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Dear Colleagues

An update in response to concerns raised in some European Nations about a potential link between blood clots and the AstraZeneca COVID-19 vaccine

1. This letter outlines our current position on the AstraZeneca COVID-19 vaccine which is based on the latest available evidence.
2. It provides reassurance that the AstraZeneca COVID-19 vaccine continues to be safe to be administered as part of our COVID-19 vaccination programme.
3. Ensuring high uptake across the priority groups is critical to the success of the vaccination programme. Health Boards should encourage all those invited to come forward for vaccination and provide clear, accurate and accessible information in response to any concerns about vaccines.
4. Annex A details a set of Frequently Asked Questions (FAQs) which may be useful in supporting vaccinators and other staff to reassure people coming forward for vaccination.

Overview

5. Some European countries have suspended their AstraZeneca COVID-19 vaccine programmes in response to a small number of cases of blood clots that occurred in a period of time after the vaccine was administered. The suspension is understood to be temporary and purely precautionary while the cases are being investigated.
6. Vaccine safety is of paramount importance and the Medicines and Healthcare products Regulatory Agency (MHRA) continually monitor the safety of vaccines to ensure that the benefits outweigh any potential risks. The safety of the public will always come first.
7. In the UK, we are keeping this issue under close review but available evidence does not confirm that the vaccine is the cause of these conditions. This position has been reached following detailed consideration of a wide range

**From Chief Medical Officer
Dr Gregor Smith**

19 March 2021

SGHD/CMO(2021)5

Addresses

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 Public Health
 General Practitioners
 Practice Nurses
 Immunisation Co-ordinators
 CPHMs
 Scottish Prison Service
 Scottish Ambulance Service
 Occupational Health Leads

For information

Chairs, NHS Boards
 Infectious Disease Consultants
 Consultant Physicians
 Chief Executive, Public Health Scotland
 NHS 24

Further Enquiries

Policy Issues

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Medical Issues

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Pharmaceutical and Vaccine

Supply Issues

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of evidence undertaken by scientists and clinicians independent of Government.

8. Blood clots can occur naturally and are not uncommon. More than 11 million doses of the AstraZeneca COVID-19 Vaccine have now been administered across the UK, and the number of blood clots reported after having the vaccine is not greater than the number that would have occurred naturally in the vaccinated population.
9. Given the extremely rare rate of occurrence of these events, the benefits of the AstraZeneca COVID-19 vaccine far outweigh any possible risks of the vaccine in the risk groups currently targeted in the UK, with the latest data suggesting an 80% reduction in hospitalisation and death from COVID-19 disease.
10. The MHRA encourages anyone to report any suspicion or concern they have beyond the known, mild side effects on the Coronavirus Yellow Card site. Reporters do not need to be sure of a link between a vaccine and a suspected side effect but are still encouraged to report.
11. For more information on COVID-19 vaccine adverse reactions, see the MHRA's weekly report. [Coronavirus vaccine - weekly summary of Yellow Card reporting - GOV.UK \(www.gov.uk\)](https://www.gov.uk/government/news/coronavirus-vaccine-weekly-summary-of-yellow-card-reporting)

Position of national and international regulators and bodies

12. In the UK, the decision to suspend the use of any vaccine is a matter for the MHRA. It has confirmed that there is no current evidence of an increase in blood clots being caused by the vaccine. It continues to recommend using AstraZeneca COVID-19 vaccine and encourages the public to get the vaccine when invited.
13. This view was underlined in a [statement](#) issued on 18 March 2021, confirming that following a rigorous scientific review of all the available data, the available evidence does not suggest that blood clots in veins (venous thromboembolism) are caused by the AstraZeneca COVID-19 vaccine.
14. However, the MHRA will continue to closely monitor any reports where cerebral sinus venous thrombosis has occurred in conjunction with lowered platelets to understand whether there is any potential association.
15. This type of blood clot can rarely occur naturally in unvaccinated people as well as in people with COVID-19 disease. In the UK, 5 possible cases of this have been reported to us so far, after 11 million doses of COVID-19 Vaccine AstraZeneca.
16. Further work with expert haematologists is under way to better understand the nature of these cases and whether there is a causal association with any of the vaccines. The MHRA is continuing to monitor this carefully, and is in regular contact with other regulators.
17. Reviews of AstraZeneca are being undertaken externally and independently, by the European Medicines Agency (EMA) and the World Health Organization (WHO). In the meantime, both bodies have provided reassuring information and continue to recommend vaccinating the population with the AstraZeneca COVID-19 vaccine.
18. In a [statement](#) on 18 March 2021, the European Medicines Agency confirmed that its investigation into cases of blood clotting has not revealed a causal link to the

AstraZeneca vaccine or specific batches. EMA reaffirmed that the benefits of the vaccine in combating the still widespread threat of COVID-19 (which itself results in clotting problems and may be fatal) continue to outweigh the risk of side effects.

19. Christian Lindmeier, a spokesperson for the WHO, on 15 March 2021 said: "As of today, there is no evidence that the incidents are caused by the vaccine and it is important that vaccination campaigns continue so that we can save lives and stem severe disease from the virus."

20. I hope this information is useful.

Yours sincerely

Gregor Smith

Dr Gregor Smith
Chief Medical Officer

Annex A Frequently Asked Questions

Why did some European countries suspend use of the AstraZeneca COVID-19 vaccine?

This is a purely precautionary step that some countries have decided to take following reports of blood clots after the vaccine had been administered. No causal link has been established between blood clotting events and the vaccine.

Is there any increased risk of thromboembolic events in people that have had the AstraZeneca COVID-19 Vaccine?

The evidence so far does not indicate a causal relation between blood clots and the AstraZeneca vaccine. Blood clots can occur naturally and are not uncommon. More than 11 million doses of the AstraZeneca COVID-19 Vaccine have now been administered across the UK, and the number of blood clots reported after having the vaccine is not greater than the number that would have occurred naturally in the vaccinated population.

Vaccinators are asked to advise patients to seek medical attention should they experience a headache that lasts for more than 4 days after vaccination, or bruising beyond the site of vaccination after a few days, to seek medical attention.

What have the MHRA and the EMA said?

Both medicine regulators continue to recommend the use of the AstraZeneca COVID-19 vaccine. They are of the view that continuing to vaccinate the population is of greater benefit. The evidence does not confirm that there is a link between the vaccine and blood clots. Both regulators continue to monitor the situation. Should the evidence change they will update their recommendations. The World Health Organization also supports this position.

What should I say to a person who has arrived for a vaccine and is worried?

The person should be reassured that all vaccines have undergone strict safety testing as part of clinical trials. No severe side-effects were noted during these trials.

Remind them that mild flu-like symptoms remain one of the most common side effects of any COVID-19 vaccine, including headache, chills and fever. These generally appear within a few hours and resolve within a day or two, but not everyone gets them.

Advise the person to seek medical attention should they experience a headache that lasts for more than 4 days after vaccination, or bruising beyond the site of vaccination after a few days, to seek medical attention.

What do I say to a person who is demanding to have the Pfizer over the AstraZeneca COVID-19 vaccine?

Reassure the person that all the COVID-19 vaccines that are used are safe. Explain that we do not offer a vaccine choice at this moment in time, unless they have had allergic reactions to vaccine ingredients in the past or the MHRA's authorisation to supply the vaccine specifies one vaccine over another, for example because of the age of the person.

Where can members of the public find more information?

Members of the public can consult the [weekly reports on vaccine safety](#).

They can also consult MHRA press releases. The most recent can be found here: [UK regulator confirms that people should continue to receive the COVID-19 vaccine AstraZeneca - GOV.UK \(www.gov.uk\)](#)