- Neurologists
- Neurosurgeons
- Haematologists
- Intensive Care Units
- Chief Executives of NHS Board

Thank you for your co-operation.

Yours sincerely

IRENE FAZAKERLEY
Pharmacy and Medicines Division

1. COVID-19 Vaccine AstraZeneca and thromboembolic events with concurrent low platelets – revisions to product information

The Medicines and Healthcare products Regulatory Agency (MHRA) and the Government's independent expert advisory body, the Commission on Human Medicines (CHM), are conducting a review of reports of extremely rare thromboembolic events including cerebral venous sinus thrombosis (CVST) occurring in conjunction with thrombocytopenia following the AstraZeneca COVID-19 vaccine.

We wrote to you on 7th April informing you of the new advice resulting from the review of case reports received up to 31st March 2021. This notification informs you of revisions to the COVID-19 Vaccine AstraZeneca product information for healthcare professionals, including further clarification on specific pre-existing medical conditions where the vaccine should not be given, and those pre-existing conditions where particular caution is needed.

The information for healthcare professionals now reads as follows:

Section 4.3: Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

Patients with a history of heparin-induced thrombocytopenia and thrombosis (HITT or HIT type 2). Patients who have experienced major venous and/or arterial thrombosis occurring with thrombocytopenia following vaccination with any COVID-19 vaccine should not receive a second dose of COVID-19 Vaccine AstraZeneca.

Section 4.4: Special warnings and precautions for use

Thrombocytopenia and coagulation disorders

Serious thromboembolic events with concurrent thrombocytopenia, sometimes accompanied by bleeding, have occurred very rarely following vaccination with

COVID-19 Vaccine AstraZeneca during post-authorisation use. This includes life-threatening and fatal cases presenting as venous thrombosis, including unusual sites such as cerebral venous sinus thrombosis, splanchnic vein thrombosis, as well as arterial thrombosis, combined with thrombocytopenia that can rapidly progress. Multifocal venous and arterial thromboses, have been reported in serious cases. The majority of the events occurred within the first 14 days following vaccination but have also been reported after this period. Risk factors have not been identified. Some cases have increased D-dimer levels >4000ng/mL, positive platelet factor 4 antibodies and/or laboratory evidence of platelet activation.

As a precautionary measure, administration of the COVID-19 Vaccine AstraZeneca in patients with a history of cerebral venous sinus thrombosis, or antiphospholipid syndrome should only be considered when the benefit outweighs any potential risks.

Healthcare professionals should be alert to the signs and symptoms of thromboembolism and/or thrombocytopenia. Vaccinated individuals should also seek immediate medical attention if four or more days after vaccination they develop new onset or worsening severe or persistent headaches with blurred vision which do not respond to simple painkillers or if they develop new symptoms such as shortness of breath, chest pain, leg swelling, persistent abdominal pain, any neurological symptoms or signs (such as confusion or seizures) or unusual skin bruising and/or petechiae. Patients with thromboembolic events and concurrent thrombocytopenia should be urgently referred to a secondary healthcare centre and to a specialist in haematology for advice on further management.

Section 4.8: Undesirable effects

Very rare events of major venous and/or arterial thrombosis with thrombocytopenia, sometimes accompanied with bleeding, have also been reported following vaccination with COVID-19 Vaccine AstraZeneca (see section 4.4).

The information for UK vaccine recipients has also been updated in line with these revisions. If you have any questions or require further assistance or clarification, please contact yellow.card@mhra.gov.uk and the YC helpline number 0800 731 6789.

This update is for information and should be cascaded through your networks, including those listed below.

- **Neurologists**
- **Neurosurgeons**

- **Haematologists**
- **Emergency medicine clinicians**
- **Intensivists**
- **Ophthalmologists**

NHS England and NHS Improvement Regional Offices: please cascade this to Community Pharmacy.

1.1.1 Access the revised product information here

Thank you,

Dr Sarah Branch

Director of Vigilance & Risk Management of Medicines

Medicines & Healthcare products Regulatory Agency