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Siobhian Brown MSP
Convener
COVID-19 Recovery Committee
The Scottish Parliament
Edinburgh
EH99 1SP

12 October 2021

Dear Siobhian

I am writing following the committee meeting on 30 September 2021, in which I agreed to address the specific issues which were put to the committee by a member of the public who volunteered in the stage 3 Novavax trial last year. I am also responding to the committee's request for clarification on the when the review dates are for the COVID-19 Certification Scheme.

On the issue of clinical trial participants, in July 2021 a letter was issued to all clinical trial participants through their research team (principal investigator). The purpose of that letter was to identify them as a clinical trial participant and explained our policy position was that all clinical trial participants should be treated 'as if they were fully vaccinated for domestic purposes'.

Following continued work over the summer, the situation has further developed. First, clinical trial participants who have received **an approved vaccine** can access their 'record of vaccination' through the same routes as people who received their vaccine as part of the national vaccination programme.

Secondly, clinical trial participants who have received a **currently non-approved vaccine**, or are on a **blinded study** were sent a 'record of vaccination' certificate identifying them as a clinical trial participant and that they should be treated as if they were fully vaccinated. These certificates were sent on the 7 September, and are currently paper-based and contain a 1D barcode. These certificates are fully equivalent to the certificates provided for all other people who have been fully vaccinated and can be used for access to domestic venues and will also permit smoother inbound entry to the UK. Our toolkit for businesses provides an example of this certificate so venues are aware that they should be accepted for entry to the venue.

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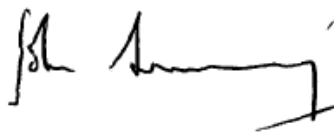
At present, the standard NHS routes for storing information derived from the national vaccination programme cannot accommodate all the technical details associated with participation in a clinical trial for the second group noted above. Work is ongoing to find a robust solution to this issue which would enable those unblinded and on non-approved vaccines to have access to the digital version of the Record of Vaccination.

You may wish to be aware that Novavax vaccine is not yet authorised for use in the UK, or yet been given emergency use approval by any registered authorities. Should the status of Novavax change we would of course review the certification arrangements for these trial participants at that time. As a result, all clinical trial participants for Novavax are currently within this second grouping even though some trial participants may be unblinded.

Everyone travelling abroad (i.e. both clinical trial participants and people within the national vaccination programme) needs to meet the requirements for their destination country when travelling. For example, they will need to ensure the vaccination they have received is recognised by their destination country and, if not, provide a negative pre-departure test etc. if stipulated by that country.

Finally, the three-weekly reviews for certification are aligned to the wider three-weekly review of all Covid restrictions. These dates are: 26 October; 16 November; and 7 December.

Yours sincerely,



JOHN SWINNEY

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