

Simona Panaitescu
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Dear Simona Panaitescu,

Thank you for contacting the Scottish Government regarding the COVID-19 Vaccination Programme. I am replying because I work in the COVID-19 Vaccine Delivery Programme.

All our decision making in responding to the COVID-19 pandemic is guided by the latest scientific evidence from the Scientific Advisory Group for Emergencies ([SAGE](#)), advice from Health Protection Scotland, and our Chief Medical Officer. The Joint Committee on Vaccination and Immunisation (JCVI) provides advice on immunisation to all UK Health Departments, including on the efficacy and safety of vaccines.

Each vaccine goes through a rigorous and independent three-phase testing process long before it can be licensed as safe and effective for use. Regulators such as the European Medicines Agency and the UK's Medicines and Healthcare products Regulatory Agency review trial results and decide whether to approve the vaccine. During a pandemic, timeframes for the testing process can be compressed, but never at the expense of safety. This will be the case for all other COVID-19 vaccines approved for use in the UK.

The safety of all vaccines and medicines is monitored by the Medicines and healthcare products regulatory agency (MHRA) on a UK wide basis. This includes reports from the Yellow Card Scheme which allows health professionals and patients across the UK to flag up suspected adverse reactions to any vaccine or medicine, as well as reports from worldwide use and on-going scientific evidence.

Concerns over the safety of vaccines are taken seriously. Please be assured that the MHRA keep the safety of all vaccines under close and continual review, and would take appropriate regulatory action if new evidence emerged which called into question the safety of any vaccines currently in use in

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Scotland. If at any time surveillance information suggests that the safety profile of the vaccine is changing then Scottish Ministers would of course consider the implications of that immediately. The Joint committee on vaccination and immunisation (JCVI) also continues to monitor all available evidence and advice can be updated if new information becomes available. Scottish Ministers will of course consider carefully any future JCVI recommendations in respect of the vaccines administered in Scotland.

Further information on the COVID-19 vaccine can be found on the NHS Scotland COVID-19 webpage - [The coronavirus \(COVID-19\) vaccine \(nhsinform.scot\)](https://www.nhs.uk/conditions/coronavirus-covid-19/vaccine/)

Will a COVID-19 vaccine be mandatory?

While the Scottish Government strongly recommends that those eligible to receive vaccines should do so, vaccination is not mandatory: individuals have a choice as to whether they themselves are vaccinated and whether they vaccinate their children. We continue to make every effort to promote and encourage vaccinations. It is clear that our view on the importance of vaccination is shared by most people in Scotland as we have some of the highest uptake rates in Europe for our national programmes.

The decision on vaccination is one of personal choice and the Scottish Government has no current plans to introduce mandatory vaccination or to impose any penalties relating to this.

Time between doses/efficacy

Data provided to the Medicines and Healthcare products Regulatory Agency (MHRA) demonstrated that whilst efficacy is optimised when a second dose is administered, both offer considerable protection after a single dose, at least in the short term.

The change in dose schedule only applies to the Pfizer BioNTech vaccine. It was originally licensed by the regulatory body in the UK (MHRA) on the basis that the second dose would be administered 21 days after the first dose. This was based on the data presented (and published publicly) to them from Pfizer from stage 3 of the clinical trial.

However, the MHRA subsequently had access to other data from Pfizer (not publicised from the manufacturer) which indicated a very high level of efficacy between the first and second dose that was longer than 21 days (up to 12 weeks). The MHRA subsequently revised the conditions of their approval enabling the vaccine to be used with a longer dose interval.

However, how vaccines are used are guided by the Joint committee for Vaccination and Immunisation (JCVI) and they met also reviewing all of the available evidence and concluded the dose schedule between 1st and 2nd doses for both the Pfizer and AstraZeneca Vaccine (which at that time was just about to be approved by the MHRA) should be up to 12 weeks given both demonstrated a high level of efficacy. The 4 CMOs also met to consider this advice and concluded that they were in full support of this approach. All have published their conclusions separately (MHRA, JCVI and 4 CMOs).

All Governments in the UK have agreed to be bound by the independent clinical advice of the JCVI and why from the 4 January, the change in dose schedule was applied to the Pfizer vaccine and

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anyone receiving the newly approved AstraZeneca vaccine.

This approach has enabled all nations to provide a first dose of the vaccine to more people than we would have with a shorter dose schedule and importantly is informed by independent clinical advice.

Everyone will still receive their second dose and this will be within 12 weeks of their first.

I hope this information is helpful to you, please be assured that the health, wellbeing, and safety of people is our priority. In developing our policy, Ministers have sought to balance the twin aims of reducing the transmission of COVID-19 with wider health and social considerations to best protect you and those around you.

Yours sincerely

Charles Willis
VACS : COVID-19 & Flu Oversight Programme

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