

22 June 2021

Dear Sir/ Madam,

Re: Open Letter from the UK Medical Freedom Alliance

Thank you for your correspondence of 23 May 2021 regarding the clinical safety of the COVID-19 vaccination programme. I am replying also on behalf of Professor Amanda Croft, Chief Nursing Officer, and Professor Alison Strath, Chief Pharmaceutical Officer.

I wish to begin by stating that the safety of the COVID-19 vaccination programme is of utmost importance to us and we are confident that the programme is based on robust scientific evidence and ethical principles. Our main priority is to reduce COVID-19 related hospitalisations and deaths, and vaccination remains one of the most effective way to achieve this.

In order to inform and advise the policy underlying the COVID-19 vaccination programme, the Scottish Government relies upon the UK Joint Committee on Vaccination and Immunisation (JCVI) to provide expert independent advice on immunisations and the Medicines and Healthcare products Regulatory Agency (MHRA) as the medicines regulator to authorise all medicinal products, including vaccines, to be used in the UK. Their advice and recommendations are based on careful review of the available published scientific evidence as well as their considerations of unpublished data from trusted and reputable organisations. We have full confidence in the governance and recommendations made by these expert scientific and regulatory bodies, with long proven track records, and will continue to base our policy decisions on their advice.

It is the view of the Scottish Government that vaccines remain one of the best ways to protect people from COVID-19. The vaccination programme so far has already saved thousands of lives and prevented thousands more hospital admissions with serious COVID disease. This is based on real world evidence collected by Public Health England and Public Health Scotland that vaccines not only prevent serious COVID-19 disease but also reduce transmission of the virus and hence reduce spread.

In relation to the safety of the vaccines, it is the responsibility of the MHRA to ensure the safety, quality and efficacy of all UK medicines, including the COVID-19 vaccines, and they have robust surveillance systems in place, monitoring this on an on-going basis. Whilst all medicines, including vaccines, can have side effects, the available clinical data shows that serious adverse events and deaths are very rare with COVID vaccines and the risk benefit analysis remains overwhelmingly in favour of vaccination. The Scottish Government has full confidence in the procedures put in place by the MHRA in monitoring and investigating any significant suspected adverse incidents potentially involving COVID-19 vaccines.

In regards to your concerns about the vaccination of pregnant women, the JCVI has advised that pregnant women should be offered COVID-19 vaccines at the same time as people of the same age or risk group. I would like to highlight that we advise all pregnant women seeking vaccination to read the Royal College of Obstetricians and Gynaecologists' information on the risks and benefits of COVID-19 vaccination before attending a vaccination appointment. The advice can be found at: www.rcog.org.uk/covid-vaccine.

Moreover, Public Health Scotland (PHS) has also produced an information leaflet on COVID-19 vaccination in pregnancy and breastfeeding and this is given to women in paper format by Health Boards. These documents aim to support women to make a personal informed choice about whether to accept a COVID-19 vaccination in pregnancy. We also advise that, if they are uncertain, that they make the decision whether to take up a vaccine appointment in consultation with their clinician.

In your correspondence you also highlight concerns over the informed consent received from individuals prior to vaccinations. The process of obtaining and recording informed consent for vaccination is guided by the Green Book Chapter on Informed Consent which in turn is taken from the JCVI and MHRA advice.

Information is also available to those seeking vaccination in the form of leaflets, published by Public Health Scotland on behalf of the Scottish Immunisation Programme that contain information to enable those invited to make a decision before they can give consent. They list common side-effects and provide links to more detailed information. They are provided to those who are invited for vaccination. The content of these leaflets, available in a variety of languages and formats, has been signed off by clinical experts, both within Scottish Government and Public Health Scotland to ensure that those invited receive clinically accurate information.

Beyond this, every person seeking vaccination will have the opportunity to talk with a vaccinator prior to consenting for vaccination. Therefore, I have complete confidence that informed consent is obtained from each individual seeking vaccination by a trained vaccinator and recorded on the Vaccine Management Tool (VMT).

I hope this letter answers the points you raise in your correspondence and will allay any concerns you may have in respect to the COVID-19 vaccination programme in Scotland.

Yours sincerely,



DR GREGOR SMITH
Chief Medical Officer