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Dear Colleagues

COVID-19 VACCINATION PROGRAMME - CHANGE IN RECOMMENDED USE OF ASTRAZENECA VACCINE

This letter provides an update on the COVID-19 vaccination programme following announcements on the use of the Oxford AstraZeneca vaccine by the Medicines and Healthcare products Regulatory Agency (MHRA) and the Joint Committee on Vaccination and Immunisation (JCVI).

Key Objectives

1. To confirm the change of recommended use of the Oxford AstraZeneca vaccine.

Background

2. The AstraZeneca COVID-19 vaccine was authorised for supply in the UK on 30 December 2020. Up to and including the 31 March 2021, 20.2 million doses of AstraZeneca had been given in the UK and the MHRA had received 79 UK reports of blood clotting cases alongside low levels of platelets following its use. Following continued investigation of the AstraZeneca vaccine and thromboembolic events, the MHRA and JCVI have provided further advice on the recommended use of AstraZeneca which will impact on delivery of the vaccination programme. The full MHRA and JCVI statements are accessible from Annex A.

3. Yesterday afternoon the MHRA issued new safety advice in regards to the potential link between the AstraZeneca vaccine and extremely rare blood clots. The current MHRA advice remains that the overall benefits of the vaccine outweigh the extremely rare adverse events reported to date in association with the AstraZeneca vaccine.

4. The data suggest there is a slightly higher incidence of clots with low platelets reported in the younger adult age groups but, as a precaution, administration of AstraZeneca in people <u>of any age who are at higher risk of blood clots</u> should be considered only if benefits outweigh potential risks. This includes pregnancy which predisposes to thrombosis. Anyone who experienced cerebral or other major blood clots

From Chief Medical Officer Dr Gregor Smith

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For action Chief Executives, NHS Boards Medical Directors, NHS Boards Primary Care Leads, NHS Boards Directors of Nursing & Midwifery, NHS Boards Chief Officers of Integration Authorities Chief Executives, Local Authorities Directors of Pharmacy Directors of Pharmacy Directors of Public Health General Practitioners Practice Nurses Immunisation Co-ordinators

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occurring with low levels of platelets after their first vaccine dose of COVID-19 Vaccine AstraZeneca should not have their second dose. Anyone who did not have side effects should come forward for their second dose when invited.

JCVI Guidance

5. Despite the MHRA not recommending new age restrictions in AstraZeneca licensing or approval, in its statement, the JCVI has advised on a precautionary basis that <u>it is preferable</u> for adults aged under 30 years with no underlying conditions to be offered an alternative to AstraZeneca where possible.

6. It signifies that reports of extremely rare adverse events of thrombosis and thrombocytopenia have been signalled in the AstraZeneca and not for Pfizer or Moderna to date. It highlights that the available data suggest there may be a trend for increasing incidence of this adverse event with decreasing age, with a slightly higher incidence reported in the younger adult age groups, albeit that numbers overall remain small across age bands so there is still some uncertainty remaining.

7. It advises that the benefit of prompt vaccination with AstraZeneca, for individuals 30 years of age and over, and those of all ages with underlying health conditions, far outweigh the risk of vaccine-related adverse events. However, JCVI is now advising that adults aged under 30 years of age without underlying health conditions that put them at higher risk of severe COVID-19 disease themselves be offered an alternative vaccine, if available. It advises that people may make an informed choice to receive the AstraZeneca vaccine to receive earlier protection when an alternative vaccine is not available.

8. Currently, there are people aged under 30 years old without additional personal risk factors who have received the AstraZeneca vaccine as part of Phase 1, for example health and social care workers, unpaid carers and household contacts of immunosuppressed adults. The JCVI advises that if these persons are still unvaccinated it is preferable for them to be offered an alternative vaccine, if available. However, it states that there are no reports at this stage of the extremely rare thrombosis/thrombocytopenia events following receipt of the second dose of AstraZeneca, therefore, all those who have received the first dose of AstraZeneca should continue with their second dose, irrespective of age.

9. JCVI advises that all individuals offered a COVID-19 vaccine should be fully informed about the benefits and risks of vaccination. This should include clear information on the extremely rare thrombosis/thrombocytopenia adverse event, how to monitor for symptoms that might be related to the adverse event, and what action should be taken by individuals and health professionals in the event of such symptoms arising. MHRA have updated information available for healthcare professionals (see Annex A).

Implications for the Programme

10. The Scottish Government's approach from the outset of the vaccination programme has been to follow JCVI advice about prioritisation and deployment, consistent with other vaccination programmes and the approach across the 4 Nations.

11. In line with this, Health Boards should now offer those under 30 years of age without underlying health conditions an alternative to the Oxford AstraZeneca vaccine – currently either Moderna or Pfizer BioNTech.





12. We recognise that this may have implications for appointments already scheduled, and locations for vaccination available for patients in some areas.

13. The national Flu Vaccines and Covid Vaccines Programme will work with Health Boards to support whatever arrangements are required as a result of this change.

Advice for the public

14. NHS Inform and the COVID vaccination helpline have been updated with advice. This includes a link to a flyer called *COVID-19 Vaccination & Blood Clotting*. www.nhsinform.scot/covid19vaccinesideeffects

Please ensure that local vaccination teams direct the public to nhsinform or 0800 030 8013. Public Health Scotland will send printed copies of this flyer to NHS Boards shortly. Other information materials will be updated in line with this urgent advice.

Action

15. Health Boards are asked to note and implement the arrangements for the change in recommended use of the AstraZeneca vaccine outlined in this letter.

16. It is crucial that individuals continue to come forward for vaccination when invited to do so. I am grateful for Health Boards's continued efforts to offer information, support and encouragement to those invited for vaccination so that public confidence in this critical programme remains high.

Yours sincerely,

Gregor Smith

Dr Gregor Smith Chief Medical Officer







ANNEX A

The MHRA statement is available here:

MHRA issues new advice, concluding a possible link between COVID-19 Vaccine AstraZeneca and extremely rare, unlikely to occur blood clots - GOV.UK (www.gov.uk)

The JCVI statement is available here:

Use of the AstraZeneca COVID-19 vaccine: JCVI statement - GOV.UK (www.gov.uk)

The MHRA has issued updated guidance for healthcare professionals on how to minimise risks, as well as further advice on symptoms for vaccine recipients to look out for 4 or more days after vaccination, this is available here:

https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccineastrazeneca/information-for-healthcare-professionals-on-covid-19-vaccine-astrazeneca



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