## DIRECTORATE FOR POPULATION HEALTH

**DPH**: Public Health Capabilities



Dr Rosamond Jones

Our Reference: 202400444527

Your Reference: An international safety concern

14 January 2025

Dear Dr Rosamond Jones,

Thank you for your email of 9 December 2024 regarding concerns from North Group members over the safety of COVID-19 vaccines.

Ministers and senior officials in the Scottish Government are receiving a large amount of correspondence and I hope you will understand that as much as they would like to, it is not always possible for them to reply personally to each case. I have therefore been asked to respond to you on this occasion as I work in the Scottish Government Public Health Capabilities Division. I apologise for the delay in responding.

I will address each of the points you have raised within your summary letter in turn, to provide clarity.

## The mRNA vaccines do not stop the transmission of COVID-19

In the early stages of the COVID-19 pandemic, the impact of COVID-19 mRNA vaccines on their ability to prevent transmission of the virus was still under investigation. Some initial real-world studies from 2021, suggested that the observed reduction in both symptomatic and asymptomatic infections suggested that vaccination had potential to reduce transmission; this was supported by a Scottish study during the pre-Delta era that showed a 30% reduction in risk of infection in the household members of vaccinated compared to unvaccinated healthcare workers after a single dose of the Pfizer BioNTech vaccine. (Shah et al, 2021)

Over time however, it became clear that the vaccines provided only modest and short-term protection against infection and therefore against transmission. As this became clear, the statements of the JCVI, the <u>Greenbook chapter 14a</u> and Scotland's vaccine information leaflets and public statements were updated to reflect this.

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The focus of the programme is now on offering vaccination to those most likely to directly benefit from vaccination, particularly those with underlying health conditions that increase their risk of hospitalisation following infection.

COVID-19 modified mRNA vaccines resulted in an unprecedented level of reported side effects and deaths & COVID-19 modified mRNA vaccines are contaminated with high and variable levels of artificial bacterially derived DNA

The Medicines and Healthcare products Regulatory Agency (MHRA) is the UK regulator of medicines, medical devices and blood components for transfusion in the UK. It has responsibility to ensure that medicines, including vaccines, meet applicable standards of safety, quality and efficacy (effectiveness). The MHRA operates in a statutory framework set by HM Government.

All COVID-19 mRNA vaccines currently in use in the UK and Scottish vaccination programmes have been subject to this process at MHRA and as with all vaccines and medicines, the safety of COVID-19 vaccines is being continuously monitored.

The MHRA keep the safety of all vaccines under close and continual review and Ministers would of course, immediately take appropriate regulatory action, if new evidence emerges which called into question the safety of any vaccines, currently in use in Scotland.

The MHRA monitors the safety of all medicines throughout their marketed life, in what is known as pharmacovigilance. Information is derived from multiple national and international sources including:

- spontaneous adverse drug reaction reporting schemes, such as the Yellow Card Scheme
- · clinical and epidemiological studies
- worldwide published medical literature
- pharmaceutical companies
- · worldwide regulatory authorities
- morbidity and mortality databases

Further information on Pharmacovigilance can be found here:

<u>Pharmacovigilance\_\_how\_the\_MHRA\_monitors\_the\_safety\_of\_medicines.pdf</u> (publishing.service.gov.uk)

Once a product is authorised by the MHRA, the JCVI then make recommendations for its use and the Scottish Government's decision-making on vaccination programmes is guided by the expert clinical advice of the JCVI.

In addition to making the approval for safety and publishing known side effects of COVID-19 vaccines, the MHRA provides continual monitoring of any new or suspected new adverse reactions.

At this time, the MHRA and the JCVI have not raised any concerns around unprecedented level of reported side effects and deaths, or contamination of vaccines with high and variable levels of artificial bacterially derived DNA in relation to the mRNA COVID-19 vaccines.

To note, the UK COVID-19 Public Inquiry Module 4 is due to look at areas that may address some of your concerns about the regulatory process, including:

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- The development, procurement, manufacture and approval of vaccines during the pandemic and:
- Vaccine safety issues including post marketing surveillance, such as the Yellow Card monitoring and reporting system and a suggested correlation between Covid-19 vaccines and cardiovascular issues.

I hope my response assures you that we take the safety of vaccines very seriously and have appropriate procedures in place, to ensure this is continually kept under review.

Yours sincerely

Lynsey McGilvary

PHC: Seasonal Vaccines and Strategy

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