Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

Office of the Chief Clinical Officer
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Oifig an Phríomhoifigigh Cliniciúil
Ospidéal Dr. Steevens|Baile Átha Cliath 8|D08 W2A8

By Email Only

Date: 19th March 2021

Re: Resumption of the COVID-19 Vaccine AstraZeneca® programme

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Dear Colleagues,

You will be aware that following reports of a small number of thromboembolic events, NIAC recommended a temporary pause of the administration of COVID-19 Vaccine AstraZeneca® on a precautionary principle on 14th March 2021 pending receipt of further information from the European Medicines Agency (EMA).

On 18th March 2021, the EMA safety committee issued their findings with regard to its review of cases of blood clotting and reaffirmed their view 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.
The EMA also concluded that "*the vaccine is not associated with an increase in the overall risk of blood clots - however the vaccine may be associated with very rare cases of blood clots associated with thrombocytopaenia with or without bleeding*".
See the following link for more information:
COVID-19 Vaccine AstraZeneca: benefits still outweigh the risks despite possible link to rare blood clots with low blood platelets | European Medicines Agency (europa.eu)
https://www.ema.europa.eu/en/news/covid-19-vaccine-astrazeneca-benefits-still-outweigh-risks-despite-possible-link-rare-blood-clots

NIAC has reviewed this information from EMA and on 19th March 2021 has recommended that COVID-19 Vaccine AstraZeneca® administration should be recommenced for use in all those aged 18 years and over.

This recommendation has been endorsed by the Department of Health and the HSE will now resume the COVID-19 Vaccine AstraZeneca® programme.

Resumption of the programme- provision of updated information for the public and healthcare professionals

Some vaccination sites have already confirmed their ability to restart the programme over this coming weekend with vaccines that remain in stock. Orders for vaccines for delivery from Monday 22nd March are being submitted.

In line with recommendations from the EMA and NIAC, we must ensure that on resumption of the programme, all patients are informed that the vaccine may be associated with rare cases of blood clots and with a risk of bleeding. They should be told what symptoms to look out for, and to seek medical advice urgently if those symptoms develop.

The EMA have updated the Summary of Product Characteristic and Patient Information Leaflet on their website- https://www.ema.europa.eu/en/documents/product-information/covid-19-vaccine-astrazeneca-epar-product-information_en.pdf

All vaccine deliveries from Monday 22nd March will come with this updated Patient Information Leaflet (PIL) which must be provided to the patient along with the updated aftercare information. Each box of 100 doses of vaccine will contain one PIL, which for the next few weeks will be the older PIL. This PIL within the box must be destroyed and not given to any patients.

All immunisation leads are requested to immediately destroy and dispose of ALL the old Patient Information Leaflets, aftercare leaflets and booklets relating to the COVID-19 Vaccine AstraZeneca® to ensure only updated materials can be provided to patients.

HSE communications will be in touch with local communications teams regarding any requirements to print information locally for clinics this weekend, particularly on Saturday. Central distribution of all materials will be organised for Sunday and early next week to support clinics. Materials can also be found on the HSE website.

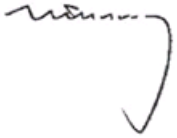
The National Immunisation Office has updated the medicine protocol for the administration of the vaccine in line with NIAC advice. A Frequently Asked Questions document is attached with this letter and is available on the NIO website.

Process for patients presenting with symptoms where thromboembolic events associated with thrombocytopenia are suspected.

Any patient presenting with symptoms that may be related to clotting or bleeding disorders in the weeks following COVID-19 Vaccine AstraZeneca® should be investigated appropriately, taking advice from local haematologists.

Healthcare professionals should seek early expert advice from the National Coagulation Centre about the specialised testing and treatment options for patients presenting with thromboembolic events that are associated with thrombocytopenia, (including Disseminated Intravascular Coagulation (DIC) or Cerebral venous sinus thrombosis (CVST) occurring within weeks following vaccination with COVID-19 Vaccine AstraZeneca®. Additional information is available on the National Coagulation Centre website http://www.stjames.ie/services/hope/nationalcoagulationcentre/
Healthcare professionals should also report all such events to the HPRA.

Yours sincerely



Dr Colm Henry
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