

Dr June Raine, CBE
Chief Executive
Medicines and Healthcare products Regulatory Agency
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Monday 30th June 2021

Dear Dr Raine

Thrombosis UK and Lyn Brown MP, Former Chair of the All Party Parliamentary Thrombosis Group, wish to raise concern regarding wording in the MHRA guidance on the use of the AstraZeneca COVID-19 vaccine dated.

We were delighted to see that the MHRA had updated its guidance on 25th June 2021 (<https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-astrazeneca/information-for-healthcare-professionals-on-covid-19-vaccine-astrazeneca>) to be more in line with advice issued by the Joint Committee on Vaccination and Immunisation (JCVI) and Public Health England (PHE).

However, the MHRA earlier statement published advised:

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

This caused considerable concern for patients with a diagnosis of antiphospholipid syndrome (APS), and in their decision making to receive and access to a COVID-vaccination, further complicated by it being in contradiction to that issued in on 7th May 2021 by the JCVI:

Green Book Chpt 14a page 22

'Thrombosis and thrombocytopenia occurring after COVID-19 vaccination

.....there is no reason to believe that individuals with a past history of clots or of certain thrombophilia conditions would be at increased risk of this very rare condition.'

And later, to guidance published by PH England issued on 9th June 2021: [COVID-19 vaccination programme Information for healthcare practitioners Republished 9 June 2021 Version 3.8](#)

Page 22: COVID-19 vaccine contraindications and precautions COVID-19 vaccine contraindications

'COVID-19 vaccine should not be given to those who have had a previous systemic allergic reaction (including immediate-onset anaphylaxis) to:

- *a previous dose of the same COVID-19 vaccine*

- any components (excipient) of the vaccine COVID-19 Vaccine
- AstraZeneca should not be given to those with a history of a previous episode of heparin-induced thrombocytopenia and thrombosis (HITT or HIT type 2) or to those who experience a clotting episode with concomitant thrombocytopenia following the first dose of AstraZeneca vaccine.'

As a result of the MHRA wording, Thrombosis UK has responded to many, many anxious APS patients either exceptionally anxious about having a COVID vaccination or who were told they were contraindicated for the Oxford Astra-Zeneca vaccine and refused a vaccination at their appointment.

Whilst the updated MHRA statement issued on 25th June 2021 is welcomed, with the absence of updated guidance for APS patients, anxiety and uncertainty remain causing unnecessary barriers to vaccination.

There **is no evidence** that individuals with a prior history of antiphospholipid syndrome or cerebral venous sinus thrombosis are at increased risk of the vaccine-induced immune thrombocytopenia and thrombosis (VITT) complication reported after the AstraZeneca vaccine.

Therefore, we ask and strongly urge the MHRA to review current wording to also include:

Thrombosis and thrombocytopenia occurring after COVID-19 vaccination

'There is no reason to believe that individual with a past history of clots or of thrombophilia, including antiphospholipid syndrome would be at increased risk of this very rare condition.

Only those with a history of a previous episode of heparin-induced thrombocytopenia and thrombosis (HITT or HIT type 2) or to those who experience a clotting episode with concomitant thrombocytopenia following the first dose of AstraZeneca vaccine are contraindicated.'

Yours sincerely



Prof Beverley Hunt OBE
Medical Director, Thrombosis UK



Jo Jerome
CEO, Thrombosis UK



Lyn Brown
Member of Parliament for West Ham
Former Chair,
All Party Parliamentary Thrombosis Group

CC Professor Lim Wei Shen, Chair of COVID-19 immunisation
CC Dr Mary Ramsay, Head of Immunisation PHE
CC Rt Hon Sajid Javid MP, Secretary of State for Health and Social Care
CC Nadhim Zahawi MP, Parliamentary Under Secretary of State (Minister for COVID Vaccine Deployment)