Domestic Covid Status Certification – Business and Regulatory Impact Assessment – January 2022

Domestic Covid Status Certification January 2022 Business and Regulatory Impact Assessment

Title of Legislation -

The Health Protection (Coronavirus) (Requirements) (Scotland) Amendment Regulations 2022 – included an amendment to the definition of fully vaccinated to include the requirement for a booster vaccination if a person's primary course of MHRA vaccine was more than 120 days ago.

The Health Protection (Coronavirus) (Requirements) (Scotland) Amendment (No. 2) Regulations 2022 – included an amendment to the definition of late night venue so that it now reads:

b) there is a dancefloor or space where dancing by customers takes place.

Publication date 24 January 2021.

Legislative Background

The Health Protection (Coronavirus) (Requirements) (Scotland) Amendment Regulations 2022 and The Health Protection (Coronavirus) (Requirements) (Scotland) Amendment (No. 2) Regulations 2022 (the 'Regulations') are made under powers to make provision for the purpose of preventing, protecting against, controlling or providing a public health response to the incidence or spread of infection, conferred on the Scottish Ministers by schedule 19 of the Coronavirus Act 2020. These Regulations, which bring into force and amend The Health Protection (Coronavirus) (Requirements) (Scotland) Amendment Regulations 2021 ("the principal Regulations"), will come in to force on Monday 17th January and Monday 24th January 2022, respectively.

Introduction

This Business and Regulatory Impact Assessment considers the impacts for businesses and consumers of amending the definition of fully vaccinated to include the requirement for a booster vaccination if a person's primary course of MHRA vaccine was more than 120 days ago and amending the definition of late night venue. The scheme will continue to accept a record of a negative test (either lateral flow device (LFD) or polymerase chain reaction (PCR)) as an alternative to proof of vaccination in order to access those settings.

Where there are potential negative impacts, mitigating actions where appropriate have been identified. The use of Covid Status Certification for international travel is beyond the scope of this impact assessment. The Scottish Government's <u>Framework for Decision Making</u> recognises that harms caused by the pandemic do not impact everyone equally.

Policy proposal

Covid Status Certification requires certain premises and events to ensure that there is a reasonable system in operation for establishing that all people in the premises can demonstrate that they are fully vaccinated, they have received a negative test result (LFD or PCR), or they are exempt and to refuse access to or remove anyone who is neither fully vaccinated, nor has received a negative test result, nor is exempt. To be considered fully vaccinated, you must have completed a course of an authorised MHRA vaccine with the final dose having been received at least 2 weeks previously. If 120 days have passed since the primary course was completed you must have had a booster dose plus 10 days (this is to ensure that the vaccine has taken effect). A negative test result means that a person has received a negative Lateral Flow Device test (LFD) or Polymerase Chain Reaction (PCR) test in the last 24 hours.

The settings covered in the original scheme on 1 October include:

- Certain late night premises with music, which serve alcohol after midnight and have a dancefloor or space where dancing by customers take place
- indoor events (unseated) planned for 500 or more people at any one time
- outdoor events (unseated) planned for 4,000 or more people at any one time
- any event planned for 10,000 or more people at any one time.

Based on evidence and a balance of the four harms¹ of the virus, the regulations were subsequently amended on 6 December to include a negative test result (either a lateral flow device (LFD) or polymerase chain reaction (PCR) from within the last 24 hours, as an alternative to proof of vaccination to gain entry to the settings in scope. Initially, the scheme – introduced on 1st October - did not include a negative test result as an alternative to proof of vaccination as we did not consider that it would be appropriate and believed it could undermine one of the policy aims of the scheme: to increase vaccine uptake. This new provision came into effect on 6 December.

This change made it possible for more people to make use of the scheme, such as those who are not yet fully vaccinated. It also means that individuals who received a vaccine not recognised by the MHRA, or who have experienced difficulty accessing their vaccination record, will be able to attend venues covered by the scheme. We hope that the inclusion of testing will encourage the greater use of regular testing and will still support us to achieve our policy objective of reducing the risk of transmission of Coronavirus.

Ministers have been clear that Covid Status Certification will not be a requirement for public services or other settings that many people have no option but to attend, such as public transport, health services and education.

The following do not qualify as events for the purposes of the scheme:

- a funeral, marriage ceremony, civil partnership registration, or a reception or gathering which relates to a funeral, marriage ceremony or civil partnership registration
- a mass participation event such as a marathon, triathlon or charity walk

¹ <u>Coronavirus (COVID-19): framework for decision making - assessing the four harms - gov.scot</u> (www.gov.scot)

- an event designated by the Scottish Ministers as a flagship event according to criteria, and in a list published by the Scottish Ministers
- a drive-in event
- an organised picket
- a protest or demonstration
- a public or street market
- an illuminated trail
- a work or business conference (not including any peripheral reception or function outside the core hours of the conference, whether or not alcohol is served)
- a business or trade event which is not open to the public for leisure purposes
- communal religious worship
- an un-ticketed event held at an outdoor public place with no fixed entry points.

The following people are exempt:

- under 18s
- people who for medical reasons cannot be fully vaccinated and cannot undertake a qualifying COVID-19 test
- people taking part (or who have taken part) in vaccine trials
- the person responsible for the premises
- workers and volunteers at the premises or event
- emergency services responders and regulators carrying out their work

The regulations require the persons responsible for a setting to ensure there is a reasonable system in operation for checking that people seeking to enter the premises are fully vaccinated, can provide record of a negative test result (either LFD or PCR), or are exempt, and to have in place a compliance plan for the system.

The amendments to the scheme will come into force on 17 and 24 January 2022. Ministers must review the Health Protection (Coronavirus) (Requirements) (Scotland) Regulations 2021 (which include Certification) at least every 3 weeks to assess whether any requirement in the regulations is still necessary to prevent, protect against or provide a public health response to the incidence or spread of infection in Scotland. We will continue to assess whether any less intrusive measures could be introduced to achieve the same combination of policy objectives in respect of the higher risk sectors concerned; if so, the policy will be immediately reviewed.

Sectoral Guidance is published on the Scottish Government website <u>here</u>. Guidance for the wider public is published on the Scottish Government website <u>here</u>.

Policy Objectives

In line with our strategic intent to <u>'</u>suppress the virus to a level consistent with alleviating its harms while we recover and rebuild for a better future', the policy objectives of Covid Certification remain to:

• **Reduce the risk of** transmission of Coronavirus, by ensuring that specified public spaces where transmission risks are higher are used only by those who are fully vaccinated including a booster when required, can provide a record of a negative test within the previous 24 hours, or are exempt. Vaccination or a negative test within the

previous 24 hours reduces (but does not eliminate) the risk of being infected, the risk of serious illness and death if they are infected and the risk of infecting others; **Reduce the risk of serious illness and death** thereby alleviating current and future pressure on the National Health Service, by reducing transmission in specified settings where transmission risks are higher;

- Reduce the risk of settings specified in the scheme being required to operate under more restrictive protections, or to close, by ensuring that the risk of transmission in these settings is reduced; and
- Increase the protection enjoyed by those using settings covered by the scheme and their contacts, by incentivising those using the settings to take up the vaccine and/or to test regularly and self-isolate if positive.

An evidence paper summarising the range of evidence available on certification schemes was published <u>here</u>. Consistent with our approach throughout the pandemic, the paper adopts a four harms approach covering the direct health harms of Covid-19, the indirect health harms, the social and the economic harms. Evidence is drawn from clinical and scientific literature, from public opinion and from international experience. A follow-up evidence paper which sets out the evidence on certification schemes since the original paper was published is available <u>here</u>. An evidence paper on the Omicron variant was published on 10 December 2021 and is available <u>here</u>. This impact assessment should also be considered alongside the latest <u>State of the Epidemic report</u>.

Public health rationale

The COVID-19 epidemic continues to pose considerable challenges. After decreasing in November 2021, new case rates rose sharply from the end of December and peaked in early January 2022. The 7 day positive PCR case rates per 100,000 are currently averaging around under a 1,000 per day (based on PCR tests only). However, it should be noted that on 5 January 2022, the Scottish Government announced that people who do not have symptoms of Covid-19 will no longer be asked to take a polymerase chain reaction (PCR) test to confirm a positive Lateral Flow Device (LFD) result. Instead, anyone with a positive LFD, who does not have symptoms, should report the result online as soon as the test is done. This means that those without symptoms who previously would have taken a confirmatory PCR test, will no longer do so. As a result, these positive cases are not directly comparable with previously reported number of cases. Weekly hospital admissions with confirmed COVID-19 have started to decrease over the last week. Case rates and age standardised hospital admissions are considerably lower in vaccinated versus unvaccinated individuals. Modelling indicates uncertainty over hospital occupancy and intensive care in the next four weeks. Hospitals are currently at, or very close to, capacity and have been in this position for many weeks now with several Health Boards operating within an environment of unprecedented pressure and heightened risk, plus a requirement for military support. This is likely to be driven by Covid-19 cases and delayed discharges but also may reflect that patients with higher acuity are now requiring admission.

Omicron is now the dominant variant across the UK². Risk assessments on Omicron (B.1.1.529) have been published by the UK Health Security Agency (UKHSA).³ The growth advantage has been designated as red, with a high confidence, indicating that Omicron has a significant growth advantage over Delta, with greater household transmission risk and secondary attack rate being seen. ^{4 5} There is high confidence that immune evasion is a substantial contributor to the growth advantage but it is also biologically plausible that increased transmissibility of the omicron variant is also contributing.

Therefore, the transmissibility of Omicron has been designated as amber with a low confidence by the UKHSA indicating that that Omicron is at least as transmissible as Delta but further analysis is required.⁶ There is also evidence of widespread community transmission of Omicron.^{7 8}

Immune evasion to both natural and vaccine derived immunity has been designated as red with a high confidence by the UKHSA indicating that there is evidence of frequent infection in humans with known prior infection or vaccination⁹. Neutralisation data, real world vaccine effectiveness against symptomatic disease, and reinfection rate all confirm substantial immune evasion properties¹⁰ ¹¹.

Infection severity has been designated as green with high confidence by the UKHSA meaning there is evidence to support a moderate reduction in the relative risk of hospitalisation compared to Delta, ranging from 15 to 80%¹² ¹³. The data published by UKHSA indicate that the risk of attending hospital or emergency care is around half that of Delta and the risk of being admitted from emergency care around is around one third of Delta¹⁴. SAGE 102 minutes identify a potential reduction of 35-65% for the risk of hospitalisation compared to Delta¹⁵. The reduction in infection severity is likely to be partly due to the nature of the variant and partly due to protection from prior infection; however, the relative contributions of the two factors has not been quantified¹⁶. Early data from COVID-19 Clinical Information Network (CO-CIN) considered by SAGE on 7 January 2022 indicate that the severity of disease being observed in hospital over the last three weeks is lower than observed in early phases of previous waves,

² SARS-CoV-2 variants of concern and variants under investigation (publishing.service.gov.uk)

^{3*}12 January 2022 Risk assessment for SARS-CoV-2 variant: Omicron VOC-21NOV-01 (B.1.1.529) (publishing.service.gov.uk)

⁴ *12 January 2022 Risk assessment for SARS-CoV-2 variant: Omicron VOC-21NOV-01 (B.1.1.529) (publishing.service.gov.uk)

⁵ <u>22 December 2021 Risk assessment for SARS-CoV-2 variant: Omicron VOC-21NOV-01 (B.1.1.529)</u> (publishing.service.gov.uk)

⁶ <u>*12 January 2022 Risk assessment for SARS-CoV-2 variant: Omicron VOC-21NOV-01 (B.1.1.529)</u> (publishing.service.gov.uk)

⁷ SAGE 98 minutes: Coronavirus (COVID-19) response, 7 December 2021 - GOV.UK (www.gov.uk)

 ⁸ Omicron in Scotland - evidence paper - gov.scot (www.gov.scot)
 ⁹ <u>*12 January 2022 Risk assessment for SARS-CoV-2 variant: Omicron VOC-21NOV-01 (B.1.1.529)</u> (publishing.service.gov.uk)

¹⁰ *12 January 2022 Risk assessment for SARS-CoV-2 variant: Omicron VOC-21NOV-01 (B.1.1.529) (publishing.service.gov.uk)

¹¹ SARS-CoV-2 variants of concern and variants under investigation (publishing.service.gov.uk)

¹² *12 January 2022 Risk assessment for SARS-CoV-2 variant: Omicron VOC-21NOV-01 (B.1.1.529) (publishing.service.gov.uk)

¹³ S1460 - SPI-M-O consensus statement to SAGE.pdf (publishing.service.gov.uk)

¹⁴ SARS-CoV-2 variants of concern and variants under investigation (publishing.service.gov.uk)

¹⁵ *S1476_SAGE_102_minutes.pdf (publishing.service.gov.uk)

¹⁶ <u>22 December 2021 Risk assessment for SARS-CoV-2 variant: Omicron VOC-21NOV-01 (B.1.1.529)</u> (publishing.service.gov.uk)

with less need for oxygen, less admission to intensive care, better outcomes, and shorter stays¹⁷. From the SAGE 101 meeting on 23 December 2021, UKHSA data suggests a doubling time of 4 to 5 days for hospitalisations¹⁸.

Infection severity in children has been designated as amber with a low confidence as, although there has been an increase in hospital admissions, further analysis is required to compare the risk of hospitalisation between Omicron and Delta, and to assess the clinical nature of the illness in children ¹⁹

The Scientific Pandemic Influenza Group on Modelling, Operational sub-group (SPI-M-O) concluded that "If omicron in the UK combines increased transmissibility and immune escape, irrespective of severity, it is highly likely that very stringent measures would be required to control growth and keep R below 1"²⁰.

Our primary and secondary health and social care services are facing arguably the most significant and increasing pressures and demands in the history of the NHS. The winter period is also posing significant challenges of increased transmission and related pressure on the National Health Service. We remain of the view that action is therefore needed across all sectors to ensure adherence to baseline measures. Drawing on the evidence so far available, we consider that Covid Status Certification has an important role to play as one such measure including as a precautionary measure in light of the new Omicron variant.

Vaccination

While no vaccine is 100% effective at preventing infection, disease and transmission, and they do not completely break the link between a high volume of positive cases and serious pressure on healthcare services, they are our best route out of the pandemic. Vaccines help prevent transmission of the virus as vaccinated people are less likely to become infected and ill than unvaccinated people (and only infected people can transmit the virus). The UK Vaccine Effectiveness Expert Panel (VEEP) is a group of scientific and analytical specialists from academia and government in the UK who provide a consensus view on vaccine effectiveness, split by variant, vaccine and dose. They have published estimates for vaccine effectiveness based on an assessment of the evidence at the time of writing and as new evidence or data emerges, SAGE will update its advice. The most recent summary, published on 24th September 2021, can be found <u>here</u>.

Vaccine effectiveness against symptomatic disease with the Omicron variant is lower compared to the Delta variant and wanes rapidly. However, boosting returns it to a comparable level²¹. Vaccine effectiveness 2 to 4 weeks after a booster dose ranged from around 65 to 75% for Omicron compared to >90% for Delta. Vaccine effectiveness against symptomatic disease drops to 55 to 70% at 5 to 9 weeks after a booster and a further drop to 40 to 50%

18 SAGE 101 minutes: Coronavirus (COVID-19) response, 23 December 2021 - GOV.UK (www.gov.uk)

¹⁷ <u>*S1476 SAGE 102 minutes.pdf (publishing.service.gov.uk)</u>

¹⁹ *12 January 2022 Risk assessment for SARS-CoV-2 variant: Omicron VOC-21NOV-01 (B.1.1.529) (publishing.service.gov.uk)

²⁰ SPI-M-O: Consensus Statement on COVID-19, 7 December 2021 - GOV.UK (www.gov.uk)

²¹ <u>*12 January 2022 Risk assessment for SARS-CoV-2 variant: Omicron VOC-21NOV-01 (B.1.1.529)</u> (publishing.service.gov.uk)

from 10+ weeks after the booster for Omicron, whereas vaccine effectiveness for Delta remains over 80% at 10 weeks^{22 23}.

Protection against hospitalisation from vaccination is much greater than that against symptomatic disease, in particular after a booster dose²⁴. Vaccine effectiveness against hospitalisations 4 weeks after dose 1 is at 58%, between 2-24 weeks after dose 2 at 64% and for 25+ weeks after dose 2 at 44%. Data released by UKHSA suggest that 2 to 4 weeks after a booster, vaccine effectiveness increases to 92%, after 5-9 weeks drops to 88% and that at 10+ weeks after booster, vaccine effective against hospitalisation remains at 83%²⁵

Early data considered by SAGE suggest that the probability of needing admission to ICU is very much higher in the unvaccinated population for the Omicron variant²⁶. There is currently insufficient data to make an assessment of vaccine effectiveness against severe disease for Omicron compared to Delta²⁷. However, though waning has been seen in vaccine effectiveness, it is thought that vaccine effectiveness against severe disease is more likely to be sustained, especially after a booster dose ²⁸. More analysis can be found in a number of large studies including EAVE-II (Early Pandemic Evaluation and Enhanced Surveillance of Covid-19) in Scotland²⁹, Real-time Assessment of Community Transmission (REACT-1) in England³⁰ and the Office for National Statistics (ONS) Covid-19 Infection Survey ONS study.³¹ Therefore, we have strong evidence that vaccines are effective at preventing disease, hospitalisations and deaths.

As of 18 January 2022, 85.5% of the eligible population (12+) received two doses of the vaccine and 67.2% (12+) received a booster or third dose. In the week 1 to 7 January 14.2% of positive cases were in unvaccinated individuals. In the week 1 - 7 January in an age-standardised population, individuals were 4 times more likely to be in hospital with COVID-19 if they were unvaccinated compared to individuals that had received a booster or third dose of vaccine³².

Vaccine uptake has progressed extremely well in the Scottish adult population with approximately 80.5% of 18 to 29 year olds and 81.8% of 16 to 17 year olds having received the first dose of the vaccine as of 18 January. At least 95% of people aged 50 and over have received two doses, but uptake of a second dose remains lower in people in their 30s (79.8%) and the 18-29 age group (72.2%) as of 18 January. Vaccine uptake has slightly increased since the scheme was announced, although it is not possible to directly attribute rises to the introduction of the Covid Status Certification. The proportion of those aged 12+ with a first dose

²² SARS-CoV-2 variants of concern and variants under investigation (publishing.service.gov.uk)

²³ SARS-CoV-2 variants of concern and variants under investigation (publishing.service.gov.uk)

²⁴ SARS-CoV-2 variants of concern and variants under investigation (publishing.service.gov.uk)

²⁵ COVID-19 vaccine surveillance report - week 2 (publishing.service.gov.uk)

²⁶ *S1476 SAGE 102 minutes.pdf (publishing.service.gov.uk)

²⁷ <u>22 December 2021 Risk assessment for SARS-CoV-2 variant: Omicron VOC-21NOV-01 (B.1.1.529)</u> (publishing.service.gov.uk)

²⁸ <u>22 December 2021 Risk assessment for SARS-CoV-2 variant: Omicron VOC-21NOV-01 (B.1.1.529)</u> (publishing.service.gov.uk)

²⁹ EAVE II | The University of Edinburgh

³⁰ The REACT 1 programme | Faculty of Medicine | Imperial College London

³¹ Office for National Statistics (24 September 2021). Coronavirus (COVID-19) Infection Survey, UK

³² COVID-19 Daily Dashboard | Tableau Public

rose to 91.8%, second dose rose to 85.5%, and a third dose or booster rose to 67.2% up to 18 January 2022³³.

Protection due to previous infection

There is limited evidence for Omicron on the duration of natural immunity due to the high levels of vaccination within the population. However, high levels of immune escape have been seen as well as a marked increase in overall reinfection rates^{34 35 36}.

Data published on 17 November, pre Omicron, showed that those who have had a COVID-19 infection previously continue to be less likely to test positive than those who had not, with estimated likelihood of testing positive similar to those who received three doses of COVID-19 vaccine more than 14 days ago and those who received two doses of Pfizer/BioNTech vaccine between 15 to 90 days ago. Those who had previous infection were 1/5th less likely to test positive for covid compared to those who had not.³⁷

Data from numerous studies pre-Omicron indicate that neutralising antibodies last from 5-7 months³⁸ for up to a year³⁹ after SARS-CoV-2 infection. Individuals with severe illness produce more antibodies⁴⁰ and vaccination of individuals who have already been infected induces higher levels of protection than following infection alone.^{41 42} Young people tend to have a stronger antibody based on immunity to SAR-CoV-2 that lasts longer. A UK based study focusing on prevalence of antibody positivity to SARS-CoV-2 after first peak of infections showed that the highest prevalence and smallest overall decline in positivity was in the youngest age group (18-24 years), and lowest prevalence and largest decline in the oldest group (>74 years).⁴³

In summary it is difficult to say definitively how long natural (post-infection) immunity will last. A NERVTAG paper (New and Emerging Respiratory Virus Threats Advisory Group) presented to

(B.1.1.529) (publishing.service.gov.uk)

³⁷ Office for National Statistics (1 December 2021)

https://www.ons.gov.uk/peoplepopulationandcommunity/healthandsocialcare/conditionsanddiseases/b ulletins/coronaviruscovid19infectionsurveycharacteristicsofpeopletestingpositiveforcovid19uk/latest#re infections-of-covid-19-uk

³⁸ British Medical Journal (30 June 2021)

https://www.bmj.com/content/373/bmj.n1605.short?rss=1&utm_source=feedburner&utm_medium=fee d&utm_campaign=Feed%3A+bmj%2Frecent+%28Latest+from+BMJ%29

4453(21)00312-1/fulltext

⁴⁰ British Medical Journal (30 June 2021)

https://www.cdc.gov/mmwr/volumes/70/wr/mm7032e1.htm?s_cid=mm7032e1_w 43 The Lancet (May 2021)

³³ COVID-19 Daily Dashboard | Tableau Public

³⁴ SARS-CoV-2 variants of concern and variants under investigation (publishing.service.gov.uk)

³⁵ <u>22 December 2021 Risk assessment for SARS-CoV-2 variant: Omicron VOC-21NOV-01</u>

³⁶ <u>SARS-CoV-2 variants of concern and variants under investigation- Technical briefing 34</u> (publishing.service.gov.uk)

³⁹ Journal of Infection (17 June 2021) <u>https://www.journalofinfection.com/article/S0163-</u>

https://www.bmj.com/content/373/bmj.n1605.short?rss=1&utm_source=feedburner&utm_medium=fee_d&utm_campaign=Feed%3A+bmj%2Frecent+%28Latest+from+BMJ%29

⁴¹ Journal of Infection (17 June 2021) <u>https://www.journalofinfection.com/article/S0163-</u> 4453(21)00312-1/fulltext

⁴² Centres for Disease Control and Prevention (13 August 2021)

https://www.sciencedirect.com/science/article/pii/S2666776221000752?via%3Dihub

Scientific Advisory Group for Emergencies (SAGE) on 27 May discussed that protection from re-infection with SARS-CoV-2 can last at least 7 months and in some studies up to one year.⁴⁴

Testing

Two main testing methods exist for detection of SARS-CoV-2: LFDs or PCR. PCR is the recommended testing method if you have COVID-19 symptoms while LFDs are recommended only for people who do not have symptoms.⁴⁵ PCR is a highly sensitive and specific technique to detect SARS-CoV-2 and is a recommended diagnostic testing method by the World Health Organisation (the WHO)⁴⁶. Specificity and sensitivity levels of >95% have been reported by SAGE for PCR testing⁴⁷.

LFD testing is effective at identifying people with the virus when they are at their most infectious and have high viral loads.⁴⁸ A peer-reviewed study on sensitivity of the LFDs carried out by University College London found that LFDs are more than 80% effective at detecting any level of COVID-19 infection and, therefore, can be an effective tool in reducing transmission.⁴⁹ Another study showed that LFDs are 95% effective and 89.1% specific at detecting COVID-19 when used at the onset of symptoms.⁵⁰ A review on the diagnostic accuracy of point-of-care antigen and molecular-based tests for diagnosis of SARS-CoV-2 infection concluded that LFDs which pass the criteria for use (e.g. WHO's priority target product profiles for COVID-19 diagnostics) can be considered as a replacement for PCR .

Data from the Assessment of Transmission and Contagiousness of COVID-19 in Contacts (ATTACCC) study show that false negative LFD test results mostly occurred 1 to 2 days prior to peak viral load and became negative at approximately the same time as viral culture became negative⁵¹. This indicates that LFDs are effective at detecting infectious cases. All the LFDs in use in the National Testing System have been shown by the British Government's Science Park, Porton Down, and University of Oxford SARS-CoV-2 lateral flow antigen test validation cell to be effective in detecting the Omicron Variant of Concern⁵².

SAGE endorsed the benefits that rapid antigen testing (such as LFD testing) could have on reducing transmission when discussing the UK Government Plan B options: "Other measures are available which, if introduced, could also make Plan B (or more stringent measures) less likely (and could potentially offer better efficiency or effectiveness) for example encouraging

⁴⁴ NERVTAG (27 May 2021)

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/99 2944/S1255 NERVTAG - Immunity following natural infection.pdf

⁴⁵ Get tested for coronavirus (COVID-19) - NHS (www.nhs.uk)

⁴⁶ Diagnostic testing for SARS-CoV-2 infection (who.int)

⁴⁷ S0519 Impact of false positives and negatives.pdf (publishing.service.gov.uk)

⁴⁸ Asymptomatic testing backed by new research studies - GOV.UK (www.gov.uk)

⁴⁹ SARS-CoV-2 antigen rapid lateral flow test (LFT) sensitivity | CLEP (dovepress.com)

⁵⁰ Comparing the diagnostic accuracy of point-of-care lateral flow antigen testing for SARS-CoV-2 with RT-PCR in primary care (REAP-2) - EClinicalMedicine (thelancet.com)

⁵¹ 20220110 Self-isolation Scientific-Summary Final-clean.pdf (koha-ptfs.co.uk)

⁵² Outcome of the evaluation of rapid diagnostic assays for specific SARS-CoV-2 antigens (lateral flow devices) - GOV.UK (www.gov.uk)

wider use of rapid antigen testing in workplaces and the community, and ensuring self-isolation of those who test positive by providing sufficient support ".⁵³

The Scottish Government recommends to take regular lateral flow tests - especially before mixing with other people or visiting a hospital or care home, regardless of vaccine status or recent periods of infection. This will almost always identify Covid during early stages of infection and thus significantly reduce disease transmission⁵⁴. The optimal testing strategy in order to gain access to a high risk setting would be to take the test as close as practically possible to the time of entry. LFDs are less sensitive than PCR but have the advantage of providing rapid results, and SAGE has endorsed the benefits that rapid antigen testing (such as LFDs) could have on reducing transmission.

Customers can display an SMS (text), email or a paper printed copy showing they have registered a record of a negative test. There is no QR code within SMS or emails and so they do not need to be scanned by the NHS Scotland Covid Check App. Venues will instead perform a visual check and no data will be retained. Individuals can get an SMS or email by registering the result of their negative LFD test on the GOV.UK website, <u>here</u> and opting in to receive notification of their result. If individuals undertake a PCR test they will automatically receive an SMS or email with the results.

The testing option requires people to have access to a standard mobile phone, mobile device or computer with an email address and access to a printer. This does not need to be a 'smart phone' and can be any mobile phone or tablet that can receive text messages or has access to email. Test results can be displayed on a mobile phone, tablet or other device, or a paper copy can be printed using a home printer or using a service which provides printing facilities, such as a public library.

For those unable to test themselves, self-test LFD kits can be administered by others (such as a family member, friend, or carer) who can also register the result on behalf of the person they tested if they are also unable to do so. For those unable to display their test results (such as people who do not have a mobile phone) when registering their result they could have it sent to another person's phone, who could then show the result on their behalf.

Settings

Higher-risk settings tend to have the following characteristics: close proximity with people from other households; settings where individuals stay for prolonged periods of time; high frequency of contacts; confined shared environments, and poor ventilation.^{55 56} These settings are considered higher risk due to the way COVID-19 spreads. COVID-19 spreads in small liquid particles when an infected individual coughs, sneezes, speaks, or breathes.⁵⁷ These droplets are able to remain suspended in the air. When people are close together or in a confined, unventilated space, it is more likely these droplets will enter another person, either through inhalation, the droplets coming into contact with their eyes, nose or mouth, or by touching an

53

S1393 SPI-B SPI-

<u>M EMG Considerations for potential impact of Plan B measures 13 October 2021.pdf</u> (publishing.service.gov.uk)

⁵⁴ Options for the use of rapid antigen tests for COVID-19 in the EU/EEA - first update (europa.eu)

⁵⁵ WHO (13 December 2020). Coronavirus disease (COVID-19): How is it transmitted?

⁵⁶ SAGE. Insights on transmission of COVID-19 with a focus on the hospitality, retail and leisure sector.

⁵⁷ WHO (13 December 2020). Coronavirus disease (COVID-19): How is it transmitted?

infected surface and then touching their eyes, nose or mouth. ⁵⁸ When people meet who do not regularly see each other or have a high frequency of contacts, it is more likely one of the individuals is asymptomatically infected through their separate social groups as the total number of extended contacts is greater. Examples of settings identified by SPI-B as high risk include public transport; places of worship, shops, malls and markets; parties; cinemas; theatres; planes; large family gatherings; cultural, sporting and political events; crowds; pubs and clubs; restaurants and cafes; hotels, cruise ships, hospitals and care homes.⁵⁹

The Virus Watch Community Cohort Study found that during a period of no restrictions (September – November 2021), hospitality was associated with an increased risk indoors but not outdoors. Participating in sports indoors or outdoors was also associated with increased risk (although it was noted that this may relate to associated social activities). It was found that there was no good evidence of increased risk from attending cinemas, theatres, concerts, indoor sports events or for beauty services⁶⁰. Evidence from Germany has found that regular cinema ventilation is sufficient to minimise the risk of COVID-19 infection⁶¹. However, studies have shown that intoxication has the potential to increase the risk of transmission of COVID-19 due to a decrease in compliance with increasing levels of intoxication, notably a reduction in physical distancing, lack of face masks when not seated and mixing with groups at other tables⁶². In addition, modelled research by the Tony Blair Institute for Global Change reported that, if the NHS COVID pass had been made mandatory for crowded indoor and mass attendance settings (including sports matches, large outdoor events, indoor performances and nightclubs) in England after the lifting of restrictions on 19 July 2021, cases and deaths over the subsequent weeks could have been reduced by as much as 30%⁶³.

By restricting access to customers who are fully vaccinated and/or who can provide a record of a negative test, it is less likely that infection will take place in these settings, and it is less likely that infections within them will lead to illness. Additionally, vaccination, boosters and regular testing will continue to be incentivised.

Consequently, we can reduce the risk of transmission of the virus and help reduce pressure on health services, while also allowing settings to operate as an alternative to closure or more restrictive measures. As such, we consider the Covid Status Certification, as part of a package of measures such as improved ventilation, to be a necessary and proportionate public health measure.

NHS Scotland Covid App and Paper Certificate

⁵⁸ WHO (13 December 2020). Coronavirus disease (COVID-19): How is it transmitted? ⁵⁹ SPI-B (2 July 2020)

S0582 High connectivity situations outside the occupational or workplace context 1 .pdf (publishing.service.gov.uk)

 ⁶⁰ S1470 Non household activities covid risk 1 .pdf (publishing.service.gov.uk)
 ⁶¹ PI 2021 12 Kinos: Good ventilation ensures low risk of infection - Fraunhofer IBP

⁶² Managing COVID-19 Transmission Risks in Bars: An Interview and Observation Study: Journal of Studies on Alcohol and Drugs: Vol 82, No 1 (jsad.com)

⁶³ Pass Time: Quantifying the Public-Health Benefits of a Covid Pass | Institute for Global Change

On 30 September we launched the <u>NHS Scotland Covid Status App</u> (the "App") for international use. This contains two unique QR codes, one for each dose of the vaccine and since 13 January has included booster doses. This product has been designed for use for international travel and domestic use. To meet international travel requirements it is necessary to include full name, date of birth and details of vaccination to meet EU standards. This version of the App can be used to demonstrate vaccine status in the settings in scope.

On 20 October, the NHS Scotland Covid Check App, which is used by venues to check QR codes, was updated so that when an international QR code is scanned for domestic purposes only, a green tick or 'Certificate not valid' representing someone's vaccination status is displayed, rather than a person's name, date of birth and vaccination details.

In order to further minimise data display, on 21 October, the Covid Status App was updated to include a domestic page. This option simply shows the person's name and a QR code. When the QR code is scanned by the NHS Scotland Covid Check App it shows either a green tick or 'Certificate not valid' representing someone's vaccination status. The domestic App has functionality to hide or display a person's name. The Privacy Notice can be found on NHS Inform: Personal information we process, How we use your data, Your Rights.

On 13 January the NHS Scotland Covid Status App was updated to reflect the Scottish Government's new definition of fully vaccinated. This means that anyone who has not received the booster dose within 120 days (four months) of completing their primary course will no longer be deemed to be fully vaccinated.

Further development work will be required to update further information such as LFD negative test status in a future release of the App. In the meantime, customers can display an SMS (text) or email which records they have received a negative test. There is no QR code within SMS or emails and so they do not need to be scanned by the NHS Scotland Covid Check App. Venues will instead perform a visual check and no data will be retained. Individuals can get an SMS or email by registering the result of their LFD test on the GOV.UK website <u>here</u>.

The latest PHS report⁶⁴, published on Wednesday 19 January showed that, as of midnight 15 January 2022, the NHS Covid Status App has been downloaded 2,431,409 times. It is important to note a single user may choose to download the App on multiple devices, so this figure does not represent unique individuals. Between 03 September 2021 (introduction of QR codes) and midnight 15 January 2022, 715,974 paper copies of COVID-19 Status have been requested. This may not represent unique users if an individual requests a second copy (for example if they have lost their paper copy or needed to order a new one to refresh the QR codes after these have been updated). 1,736,949 PDF versions of COVID-19 Status have been downloaded. This provides a measure of the total number of times a new QR code has been generated via PDF. An individual can generate more than one successful QR code so the figure does not represent unique users. We continue to monitor user activity closely.

For those who do not have digital access or would prefer a paper copy, a record of vaccination can still be requested by phoning the Covid-19 Status Helpline on 0808 196 8565. The paper record of vaccination will then be posted to the address that is held on the National Vaccination Service System (NVSS).

When registering an account on the App the user needs to verify their identity. This is for privacy protection as health data is special category data and protected by GDPR and human rights legislation and so additional safeguards and security measures are required to verify a person's identity before they are given access to their health records. The App uses biometric verification software following an options appraisal process which, at that point in time, did not identify another feasible option that met secure authentication requirements.

This means users are asked to scan a photo of their passport or driving licence and then to take a live photo of themselves. The software then uses their live photo to compare likeness with the photo in their ID and confirm their identity. There is manual verification for the small number of cases which fail the automatic process. For the limited number of cases where a person's identity cannot be verified in the App, individuals can call the Covid-19 Status Helpline, or use NHS Inform to request a paper Certificate, which will be posted to them.

Additional forms of ID are being added to those that can be used already with biometric processing to ensure that inequalities in access are reduced. Further exploratory work on alternative (non-biometric) identity verification routes is underway.

Alternative routes to prove vaccination status, that did not require using the NHS Scotland COVID Status App, were already established (people can download a PDF or request a paper Certificate).

Many countries accept negative PCR tests or recovery status as an alternative to vaccination. These functions were made available in the Covid Statues app in mid-December. Further development work is being undertaken to extend the inclusion of PCR and LFDs for domestic use. Further information, such as LFD negative test status, will be added in a future release of the App. In the meantime, customers can display an SMS (text) or email which records they have received a negative test. There is no QR code within SMS or emails and so they do not need to be scanned by the NHS Scotland Covid Check App. Venues will instead perform a visual check and no data will be retained. Individuals can get an SMS or email by registering the result of their LFD test on the GOV.UK website <u>here</u>.

The testing option requires people to have access to a standard mobile phone, mobile device or computer with an email address and access to a printer. This does not need to be a 'smart phone' and any mobile phone that can receive text messages or has access to email is sufficient. Test results can be displayed on a mobile phone, tablet or other device, or a paper copy can be printed. In Scotland, it is estimated that 88% of households had internet access in 2019, however this varied by household net income and deprivation. The proportion of internet users reporting that they access the internet using a smartphone increased from 81 per cent in 2018 to 86 per cent in 2019⁶⁵.

Exemptions

⁶⁴ Public Health Scotland COVID-19 Statistical Report

⁶⁵ Scottish household survey 2019: annual report - gov.scot (www.gov.scot)

There are medical exemptions for domestic Covid Status Certification for the very limited number of people who can neither be safely vaccinated or tested. In the vast majority of cases, a successful route to safe vaccination or testing can be found. Local vaccination centres can help to answer questions about the vaccine and can advise what arrangements may be put in place to enable safe vaccination. In the rare cases where that support does not lead to vaccination, an exemption is offered to the individual which can be used for international use only. If the individual cannot be tested either, they will be advised to obtain proof of evidence from their primary or secondary care clinician in the form of a letter. This evidence will then be assessed by a Scottish Government clinician who will work with the Resolver Group to provide the necessary support on a case-by-case basis to determine whether the individual is also exempt from testing.

For more information on exemptions see the NHS Inform website <u>here</u>, call the Covid-19 Status Helpline or visit your local vaccination centre. Medically exempt individuals are provided with paper Certificates which have enhanced security features. Medical exemptions cannot be displayed on the international section of the App due to EU specifications. They are under consideration for a future release of the domestic section of the App. We continue to engage across the four nations to ensure that work around exemptions is taken forward collectively.

All clinical trial participants have received a letter from their Principal Investigator which can be used for proof of their trial status. Clinical trials participants are encouraged to undertake testing and provide a record of a negative test, as they may have received a placebo dose.

While children are exempt from the requirement to prove vaccine status for domestic purposes, 12-17 year olds who have been vaccinated may choose to download a PDF via NHS Inform, or they may choose to request a paper Certificate by calling the Covid-19 Status Helpline for paper copies.

The paper Certificates are in English. Information about what information the Certificates contain can be requested in other languages and alternative formats including Easy Read, audio and Braille. Information can be found on NHS Inform <u>here</u>, or when people request their Certificate.

For more information on the Covid Status Certificate see the Scottish Government website <u>here</u>.

Consultation

We have not undertaken any public consultation on these updates to existing measures which resulted in the above regulations changes. However, Scottish Government Ministers and officials have continued to engage with a wide range of sector representatives, to date at roundtables and over 20 sectors and stakeholders (<u>Annex A</u>) from a range of specialisms, including events, music, sport, hospitality, cinema, theatre, music, museum, rural and the night-time economy, as well as business organisations, trade unions and the legal profession. They have represented the views of businesses; their diverse feedback has been considered and has informed this impact assessment.

Through this engagement a number of key themes emerged.

Direct Costs to ensure compliance and enforcement

There are continuing concerns about having enough staff to implement the current scheme, given that the affected sectors are already facing a shortage of qualified stewards and front of house staff in general, as well as concerns for staff safety from both Covid and potentially dissatisfied customers/public order issues. Discussion with Securities Industries Authority (SIA) have noted however that there is a historically high level of licenced staff presently in UK but a significant number of these are currently working in other sectors. Licenced premises do not need to use SIA licenced members of staff to conduct checks of proof of vaccine status or record of test results or to refuse entry or service to customers who do not meet Covid Status Certification requirements.

However this does not remove the need for SIA staff from venues which already require them as part of their licence or insurance conditions. Also premises will want to carry out appropriate risk assessments to determine whether SIA staff are required in their circumstances.

Costs were a concern mentioned by many: costs of new scanners, as stakeholders consider that it would not be appropriate for staff to use personal phones to scan QR codes; additional staffing costs; and other infrastructure. Upon providing stakeholders with further information about the technical infrastructure, the cost infrastructure concern reduced, but the staffing issue remained live.

Businesses are also concerned about the potential increase in the cost of their insurance if they are unable to staff doors with qualified door staff, which for some may be a condition of their insurance cover. The hospitality industry reported that it can take up to 3 months to complete all training and checks for newly trained and accredited door staff, SIA have confirmed the number of SIA trained staff has increased.

<u>Complexity, Justification and Communication of the policy</u>The amendments are not extending the scope of the existing scheme and it is therefore anticipated that there will be minimal additional requirements and associated costs and resources needed to ensure appropriate compliance.

There is generally a request from sectors for better information about how any amendments to the scheme would work on the ground, and for clear guidance for all businesses impacted on how to deliver the Covid Status Certification successfully. Sectors in scope (hospitality) stated that previously SG's communications campaign had not been effective. Stakeholders seek a clear communications and marketing programme to ensure that there is a clear understanding of which venues are in scope and how the scheme will be implemented and enforced.

Legal Processes and equality issues

The night-time sector has raised concerns that they may face legal challenge on equality grounds from any customers who they are required to refuse entry, Scottish Government is not aware of any challenges to date, however, the introduction of LFDs could be seen as a way to

mitigate many of the equality issues given the wide availability and access to free LFD tests across Scotland.

Following the First Minister's announcement to include LFD testing from 6 December, the following was released:

Scottish Chambers of Commerce (SCoC) - 23 November 2021

Dr Liz Cameron, Chief Executive of the Scottish Chambers of Commerce

"Businesses across Scotland will be incredibly relieved that the First Minister has listened to the concerns of the business community.

"Although this will have been a difficult decision on balance for the Scottish Government, it was the right one, and it keeps Scotland moving in the right direction. It is now essential that businesses and individuals continue to follow the relevant COVID-19 restrictions and guidelines to ensure our economy remains open and growing.

"Businesses and consumers will now be reassured that they can make plans over the coming weeks in the run up to Christmas and New Year, without the fear of additional economic deterrents or vaccine certification burdens being placed on them.

"Scotland's businesses continue to do everything they can to support public health measures and to limit the spread of the virus, having invested millions into making workplaces Covid secure for employees, customer, suppliers and communities."

On Lateral Flow Tests:

"We are pleased that the Scottish Government have looked again at the available evidence and have acknowledged the clear benefits that LFD's provide.

"This is what businesses were calling for and it will also significantly ease and improve access to hospitality settings for consumers.

"Scotland was one of the few countries in Europe, where a vaccine certification scheme is in place, to not accept evidence of a recent negative Lateral Flow Test (LFD) in lieu of an individual's Covid vaccination status and confirmation that this will change from next month will be very welcome news for businesses, employees and customers."

Federation of Small Business (FSB) – 23 November 2021

FSB on vaccine passport Covid decision:

Andrew McRae, the Federation of Small Businesses (FSB) Scotland policy chair, said: "It's a relief that Ministers have taken on board the evidence from the FSB and others. Extending the vaccine passport scheme would have meant many local and independent Scottish hospitality and leisure firms making big changes to how they operate during a key trading period. These businesses will now have a weight off their shoulders.

"Feedback from our members showed that small cafés, restaurants and similar operators were worried that the extension would have put pressure on staff and driven up costs. It would have undermined many of these firms' plans for the festive period, many of whom are amongst the businesses hardest hit by this crisis.

"We agree with the First Minister that citizens, government and businesses of all sizes have a role in keeping this virus under control. That's why we'd urge all smaller firms to look again at the current Covid rules and ask themselves if they're doing everything in their power to play their part."

Confederation British Industry (CBI)

Tracy Black, CBI Scotland Director, said:

"Businesses still working hard to get back on their feet will welcome the Scottish Government's decision not to expand Covid certification. Many firms would have faced practical challenges and increased costs to implement measures at a time when bumper trading is needed to clawback lost or diminished revenues.

"Today's decision strikes the right balance between managing the virus and protecting our economic recovery.

"However, we cannot afford to lose sight of the fact that COVID-19 remains a threat. That means redoubling our efforts on mass rapid testing, maximising world-leading vaccine uptake, and continuing to deliver Covid-secure workplaces to keep staff and customers safe, and the economy open."

The Scottish Tourism Alliance (STA)

Marc Crothall, Chief Executive of the Scottish Tourism Alliance said:

"The Scottish Tourism Alliance welcomes the First Minister's announcement that vaccine passports will not be extended to the hospitality sector and that alternative measures can be used within businesses already implementing the scheme.

Our organisation has, since the outbreak of the pandemic, been in full support of evidencebased measures to balance the protection of public health and the economy, the proposal to extend vaccine certification to hospitality was in our view harmful to the sector, the wider tourism economy across all areas of Scotland and would have effectively stalled what is already a long and challenging road to recovery for one of the worst hit industries.

The next few weeks are crucially important to the sector in terms of recouping lost earnings as a result of the introduction of previous restrictions; I am sure that many businesses will feel a sense of overwhelming relief that they will be able to trade as planned.

The STA and other trade bodies and business groups had been consulted in the proposals to extend the vaccination certification scheme and I am delighted that the collective views and

evidence we have presented have been given the thorough and due consideration we expected.

The feeling of optimism across our tourism and hospitality sectors was significantly eroded following the First Minister's announcement last week with businesses looking towards weeks and months of immense challenge and uncertainty.

We can now hopefully look forward to a thriving season ahead, one which is pivotal to our economic recovery and I know that all businesses within our sector will be doing their utmost to ensure public safety and limit the spread of the virus to ensure a safe and buoyant festive period

The STA will encourage our members and the wider industry to promote testing to their customers in a supportive, positive manner and we look forward to our continued conversations with both governments as we navigate the road ahead back to recovery."

Scottish Hospitality Group - 23 November 2021

The Scottish vaccine passport scheme will not be extended, at least for the time being, the First Minister revealed yesterday. The news came after weeks of lobbying by all Scotland's trade bodies.

In further good news, the First Minister also said that venues such as night clubs and late-night venues, who currently require a vaccine passport, from December 6th, can ask customers to show a negative lateral flow test instead. Although the NTIA is still campaigning to have the need for Vaccine passports in late night venues to be removed completely.

After the announcement Stephen Montgomery of the Scottish Hospitality Group said, "The announcement is very welcome news and gives the trade some stability coming into the Christmas period and allows customers to come out and enjoy themselves. It is a sensible decision based on the evidence

"We have said all along that working in partnership with us makes for a better result.

"I would like to thank the First Minister, Ivan McKee, Jason Leitch, and officials, for listening to our issues and for meeting us. We now look forward to working with them to further iron out the issues that the current vaccination scheme still has."

The Night Time Industries Association Scotland's said, "Whilst NTIA Scotland remain opposed to the continued application of vaccine passports in late night settings, we are encouraged by Scottish Government's decision today that the scheme will not be rolled out further at this time. This is a sensible and pragmatic decision which takes into account the extraordinary harm businesses have suffered as a result of restrictions over the last 2 years, the lack of evidence that this scheme has any meaningful impact on vaccine uptake, concerns around human rights, and also recognises that the current trajectory of infections and hospitalisations is falling.

"Vaccine passports have however been devastating to businesses already affected, with turnover down around 40%, so we now call on Scottish Government to urgently review whether continued application of the scheme is either necessary or proportionate and provide urgent financial grant support to those businesses that remain in scope of the scheme.

"It is a positive step in the right direction that Lateral Flow Tests will now be included as an alternative to double vaccination, which will safeguard late night venues in particular, and is something the trade body has advocated for from the inception of this scheme.

"This brings Scotland in line with other European nations, and partially alleviates at least some of the equalities and social exclusion harms that were previously the case. However, the experience in Wales indicates that affected businesses, even with LFT inclusion, have still suffered a 26% decrease in trade.

Our sector are working positively and constructively with government to increase public awareness and maximise Covid safety during the vital Christmas trading season."

Background

On the 1 October the Scottish Government introduced the Covid Vaccine Certification. The requirement for persons responsible for late night premises or a relevant event to ensure a reasonable system is in operation for checking Certification came into force on the 18 October 2021.

The Scheme was introduced in line with our strategic intent to 'suppress the virus to a level consistent with alleviating its harms while we recover and rebuild for a better future' and the policy objectives were to:

- reduce the risk of transmission of Coronavirus
- reduce the risk of serious illness and death thereby alleviating current and future pressure on the National Health Service
- allow higher risk settings to continue to operate as an alternative to closure or more restrictive measures
- increase vaccine uptake

Legislative amendments

Since these regulations were amended in early December, the new Omicron variant of Covid-19 has emerged and is now dominant in Scotland. There is evidence to indicate Omicron is more transmissible than other variants and partially escapes immunity from vaccines as well as previous infections ⁶⁶. The modelling in Scotland up to 3 January 2022 estimates a doubling time of 3.88-3.95 days⁶⁷. Omicron became the dominant variant in Scotland on 17 December 2021.⁶⁸

Covid Status Certification has been amended so that the definition of "fully vaccinated" includes the requirement for a booster vaccination if a person's primary course of an MHRA vaccine was more than 120 days ago. These amendments come into force on 17 January 2022. The amendments to the definition of late night venue come into force on 24th January 2022.

⁶⁶ <u>22 December 2021 Risk assessment for SARS-CoV-2 variant: Omicron VOC-21NOV-01 (B.1.1.529)</u> (publishing.service.gov.uk)

⁶⁷ Coronavirus (COVID-19): modelling the epidemic (issue no.84) - gov.scot (www.gov.scot)

⁶⁸ Scottish Government (17 December 2021) <u>https://www.gov.scot/publications/coronavirus-covid-19-update-first-ministers-speech-17-december-2021/</u>

Ministers must review The Health Protection (Coronavirus) (Requirements) (Scotland) Amendment Regulations 2021 (which makes provision for Covid Status Certification) at least every 3 weeks to assess whether any requirement in the regulations is still necessary to prevent, protect against or provide a public health response to the incidence or spread of infection in Scotland.

We will continue to assess whether any less intrusive measures could be introduced to achieve the same combination of policy objectives in respect of the higher risk sectors concerned; if so, the requirements will be immediately reviewed.

Sectoral Guidance is published on the Scottish Government website <u>here</u>. Guidance for the wider public is published on the Scottish Government website <u>here</u>.

An evidence paper summarising the range of evidence available on certification schemes was published <u>here</u>. Consistent with our approach throughout the pandemic, the paper adopts a four harms approach covering the direct health harms of Covid-19, the indirect health harms, the social and the economic harms. Evidence is drawn from clinical and scientific literature, from public opinion and from international experience. A follow-up evidence paper which sets out the evidence on certification schemes since the original paper was published is available <u>here</u>. An evidence paper on the Omicron variant was published on 10 December 2021 and is available <u>here</u>. This impact assessment should also be considered alongside the latest <u>State of the Epidemic report</u>.

On the 4 November, in response to a question asked by the Covid-19 Recovery Committee, the Deputy First Minister stated that 'Vaccination Certification could be extended to other sectors'.

In a statement to Parliament on 9 November the Deputy First Minister stated that Ministers had been 'considering [...] whether we may need to extend the Covid Certification scheme to bring more settings into scope, such as indoor hospitality and leisure settings.'

On 16 November, in a statement to Parliament, the First Minister stated that:

"we will be assessing in the coming days whether, on the basis of current and projected vaccination uptake rates, [whether] we are now in a position to amend the scheme so that in addition to showing evidence of vaccination to access a venue, there will also be the option of providing evidence of a recent negative test result. [...]

We are also considering whether an expansion of the scheme to cover more settings would be justified and prudent given the current state of the pandemic."

On the 19 November the Scottish Government published a follow up Evidence Paper which sets out the evidence published on certification since the original Evidence Paper (published here) surrounding Certification, including information on vaccination and testing. This can be found on the Scottish Government website here.

On the 23 November the First Minister gave an update to Parliament on the state of the pandemic and provided information on the expansion of Covid Status Certification:

'Firstly, for at least a further three week period, we will retain vaccine certification for the venues and events currently covered by the scheme - that is late night licensed premises with a designated area for dancing; unseated indoor events of 500 people or more; unseated outdoor events of 4,000 people or more; and any event with 10,000 people or more.

Given the current state of the pandemic, it is our judgement that it would not be appropriate at this stage to remove this protection against transmission.

Secondly, however, we decided that from 6 December it will be possible to access venues or events covered by the scheme by showing either proof of vaccination, as now, or a record of recent negative lateral flow or PCR test result taken within the last 24 hours.'

Options Considered

Option 1: Retain mandatory Covid Status Certification in higher risk settings, with proof of vaccination *or* record of a negative test (LFD or PCR result) accepted (current policy).

Option 2: Retain mandatory Covid Status Certification in higher risk settings and amend the definition of fully vaccinated to include the requirement for a booster vaccination if a person's primary course of MHRA vaccine was more than 120 days ago and amend the definition of late night venue, with proof of vaccination *or* record of a negative test (LFD or PCR result) accepted.

Option 1: Retain mandatory Covid Status Certification in higher risk settings, with proof of vaccination or record of a negative test (LFD or PCR result) accepted (current policy).

Option 1 would feature:

- Covid Status Certification for access to specified settings required for entry either certificate of vaccine or record of a negative test (LFD or PCR within specified time frame of 24 hours)
- Mandated in regulations
- Public use of paper Vaccine Certification or digital NHS Scotland Covid App or demonstration of a negative LFD or PCR result as reported to the public reporting system
- Event/venue use of Verifier App NHS Scotland Covid Check app to verify QR code for vaccine certification
- Implementation and compliance supported through Scottish Government Guidance

Option 2: Retain mandatory Covid Status Certification in higher risk settings and amend the definition of fully vaccinated to include the requirement for a booster vaccination if a person's primary course of MHRA vaccine was more than 120 days ago and amend the definition of late night venue, with proof of vaccination *or* record of a negative test (LFD or PCR result) accepted.

Option 2 would feature:

• Covid Status Certification for access to specified settings required for entry, either certificate of completion of primary vaccine course, or booster vaccination if a person's

primary course of MHRA vaccine was more than 120 days ago *or* record of a negative test (LFD or PCR within specified time frame of 24 hours)

- Amended definition of late night venue covered by certification
- Mandated in regulations
- Public use of paper Vaccine Certification or digital NHS Scotland Covid App or demonstration of a negative LFD or PCR result as reported to the public reporting system
- Event/venue use of Verifier App NHS Scotland Covid Check app to verify QR code for vaccine certification
- Implementation and compliance supported through Scottish Government Guidance

Sectors and Groups Affected

The change to definition of full vaccination will affect:

- Late night venues with music alcohol and dancing;
- Certain indoor cultural performance venues associated with live events, particularly larger venues that stage unseated performances;
- Certain outdoor venues associated with large cultural or sporting gatherings, such as larger sports stadia and race courses;
- Conference centres, in instances where staging large scale seated or unseated live events, trade fairs open to the public, markets or exhibitions;
- Businesses involved in the organization and staging of live events, such as performers, event promoters, staging and production businesses, associated supply chain businesses;
- Business events that entail a 'peripheral' reception or function outside of the core hours of the event, which would not be excepted should they meet the criteria for certification. Business event professionals note that the majority of high value business events in Scotland encompass receptions that would be in scope (500+);
- Ancillary businesses dependent on live events (e.g. food and drink sales, merchandising);
- Prospective attendees at settings in scope;
- Local Authorities, as they would be required to undertake monitoring and enforcement activities arising from regulations;
- Royal Mail postal services in connection to the distribution of postal test kits
- Pharmacy services in connection to the distribution of test kits

The amendment to the definition of late night venues will affect late night venues with music alcohol and dancing. However this is a technical change that is intended to clarify the regulations and is not intended to bring new settings in scope.

Scottish Ministers will also continue to assess whether any less intrusive alternative measures could be introduced to achieve the same combination of policy objectives in respect of the higher risk sectors concerned. The current default position would be that Covid Status Certification provisions, along with the rest of the Principal Regulations would be due to expire on 28

February 2022.

Assessment of Options

This BRIA has set out the relative costs and benefits of options with the intended effect of suppressing the virus whilst acknowledging and minimising the economic harms faced by businesses.

Option 1: Retain mandatory Covid Status Certification in higher risk settings, with proof of vaccination or record of a negative test (LFD or PCR result) accepted (current policy).

Costs

Under this option, it is not anticipated that there would be additional costs on businesses within scope directly associated with continued implementation, outside of existing potential costs arising from: direct costs incurred by affected businesses to ensure compliance with the Regulations; reductions in footfall and attendance at venues and events covered by the Regulations; cancellation of events and refunds to customers and associated cash-flow impacts. These existing costs were presented in previous BRIA and the Scottish Government's certification evidence papers, and are reprised in the sections below where relevant for ease of reference.

There is clear guidance around how and when to take a LFD test, however, some businesses within scope have indicated that where customers do not have either proof of vaccination or record of a negative test result the business may decide to provide a test kit so that the customer can leave and take the test safely. Any costs of this would fall to that business and if businesses choose to do so, there would potentially be an ongoing cost arising from businesses purchasing additional stock on an ongoing basis.

However, this practice is strongly discouraged by the Scottish Government in updated <u>Guidance</u> which clearly states that businesses should not distribute test kits to prospective customers. The distribution of test kits needs to be carefully managed to meet regulatory requirements to be able to recall test kits from users in the event of a performance or safety issue with the tests. Additionally, lateral flow tests are designed to be used at room temperature, on a flat, clean, dry surface with the ability of the user to wash their hands thoroughly before use to avoid contaminating the test. Individuals should be encouraged to test before they leave home to reduce the transmission risk.

Implementation Costs

The previous BRIA's and the Scottish Government's Evidence Papers⁶⁹ described a range of potential cost impacts on businesses associated with implementation and delivery of certification.

Examples of these costs included:

- Additional resource for recruiting or training staff to check certification.
- Dedicated hardware to scan or read Covid Status Certification (mobiles/tablets) and/or install technology to check QR codes at automatic entry barriers.

⁶⁹ The BRIA for certification regulations introduced in October 2021 is available at: <u>Coronavirus (COVID-19)</u> domestic vaccine certification: business and regulatory impact assessment - gov.scot (www.gov.scot). The Evidence Paper published in September 2021 is available at: <u>Coronavirus (COVID-19) vaccine certification: evidence paper - gov.scot (www.gov.scot)</u>. The Evidence Paper published in November 2021 is available at: <u>Coronavirus (COVID-19) vaccine certification: evidence paper - gov.scot (www.gov.scot)</u>. The Evidence Paper published in November 2021 is available at: <u>Coronavirus (COVID-19) vaccine certification: evidence paper update - gov.scot (www.gov.scot)</u>.

- Cancellation of tickets and refunds
- Additional policing costs arising if there are scenes of disorder at sports stadia due to long queues caused by Covid Status Certification checks.
- For business events, additional complexity of exempting one element of the programme (e.g. standing receptions), with associated cost and reputational risk of denying delegates who are attending this and all other elements in a work capacity. Business event professionals have shared that the majority of high value business events in Scotland encompass receptions that would be in scope (500+).
- Costs to Local Authorities of monitoring and enforcing Covid Status Certification

While some of these items of cost, particularly related to technology, could be described as one-off implementation costs that businesses would face and may have already incurred, those associated with recruitment, training and payment of staff, and LA enforcement costs, would potentially be ongoing direct costs associated with implementation and compliance.

The NHS Scotland Covid App will continue to be provided for free, the accompanying <u>Guidance</u> on how to implement within businesses now being live on the Scottish Government website.

The extent of ongoing costs borne by businesses affected by Covid Status Certification will likely vary across businesses, depending on the scope to integrate them into existing staff functions, use existing IT infrastructure, or physical infrastructure. These costs may be higher for businesses that have not delivered a similar function historically, such as venues that do not charge for entry and have previously not had a need for door staff but may now require some to check vaccination status at the point of entry.

Staff costs represent a large component of the overall running costs of businesses in some of these sectors. For example, in the Accommodation and Food Services sector overall, labour costs are estimated to account for 44% of total costs at a sectoral level, compared to 26% across all sectors, while in Arts, Culture and Entertainment sector labour costs are estimated account for around 27% of total costs.⁷⁰

Impacts on staff costs would likely vary across businesses depending on several factors, particularly whether the Regulations' requirements are accommodated within existing staff responsibilities or require additional staff. If additional staff is required, costs would be influenced by factors such as numbers of staff required, and number of hours required each week. Hourly and weekly gross wage costs for occupational groups that would be affected by the regulations are set out in Table 2 below. It should be noted that these statistics do not include non-wage labour costs, such as Employers' NIC and pension contributions:

	Mean Gros	s Hourly Pag	y, £	Mean Gross Weekly Pay, £			
	All	Part-Time	Full-Time	All	Part-Time	Full-Time	
Security Guards & Related Occupations (SOC 9241)	£12.60*	£11.73**	£12.71*	£496.80*	£326.80**	£526.80*	

⁷⁰ Scottish Annual Business Survey, Scottish Annual Business Statistics (SABS) 2019 Scottish. Note that SABS excludes financial sector & parts of agriculture and the public sector.

B	ar Staff	(SOC	£9.81**	£8.64*	Х	£178.60**	£121.20*	Х	
92	274)								

Table 2. Gross Mean Hourly and Weekly Pay, Selected Occupations, 2021. Source: ONS, Annual Survey of Hours and Earnings 2021, Tables 15.1a, 15.5a Estimates marked * are considered reasonably precise, estimates marked ** are considered acceptable, x denotes an estimate which is considered unreliable for practical purposes It is noted that there is a widely reported difficulty in securing sufficient numbers of stewarding and hospitality staff at present, due to labour shortages. For instance, in the period 15-28 November 2021, 49.4% of businesses in the Accommodation and Food Services Sector reported that vacancies were more difficult to fill compared to normal expectations for the time of year, and 42.3% reported having a worker shortage⁷¹. Hospitality stakeholder organisations have consistently highlighted challenges in the availability of SIA-accredited door staff. There is also evidence of continued strong growth in vacancies in areas like hospitality⁷². These could create challenges for affected businesses across affected sectors in recruitment of numbers of staff required as a result of regulations.

Feedback from Event Sector member organisations to Scottish Government officials has indicated that those affected may have experienced additional costs associated with implementation. Feedback from one theatre group has indicated that additional staffing costs associated with implementing Covid Status Certification have been of the order of £6,600 per week at a specific larger venue⁷³. Sports sector stakeholders have reported that additional stewarding has been necessary to implement Covid Status Certification as currently designed⁷⁴.

The magnitude of these costs in coming months will be closely linked to the level of enforcement expected from businesses, the type and footprint of venues, and flow of customers at venues and events. Current Covid Status Certification arrangements have varied across settings with guidance taking account of the differences between a venue where there are a smaller number of people queuing to enter the premises compared to a large event such as a sporting event with multiple entrances and larger crowd control required: for instance, late night venues have been required to operate a 100% check on entry, given the option for a visual check. For large events, spot check arrangements have been in place.

This option may have further financial impacts on events which run over a prolonged period of time such as trade fairs and exhibitions which often run over a number of days. The combination of extended event times and changeover in attendees may require additional staffing capacity to allow for Covid Status Certification checks, in addition to standard ticket checks.

For business events there is additional complexity of exempting one element of the programme (e.g. standing evening receptions), with associated cost and reputational risk of denying delegates who are attending this and all other elements in a work capacity. Business event professionals have shared that the majority of high value business events in Scotland encompass receptions that would be in scope (500+).

⁷¹ BICS weighted Scotland estimates: data to wave 43 - gov.scot (www.gov.scot)

⁷² Coronavirus (COVID-19) vaccine certification: evidence paper update (www.gov.scot). Page 47.

⁷³ Source: feedback to officials from Ambassadors Theatre Group, November 2021

⁷⁴ <u>Coronavirus (COVID-19) vaccine certification: evidence paper update (www.gov.scot)</u>. Page 40.

There have also been reported incidences reported of individual premises changing their offerings and business models (such as through reducing opening hours or converting their premises) to avoid falling within the requirements of certification⁷⁵. These may have resulted in costs to individual businesses arising from decisions around implementation of certification.

Anti-Social Behaviour

Stakeholder representative groups have also consistently highlighted the risk of increased antisocial behaviour, should customers be refused entry on grounds of not having appropriate certification. Hospitality and Event industry stakeholder groups have provided anecdotal feedback of increased aggression towards security staff and stewards in some contexts. This could impact on recruitment and retention of staff, and importantly, on staff wellbeing.

Local Authority Enforcement Costs

As outlined in the original BRIA, there are costs associated with Option 1 in relation to enforcement. The Local Authority Covid-19 Expert Officer Group originally estimated the costs to Local Authority Regulatory service at £225,000, based on the assumption that there are 2,000 businesses and 500 events in scope in the initial 6 months from Oct 1. Scottish Government have committed to monitoring and evaluating the impact of the scheme on local authority resources and have allocated funding of £2.9 million to local authorities to year end to support with Covid compliance activity. The premises in scope have not been expanded therefore there is no additional types of premises where LAs would have a role in enforcement.

It is acknowledged that the previous definition of late night venues covered by Covid Status Certification may have created ambiguity and limited the ability of Local Authorities to engage with premises where the dancing on the designated dancefloor continued. The new definition incorporating 'any space where dancing by customers takes place' provides greater clarity and scope for Local Authorities to engage in a proportionate way following the 4Es and better ensures that the spirit of the scheme is reflected in practice.

Loss of revenue through reductions in footfall and attendance

Businesses subject to Covid Status Certification may experience a reduction in customer footfall and attendance, as those without proof of vaccination would be refused entry – although this could be mitigated by the inclusion of testing. Customers may view Covid Status Certification as a barrier, especially if groups socializing together are divided into certified and non-certified. This could lead to a reluctance to visit venues and attend events where Covid Status Certification is needed, opting to visit venues and events which do not require it. Those affected may also choose to stay at home or go out earlier in the evenings to avoid certification. The anticipation of delays in entry and experience of the customers entering venues and events where Covid Status Certification is required may influence choice, opting for less onerous options. Taken together, these may result in loss of direct footfall for some businesses. Loss of trade and revenue for participating venues could heighten pressures on individual businesses' viability.

The previous BRIA and the Scottish Government's Evidence Papers described the potential for impacts on footfall and revenues for businesses affected by certification. It is challenging to

⁷⁵ For instance: <u>Edinburgh nightclub scraps Covid vaccine passports amid huge decline in footfall -</u> <u>Edinburgh Live</u>

directly identify the impact of Covid Status Certification on losses of footfall and turnover experienced by individual businesses, owing to the relatively short space of time that Covid Status Certification has been in place, and potential impacts from other contributory factors. However, emerging reports from stakeholder organisations in the hospitality sector have consistently suggested that nightclubs and late night settings affected by Covid Status Certification have experienced substantial reductions in footfall and revenues since introduction of certification. Trade bodies have consistently provided reports of members experiencing reduced footfall and takings. Hospitality stakeholders advised of members experiencing footfall reductions of 20%-40%; falls in revenue of around 40% in affected venues⁷⁶, while a joint hospitality industry survey suggested that 87% of respondents that had been affected by Covid Status Certification saw trade levels fall by over 20%⁷⁷.

Events sector stakeholders have also provided anecdotal evidence of business impacts. Individual events organisers have advised of larger drop-offs in actual attendance compared with ticket sales than would typically be expected⁷⁸.

Footfall in the settings that currently fall within Covid Status Certification requirements is potentially substantial. YouGov polling for 2-4 November⁷⁹ suggests 5% of those polled had been in a nightclub or late night venue in the previous week, while 10% had been to any sort of venue/event eligible for Covid Status Certification (a nightclub or late night venue or large event). Generally levels for each of these are higher among 18-29 year olds than other. Updated figures for December have been published <u>here</u>. Pre-pandemic, there was also evidence to suggest that larger portions of 16 to 24 year olds, 25 to 34 year olds, and 35 to 44 year olds had attended live music events in the previous year than the share of the population overall⁸⁰.

Footfall could be impacted in the following ways:

- Those without Covid Status Certification or record of a negative test would be refused entry (which in turn depends on numbers vaccinated)
- Others may be reluctant to attend if non-certificated friends were unable to attend
- Entry delays could deter customers if onerous.

The extent of economic harm would arise from the numbers of unvaccinated people within the population overall, and those who are not fully vaccinated in the previous fortnight at the point at which c Covid Status Certification requirements would come into effect. If people within this group were unable to enter settings, this would represent a loss to the potential customer base to affected businesses and sectors, and therefore a source of economic harm. The depth and duration of economic harm would depend on the speed with which people became vaccinated and eligible for certification, and the availability of alternatives to vaccine certification, such as a record of a negative test result.

⁸⁰ <u>Scottish household survey 2019: culture and heritage - report - gov.scot (www.gov.scot)</u>, Table 3.3.

 ⁷⁶ <u>Coronavirus (COVID-19) vaccine certification: evidence paper update (www.gov.scot)</u>, page 40
 ⁷⁷ Source: joint NTIA, SBPA, SHG, SLTA, UKH survey – results shared with SG in w/b 15/11; shared with Covid-19 committee in evidence pack for meeting of 18/11/21: <u>Microsoft Word - NTIA SLTA</u> Evidence .docx (parliament.scot)

 ⁷⁸ Coronavirus (COVID-19) vaccine certification: evidence paper update (www.gov.scot), page 40
 ⁷⁹ Coronavirus (COVID-19) vaccine certification: evidence paper update (www.gov.scot), pages 47-48.

Opinion polling is carried out by YouGov for the Scottish Government: conducted fortnightly with a sample of c.1000 adults 18+ across Scotland – demographically and geographically representative of the online population; fieldwork conducted mainly Tuesday/Wednesday on the dates shown with a small number of interviews on the Thursday morning.

Under the current requirement for a minimum of 2 weeks between individuals receiving their second dose of vaccine and being eligible for certification, vaccine uptake data⁸¹ suggests that:

- Around 89.1% of the overall population aged 18+ had received two doses of vaccine by 3rd January, and would therefore be eligible to access Covid Status Certification by 17th January.
- Among younger age groups, this proportion fell to 71.6% of those aged 18-29, 79.4% of those aged 30-39, and 88.7% of those aged 40-49

Should those currently unable to access Covid Status Certification be unable to access premises that require it, this could generate reductions in footfall and turnover for affected premises.

In addition, industry stakeholders have highlighted that there may be negative impacts arising from groups of customers choosing to avoid venues where Covid Status Certification is required in response to some of their members not having appropriate vaccination certification. There may also be impacts on footfall at individual venues should the process of checking Covid Status Certification add to the time taken to enter venues.

Under this option, as the percentage of the population who are vaccinated increases and plateaus, the inclusion of testing could potentially be perceived by some customers as creating more risky environments as vaccination is not incentivized. This could lead to loss in revenue through a small reduction in footfall and attendance.

Loss of revenue through cancellation of events and customer requested refunds

Live events businesses, including concerts and trade fairs open to the public, may also experience additional impacts under this option if unvaccinated customers who had bought tickets for events before the commencement of this option are subsequently unable to attend. This may generate demand for refunds or transferability of tickets leading to additional cash-flow pressures for event organisers who may not be protected in Terms and Conditions, as it was not a stated condition of entry. To date there has been no funding from Scottish Government to support any events to cover the cost of cancellations as a result of Covid Status Certification being introduced.

Customer cancellation costs may partly come from overseas visitors who have difficulties proving their vaccination status. The Verifier app for business has been developed to be able to read QR codes from the other UK nations and Crown dependencies, as well as from any individual using the EU Digital Covid Certificate scheme, which Scotland is now part of Visitors from other nations, such as USA, can provide the same proof of vaccination status that is accepted for entry into the UK. There is significant variation across the globe on what vaccine certifications/proof of vaccination look like and how they work – and not all will be acceptable if they are not to a certain standard. For domestic Covid Status Certification purposes, only MHRA-authorised vaccine are acceptable and this does not include the WHO list vaccines (including the Chinese vaccines Sinopharm and Sinovac and the Indian vaccine Covaxin). However, there is still a risk of lost business at larger events that have a significant international

⁸¹ COVID-19 Daily Dashboard | Tableau Public

audience beyond the EU. For example, Edinburgh's Hogmanay in 2019 had visitors from 58 different countries. This risk may be reduced by the ability to accept a record of a negative test.

If live events businesses are unable to ensure that their show is financially secure in advance - through guaranteed ticket sales - they may cancel events. Equally, if ticket sales are at risk, there could be a subsequent impact on the ability of event organisers to secure exhibitors, performers and sponsors – a major source of revenue – and similarly may cancel events due to a lack of viability. Cancellation of events may also arise if the direct costs of ensuring compliance, such as additional stewarding, threaten the viability of the event. Cancellation of events would impact on a number of sectors, including the tourism industry.

Events sector stakeholders have also provided anecdotal evidence of business impacts⁸². Individual events organisers have advised of larger drop-offs in actual attendance compared with ticket sales than would typically be expected. Individual events have also provided anecdotal evidence of small numbers of individuals being refused entry to specific events as a result of certification, and of refunds being requested, but with these potentially having varied by event type. There have also been examples where Covid Status Certification has been mentioned as a factor in organisation of specific events, Covid Status Certification requirements, specifically the additional queueing time, were cited as one of the reasons for Glasgow cancelling the George Square Lights 'switch on' and Christmas market⁸³.

Under this option, as the percentage of the population who are vaccinated increases and plateaus, the inclusion of testing could potentially be perceived by some customers as creating **more** risky environments as vaccination is not incentivized. This could lead to loss in revenue through a small increase in cancellation.

Wider Impacts

The Royal Mail postal services could be impacted upon. The UK Government have a contract in place with Royal Mail for the distribution of postal test kits (PCR and LFD) with agreed volumes to cover any demand that arises (up to agreed thresholds) and those contracts cover all parts of Scotland including rural areas and islands. The addition of testing for domestic Covid Status Certification purposes has had a minimal impact on the volumes handled through that contract in addition to the 2-3 million tests that we are already distributing each month by post in Scotland a) because the scope of settings covered remains relatively small; (b) the numbers of people likely to need a test because they are not vaccinated is not likely to be significant and is reducing as more people become fully vaccinated; and c. a significant number of people have already accessed tests due to the encouragement to test before they socialise and therefore will not need additional tests sent to them.

In addition, pharmacies have a similar dedicated contract in place for the distribution of LFD tests, with agreed volumes to cover any demand that arises (up to agreed thresholds) and those contracts cover all parts of Scotland including rural areas and islands. The addition of testing for domestic Covid Status Certification purposes has had a minimal impact on the volumes handled through that contract in addition to the 1 million+ tests that we are already distributing each month through pharmacies.

⁸² Coronavirus (COVID-19) vaccine certification: evidence paper update (www.gov.scot), pages 39-40.

⁸³ Coronavirus (COVID-19) vaccine certification: evidence paper update (www.gov.scot), page 40.

Benefits

The previous BRIAs and the Scottish Government's Evidence Papers⁸⁴ described a range of potential cost impacts on businesses associated with implementation and delivery of certification. These are repeated below, where relevant, for ease of reference.

Vaccine Covid Status Certification is a protection measure providing some public health benefit and would reduce the risk of infection and transmission within the current scope of settings of the virus and subsequent hospitalisations and pressure on the NHS. SAGE said that one approach to reducing the risk of non-isolated cases entering high risk settings is a COVID certification scheme - based on negative testing, vaccination, or record of a prior infection. SAGE considered with a medium confidence that a certification scheme could have medium effectiveness.⁸⁵

It would also continue to increase customers' options to socialise, providing wider social benefit while offering increased protection through vaccination and testing.

Reducing transmission benefits business as it would reduce the likelihood of implementing more onerous restrictions or closing sectors completely.

There may also be additional benefits to affected venues and businesses should this option result in a competitive advantage for settings in scope, as they would be perceived as 'less risky' environments. This may provide reassurance to previously reluctant or risk-averse customers and encourage greater attendance, with positive revenue impacts.

This is supported by evidence on public attitudes: research carried out by YouGov for the Scottish Government highlighted attitudes towards the benefits and concerns of the Covid Status Certification. The public demonstrate a high awareness of existing Covid Status Certification and are generally supportive recognising the benefits it can bring. The **overall support is 60%**, with around a fifth (20%) opposing it. Opposition to the scheme is down from polling carried out in September, October and November. (YouGov, fieldwork: 14-15 Dec). Among those likely to visit such a venue, **28% are more likely to visit a venue that requires a vaccine certificate**, whereas 22% are less likely to do so (14-15 Dec). **65% agree the scheme is a good thing if it helps prevent the return of other strict measures**, 15% disagree (14-15 Dec). 52% agree the scheme should be rolled out to other types of events / venues, with 27% disagreeing (14-15 Dec).

By widening the scheme to include testing, many of the concerns raised by the night-time sector around equalities and potential inequalities faced by those – such as international students with non-MHRA vaccines – who were previously unable to access settings subject to Covid Status Certification have been mitigated against. The potential legal challenge from customers who are refused entry is also mitigated against, given the ease of access to free

⁸⁴ The BRIA for certification regulations introduced in October 2021 is available at: <u>Coronavirus (COVID-19)</u> domestic vaccine certification: business and regulatory impact assessment - gov.scot (www.gov.scot). The Evidence Paper published in September 2021 is available at: <u>Coronavirus (COVID-19) vaccine certification: evidence paper - gov.scot (www.gov.scot)</u>. The Evidence Paper published in November 2021 is available at: <u>Coronavirus (COVID-19) vaccine certification: evidence paper - gov.scot (www.gov.scot)</u>. The Evidence Paper published in November 2021 is available at: <u>Coronavirus (COVID-19) vaccine certification: evidence paper update - gov.scot (www.gov.scot)</u>.

⁸⁵ S1216 Considerations in implementing longerterm baseline NPIs.pdf (publishing.service.gov.uk)

LFD tests across Scotland. The Equalities Impact Assessment explored these issues in fullness and can be found <u>here</u>.

Under this option, those without vaccine status including those who have been vaccinated with a non-MHRA vaccine, continue to able to gain entry to late night venues with **music**, **alcohol and dancing**, or specified indoor and outdoor live events, expanding the potential customer base and revenue opportunity.

Under the current requirement for a minimum of 2 weeks between individuals receiving their second dose of vaccine and being eligible for certification, vaccine uptake data⁸⁶ suggests that:

- Around 89.1% of the overall population aged 18+ had received two doses of vaccine by 3rd January, and would therefore be eligible to access Covid Status Certification by 17th January
- Among younger age groups, this proportion fell to 71.6% of those aged 18-29, 79.4% of those aged 30-39, and 88.7% of those aged 40-49

This suggests a substantial portion of younger demographics may have been unable to access certification, and would not be able to do so for several weeks. Business organisations representing nightclubs and late night hospitality settings have also provided consistent feedback of reduced footfall and revenues as a result of vaccine certification. Under this option, those unable to access Covid Status Certification would continue to be able to access hospitality and events settings with a record of a negative test result, which would increase the potential eligible customer base for these businesses and reduce scope for cancellations. It also potentially reduces the scope for larger groups to be discouraged from attending hospitality settings or events if individual members of their group were not able to access certification.

Increasing the potential customer base is important for the sectors covered by certification, as they have been significantly affected by the impact of the pandemic as a result of restrictions that have required long periods of closures and limits on their operating capacity⁸⁷. Some of the hospitality businesses affected by Covid Status Certification generate a substantial portion of annual turnover being generated in December⁸⁸, meaning that continued introduction of proof of a negative test result within Covid Status Certification arrangements may be of particular importance to reducing footfall and revenue losses in the coming weeks.

These measures may also provide a degree of additional reassurance to customers that others in affected venues will be fully vaccinated, or will have demonstrated that they have recently had a negative Covid test result. There may also benefits to affected venues and businesses should this option result in a competitive advantage for settings in scope, as they would be perceived as 'less risky' environments, owing to an absence of unvaccinated people. These may provide reassurance to previously reluctant or risk-averse customers and encourage greater attendance, with positive revenue impacts.

⁸⁶ COVID-19 Daily Dashboard | Tableau Public

⁸⁷ <u>Coronavirus (COVID-19) vaccine certification: evidence paper update (www.gov.scot)</u>. See pages 45-46 for an overview of pandemic impacts on the broad sectors containing hospitality and events businesses.

⁸⁸ <u>Coronavirus (COVID-19) vaccine certification: evidence paper update (www.gov.scot)</u>, page 46.

However, it may not fully offset the negative impacts on footfall in these settings that could stem from Covid Status Certification being in place. For instance, it may not address footfall lost from spontaneous decision-making if individuals have not taken a Covid test within the required timeframe. There may also be lost footfall from individuals or groups who have chosen not to take up vaccination and who choose not to take tests or share results. Individuals or groups may also continue to choose to socialize in settings where testing or Covid Status Certification is not required.

Individual businesses may also look to offer lateral flow devices to customers at point of entry, should they be unable to offer evidence of vaccination or a negative test result. This could potentially reduce losses in footfall, and reduce risks of anti-social behavior in settings. However, this practice is strongly discouraged by the Scottish Government in updated <u>Guidance</u>, which clearly states that businesses should not distribute test kits to prospective customers. The distribution of test kits must be carefully managed to meet regulatory requirements to be able to recall test kits from users in the event of a performance or safety issue with the tests. Lateral flow tests are designed to be used at room temperature, on a flat, clean, dry surface with the ability of the user to wash their hands thoroughly before use to avoid contaminating the test. Individuals should be encouraged to test before they leave home to reduce the transmission risk.

However, where individuals have received two doses, vaccine efficacy has been shown to decline over time – particularly in relation to Omicron - in terms of preventing infection and severe illness. Two doses of vaccine have also been shown to be less beneficial for individuals in terms of reducing risk of harm from the Omicron variant of Covid than having two doses and an additional booster dose. This suggests that, under this option, the public health benefit of current Covid Status Certification arrangements could potentially decrease over time.

Option 2: Retain mandatory Covid Status Certification in higher risk settings and amend the definition of fully vaccinated to include the requirement for a booster vaccination if a person's primary course of MHRA vaccine was more than 120 days ago and amend the definition of late night venue, with proof of vaccination or record of a negative test (LFD or PCR result) accepted.

<u>Costs</u>

Implementation and Operating Costs

It is anticipated that there would be limited additional costs on most businesses within scope directly associated with implementing this option, over and above those associated with continued implementation of certification more generally.

This option represents an amendment to the definition of fully vaccinated, with the technical functionality to demonstrate expiration and the addition of boosters in the app, PDF and paper certificates. The amendments also seek to clarify the definition of a late night venue, to reduce scope for uncertainty among Local Authorities and businesses affected by certification, and to reduce risks of avoidance behaviour. As a result this change is not intended to bring additional settings in scope. Any individual who is cannot provide proof of full vaccination can provide a record of negative test (LDF or PCR result).

There may be some, albert modest, compliance costs for individuals making use of paper or PDF copies of vaccine certificates, as these would need to be updated to reflect evidence of an individual's last 2 doses of vaccination (+2 weeks) and booster status (+10 days), if issued in advance of 13 December 2021. PDF's can be downloaded immediately so present a minimal risk of delayed compliance, paper certificates will need to be requested and delivered, meaning an individual could be without Covid Status Certification and temporarily unable to access premises and events within scope of the scheme. It is not anticipated that users of the NHS Scotland Covid Status app will be affected by the amendment; boosters were added to the Covid Status App for international use on 9th December and from the 13th January booster information is now also contained within the domestic QR code. Booster information will appear within around 24 hours in the international section and will become part of the domestic QR code 10 days after receiving the booster, in line with the regulatory definition of 'fully vaccinated' for domestic Covid Status Certification purposes. The alternative of a record of a negative test would minimise the risk.

There is clear guidance around how and when to take a LFD test. However, some businesses within scope have indicated that where customers do not have either proof of vaccination or record of a negative test result the business may decide to provide a test kit so that the customer can leave and take the test safely. Any costs of this would fall to that business and if businesses choose to do so, there would potentially be an ongoing cost arising from businesses purchasing additional stock on an ongoing basis.

However, this practice is still strongly discouraged by the Scottish Government in updated <u>Guidance</u> which clearly states that businesses should not distribute test kits to prospective customers. The distribution of test kits needs to be carefully managed to meet regulatory requirements to be able to recall test kits from users in the event of a performance or safety issue with the tests. Additionally, lateral flow tests are designed to be used at room temperature, on a flat, clean, dry surface with the ability of the user to wash their hands thoroughly before use to avoid contaminating the test. Individuals should be encouraged to test before they leave home to reduce the transmission risk.

Wider Impacts

It is recognised that some people will not have had the opportunity to complete their primary course or booster for various reasons e.g. a period of recent infection, they have become newly eligible etc. and that those who have completed their primary course less than 2 weeks ago and those that had their booster less than 10 days ago will therefore not be considered fully vaccinated for the purposes of certification. The offer of COVID-19 vaccination - for all doses - will remain open to those newly eligible, or those who have not yet taken up the offer of vaccination or booster. As the scheme provides for the ability to alternatively provide a record of a negative test (LFD or PCR) we anticipate that the overall impact would therefore be minimal.

Under this option, there may be a risk of economic harm through losses of footfall, or individuals being **unaware** of the change in vaccination status. The extent of economic harm would arise from the numbers of unvaccinated or insufficiently vaccinated people within the population overall to access Covid Status Certification in the period between vaccination (2 weeks) or booster (10 days) and full efficacy, to the amendment in certifications definition of fully vaccinated. If people within this group were unable to enter settings, this would represent a loss to the potential customer base to affected businesses and sectors, and therefore a source

of economic harm. There is a greater risk to loss of spontaneous footfall. However, the provision of a record of a negative test remains and would mitigate against such impacts.

Under the current requirement for a minimum of 2 weeks between individuals completing their primary course of MHRA vaccine and 10 days in between receiving their booster and being eligible for certification, vaccine uptake data⁸⁹ suggests that:

- Around 89.1% of the overall population aged 18+ had received two doses of vaccine by 3rd January, and would therefore be eligible to access Covid Status Certification by 17th January
- Among younger age groups, this proportion fell to 71.6% of those aged 18-29, 79.4% of those aged 30-39, and 88.7% of those aged 40-49
- Around 69.2% of the overall population aged 18+ had received a third or booster dose of vaccine by 7th January, and would therefore be eligible to access Covid Status Certification by 17th January
- Among younger age groups, this proportion fell to 34.7% of those aged 18-29, 47.3% of those aged 30-39, and 66.1% of those aged 40-49⁹⁰

Should those currently unable to access Covid Status Certification be unable to access premises that require it, this could generate reductions in footfall and turnover for affected premises. The depth and duration of economic harm would depend on the speed with which people became vaccinated/boosted and eligible for certification, and the availability and use made of alternatives to vaccine certification, such as a record of a negative test result obtained via lateral flow devices or PCR tests. This may present risks for settings where footfall depends on consumer spontaneity, or larger groups of consumers where some members may lack sufficient vaccination.

Under this option, as the percentage of the population who are vaccinated increases and plateaus, implementing Covid Status Certification to include testing could potentially be perceived by some customers as creating **more** risky environments as vaccination is not incentivized. This could lead to loss in revenue through a small reduction in footfall, attendance and an increase in cancellations.

As per Costs within Option 1 the Royal Mail postal services and pharmacies distributing test kits have experienced a minimal impact upon inclusion of record of a negative test in December. There is no anticipated further impact.

The amendment to the definition of late night venues covered by Covid Status Certification is intended to clarify the definition and is not intended to bring new settings in scope. However it may create additional compliance or revenue costs for individual businesses that are obliged to implement Covid Status Certification or amend business models as a result. It is acknowledged that industry organisations have raised concerns that the change in definition risks bringing premises into scope that have previously taken steps to legitimately remove themselves from Covid Status Certification requirements⁹¹.

⁹⁰ COVID-19 Daily Dashboard | Tableau Public

⁹⁰ COVID-19 Daily Dashboard | Tableau Public

⁹¹ Written correspondence from the NTIA provided to officials on 20th January suggested that without sensitive and careful drafting of proposed changes to the definition, an attempt to close the 'loophole' of concern might bring up to 1,000 non-nightclub premises into scope that had previously legitimately amended their business models to take themselves out of scope of certification requirements. The Scottish Government view is that this change will

However, it is not intended or envisaged by Scottish Government that the change of definition will expand the range of premises that potentially fall within the scope of Covid Status Certification beyond those that were within the original intent of certification. It is designed to address instances where businesses whose activities fell within the spirit of Covid Status Certification regulations, but who made use of lack of clarity in the existing definition to avoid requirements of Covid Status Certification without making alterations to their business model. It is not currently possible from official data to evidence the number of businesses, if any, that will be affected by the change in definition. However, initial engagement with Local Authority regulators indicates a very small number of additional premises overall.

This change may also have impacts on footfall for individual businesses that fall within scope of the amended definition, though these would be mitigated to some extent by the continued inclusion of the option of provision of a negative test result. It is currently unclear how many businesses may fall within this.

Benefits

This option could provide public health benefit as it would contribute to reducing the risk of infection and transmission of the virus and subsequent hospitalisations and pressure on the NHS over and above that provided by Option 1. This option would retain customers' options to socialise, providing wider social benefit while offering increased protection through vaccination, boosters and testing. SAGE said that one approach to reducing the risk of non-isolated cases entering high risk settings is a COVID certification scheme - based on negative testing, vaccination, or record of a prior infection. This option will maintain or increase the public health benefit relative to Option 1, by reflecting the increased protection offered by completion of a primary course of MHRA vaccine and booster if more than 120 days since primary course, particularly against Omicron.

SAGE said that one approach to reducing the risk of non-isolated cases entering high risk settings is a COVID certification scheme - based on negative testing, vaccination, or record of a prior infection. SAGE considered with a medium confidence that a certification scheme could have medium effectiveness.⁹²

The amendment to the definition of fully vaccinated and boosters may also provide a degree of additional reassurance to customers that others in affected venues will be fully vaccinated, or will have demonstrated that they have recently had a negative Covid test result. There may also be benefits to affected venues and businesses should this option result in a competitive advantage for settings in scope, as they would be perceived as 'less risky' environments, owing to an absence of unvaccinated or untested people. Both amendments may provide reassurance to previously reluctant or risk-averse customers and encourage greater attendance, softening impacts of restrictions.

not affect those that have taken legitimate and genuine steps to remove themselves from certification by amending their business models and practice. Businesses who are already genuinely out of scope based on the previous regulations will remain out of scope, unless they are trading after 12pm, clearly have a space where dancing is taking place and no discouragement of this is happening.

⁹² S1216 Considerations in implementing longerterm baseline NPIs.pdf (publishing.service.gov.uk)

Option selected: Option 2

As part of a package of protective measures, such as mandatory face coverings in some settings, provision of contact details in hospitality, test and protect with support for people to self-isolate and, Covid Status Certification should ensure that only fully vaccinated individuals, or those who can provide a record of a negative test within 24 hours, or people who are exempt, are present in these settings or at these events, reducing the risk of infection and severe illness leading to hospitalisation amongst attendees. SAGE have acknowledged the potential benefits of introducing a vaccine certification scheme in conjunction with a package of other NPIs to limit contact between infected and susceptible individuals, thereby minimising the risk of infections and serious disease.

Therefore, the Scottish Government considers that, based on the current state of the pandemic, the scientific evidence and balancing the direct harm of Covid (Harm 1) with the harm on wider society and the economy (Harms 2, 3 and 4), Option 2 is proportionate to protect public health.

The retention of Covid Status Certification in existing higher risk settings and amendment to the definition of fully vaccinated and inclusion of boosters, alongside the amendment in the definition of late night premises, will ensure that Covid Status Certification is providing increased protection against COVID-19 and Omicron particularly. Any further Regulatory changes would require the completion of a further Business Regulatory Impact Assessment.

Supporting implementation in line with our policy aims

For more information on the Covid Status Certificate see the Scottish Government website here.

Policy Objectives

In line with our strategic intent to 'suppress the virus to a level consistent with alleviating its harms while we recover and rebuild for a better future', the policy objectives of Covid Status Certification are to:

- Reduce the risk of transmission of Coronavirus, by ensuring that specified public spaces where transmission risks are higher are used only by those who are fully vaccinated, including a booster or have tested negative in the previous 24 hours
- Reduce the risk of serious illness and death thereby alleviating current and future pressure on the NHS, by reducing transmission in higher risk settings. Vaccination reduces (but does not entirely eliminate) the risk of being infected, the risk of serious illness and death if infected, and the risk of infecting others
- Reduce the risk of settings specified in the scheme being required to operate under more restrictive protections, or to close, by ensuring that the risk of transmission in these settings is reduced, reducing overall cases of Covid
- Increase the protection enjoyed by those using settings covered by the scheme and their contacts, by incentivising those using the settings to get vaccinated and to test regularly and self-isolate if positive

Sectoral guidance: to support effective implementation consistent with our policy aim, we have provided information to the sectors where Covid Status Certification is mandated on the

policy and regulations, and the reasonable implementation, enforcement and handling of exemptions. This guidance can be found on the Scottish Government website <u>here</u>.

Ministers have been clear that Covid Status Certification will not be a requirement for public services or other settings that many people have no option but to attend such as retail, public transport, health services and education. We recognise that some businesses, outside the regulated settings, are asking people for evidence they have been fully vaccinated as a condition of entry or as a condition of employment. We emphasised in our guidance that businesses which are not covered by the Government's scheme would need to consider carefully their obligations under all relevant law including data protection, the Equality Act and Human rights. For more information see the Equality and Human Rights Commission Guidance for Employers <u>here</u>.

Public guidance: Updated public guidance providing information on what Covid Status Certification is, the policy objectives, where it is regulated and why, and the steps to attain Covid Status Certification can be found <u>here</u>. Our Guidance will be clear about the settings in which use of Covid Status Certification is required. It will explain that the scope of the Regulations has been carefully and deliberately limited to activities where the balance of public health risk clearly outweighs other rights considerations, and is designed to respect the rights of individuals. Specific protections have been put in place to ensure the scheme operates in a lawful manner.

Ongoing stakeholder engagement: We will continue to engage with stakeholders and gather intelligence on the impact of Certification. We will create feedback loops and build this evidence into the policy.

Exceptions: There will be exceptions for premises being used for certain purposes, including communal religious worship, un-ticketed events held at an outdoor public place with no fixed entry points and certain business events that individuals are required to attend for work purposes (not including any peripheral reception or function outside the core hours of the conference).

<u>Review</u>

As the regulations have been laid under the Coronavirus Act 2020 there is a requirement to review the regulations every 21 days. The Covid Status Certification provisions will expire on 28 February 2022, as with all other Covid measures under the Health Protection (Coronavirus) (Requirements) (Scotland) Amendment Regulations 2022 and The Health Protection (Coronavirus) (Requirements) (Scotland) Amendment (No. 2) Regulations 2022. If Ministers wish to extend the measures further then additional regulations will be required.

Scottish Firms Impact Test

We have considered the impact that these regulations will have on Scottish businesses. The businesses affected by these regulations will largely be those affected by the previous

regulations on certification. This means the analysis presented in the Scottish Firms Impact Test is similar to that presented in the previous BRIA for vaccine certification⁹³.

There may be a positive impact on footfall and revenues compared to existing arrangements, though it may not fully reverse losses in footfall caused by Covid Status Certification as some consumers may alter their behaviour and favour settings where Covid Status Certification is not required. Other consumers could favour settings where Covid Status Certification is required.

• Will it have an impact on the competitiveness of Scottish companies within the UK, or elsewhere in Europe or the rest of the world?

As has been the case throughout the pandemic, policy divergence could present challenges for organisations operating across different parts of the United Kingdom as they implement different rules and regulations around Certification, and adapt their messaging which could lead to additional costs.

While some aspects of the policy are aligned, there is not a completely aligned 4 nations approach to the mandatory use of Certification.

- On 17 September, Wales announced that, from 11 October, individuals over 18 years old will have to prove they have a COVID pass, which includes testing as an alternative to vaccination, in order to attend the same settings that are in scope for Scottish Certification.⁹⁴ An extension to this scheme was announced to include theatres, cinemas and concert halls from 15 November 2021.⁹⁵
- The UK Government stated in their report 'COVID-19 Response: Autumn and Winter Plan' (14th September 2021) that a contingency 'Plan B' may be implemented that would include a vaccine certification scheme without the option to test negative or to provide a record of recovery from a previous Covid-19 infection within a predetermined time period.⁹⁶ The UK Government subsequently published a call for evidence on the proposal for mandatory COVID certification in their Plan B scenario (27th September 2021).⁹⁷ They proposed the use of certification in all nightclubs, and other venues open after 1am with alcohol, music and dancing and the same events thresholds as the Scottish Government. They are also considering the same exemptions with the addition of 'commemorative events' and 'diplomats or someone working for an international organisation'. On 19 January 2022, UKG announced that mandatory Covid-19 passes will not be needed to gain entry to large scale events and venues from 27 January.
- Northern Ireland announced on 17 November that certification entry regulations for nightclubs, bars, restaurants, cinemas and a range of other settings will come into effect on 29 November with a grace period prior to enforcement commencing from 13 December. It covers similar settings to Scotland's scheme, <u>plus</u> hospitality, cinemas, theatres, concert halls and conference centres.

⁹³ <u>Coronavirus (COVID-19) domestic vaccine certification: business and regulatory impact assessment</u> <u>- gov.scot (www.gov.scot)</u>

⁹⁴ Welsh Government (17 September 2021). Covid pass for events & nightclubs announced

⁹⁵ Strengthened measures to reduce high coronavirus cases in Wales | GOV.WALES

⁹⁶ <u>COVID-19 Response: Autumn and Winter Plan 2021 - GOV.UK (www.gov.uk)</u>

⁹⁷ <u>Proposal for mandatory COVID certification in a Plan B scenario: call for evidence - GOV.UK (www.gov.uk)</u>

- The Northern Ireland Executive has agreed to lift restrictions on the 21st & 26th January and reduced the areas Covid Passports will be legally required to nightclubs and indoor unseated events with 500+ people.
- Wales introduced a mandatory NHS Covid Pass on 11 Oct, and on 15 Nov extended the scheme to theatres, cinemas and concert halls. Nightclubs closed in Wales from 27 Dec.
- Wales introduced a mandatory NHS Covid Pass on 11 Oct, and on 15 Nov extended the scheme to theatres, cinemas and concert halls.
- Wales from 21 January Covid Pass required to attend large outdoor events; from 28 January Covid Pass required for large indoor events, nightclubs, theatres, cinemas and concert halls.

The reduced divergence between policy across the UK could create competitive advantages and disadvantages for Scottish businesses, potentially in areas close to the border between Scotland and England. Some consumers may feel more secure in an environment with more widespread measures, and therefore prefer to travel to or do business in Scotland. Others businesses, particularly with high numbers of international clients and customers, may prefer to visit business in England where the requirement for individuals to present their vaccine or testing status is less extensive than in Scotland. This may be seen as a less burdensome option. Day visiting tourists may choose to visit England rather than Scotland for the same reasons. However, Covid passes have been in operation in other countries for some time and operated across wider settings so a limited Covid Status Certification scheme may not deter prospective visitors to Scotland who may be familiar with similar schemes. It is uncertain at present whether consumer behaviour will lead to wider use of Covid Status Certification in Scotland becoming a net advantage or disadvantage for Scottish business.

A reinsurance scheme for events has recently been introduced by the UK Government.⁹⁸ However, it is unlikely that those events covered by Covid Status Certification in Scotland will be eligible for insurance to cover costs of implementation, as the insurance policy has to be in place before the measure affecting operation of the event is announced. This could put Scottish event organisers at a disadvantage compared to businesses in England if a scheme is introduced at a later date there.

Events Industry in the UK

As the requirement for Covid Status Certification applies to unseated indoor events of 500 or more people, customers may choose to attend unseated outdoor events where there is no requirement for Covid Status Certification measures until 4,000 people are planned to attend, which may give some venues a competitive advantage. However, due to the climate and weather in Scotland, it is worth noting that it is not viable for events to take place outside for large parts of the year and would likely have little impact over the autumn and winter months. Any event with 10,000 or more people falls within Covid Status Certification scope.

With additional costs incurred through Certification, larger events could well struggle to break even and might therefore lose out in comparison to smaller venues who can continue to host unseated events under 500 attendees.

⁹⁸ Live Events Reinsurance Scheme - GOV.UK (www.gov.uk)

• How many businesses and what sectors is it likely to impact on?

As the settings affected by Covid Status Certification will not been altered by these regulations, businesses affected will lie within the Event Sector, Nightclubs and Late Night Settings, and Sports Venues.

There is emerging data on shares of businesses that may make use of Covid Status Certification within these sectors. Recent data from the Business Insights and Conditions Survey suggest that for the period $15^{th} - 28^{th}$ November 2021, 15% of businesses in the Arts, Entertainment and Recreation sector and 19% of businesses within the Accommodation and Food Services sector were using, or intending to use, customer Covid-19 checks. These include vaccine certification. Within the Accommodation & Food Services sector, 28% of businesses in the Accommodation sector and 15% of businesses in Food and Beverage Services sector were using, or intending to use, customer Covid-19 checks sector were using, or intending to use, customer Covid-19 checks sector were using, or intending to use, customer Covid-19 checks sector were using, or intending to use, customer Covid-19 checks⁹⁹.

Event Sector

Direct and indirect impacts on the Events Industry arising from Covid Status Certification would accrue to venue operators, but also potentially on event organisers, performers, support businesses and ancillary businesses, operating across a range of event types, depending on audience numbers. It is not currently possible to indicate the full range of individual events that would be impacted by the regulations, or the associated number of wider businesses affected. The following data therefore presents a summary of data on businesses associated with staging and supporting of events in Scotland overall.

It is estimated, based on the Inter-Departmental Business Register 2021 and 2020 Business Register and Employment Survey, that there are 3,725 Events Industry businesses in Scotland. Event catering businesses, performing arts, activities of sports clubs and activities of exhibition and fair organisers are such businesses in Scotland that fall under this classification.¹⁰⁰ These businesses operate across 4,560 sites (as some businesses may have more than one site) and are estimated to employ around 42,250 people (2% of Scotland's jobs in 2020). It is unclear what proportion of these businesses will be affected by the introduction of Covid Status Certification as detailed data is unavailable on the scale of services/business revenue generated from the settings within scope. We currently have no specific data on supply chains for these businesses.

⁹⁹ <u>BICS weighted Scotland estimates: data to wave 44 - gov.scot (www.gov.scot)</u>. Estimates are based on businesses that have not permanently stopped trading, with more than 10 employees, and a presence in Scotland.

¹⁰⁰ Events Industry defined here using the following SIC2007 codes:

^{5621 :} Event catering activities

^{9001 :} Performing arts

^{9002 :} Support activities to performing arts

^{9004 :} Operation of arts facilities

^{9311 :} Operation of sports facilities

^{9312 :} Activities of sport clubs

^{68202 :} Letting and operating of conference and exhibition centres

^{74209 :} Other photographic activities (not including portrait and other specialist photography and film processing)

^{79909 :} Other reservation service activities (not including activities of tourist guides)

^{82301 :} Activities of exhibition and fair organizers

^{82302 :} Activities of conference organizers

^{93199 :} Other sports activities (not including activities of racehorse owners)

It is likely that most of these are based in cities and larger towns although it is not possible to obtain detailed data at this time.

Small businesses are the majority of the sector. Figures from the Inter Departmental Business Register indicate that in 2021, 97% of businesses in the Events Sector had fewer than 50 employees, 2% had between 50 and 249 employees and 1% had more than 250 employees.

The Business Register and Employment Survey 2020 indicates that, overall, more than half (54%) of employees in the sector work part-time.

Approximately 15,100 (25.6%) of workers in the events industry were self-employed. This is a higher proportion than for the workforce as a whole (11.6%). The proportion of women working in the events industry is higher than the proportion in the overall workforce – 55.4% and 49.2% respectively. However, for Events Catering Activities, women make up 59.6% of the workforce and for Other Reservation Service and Related Activities they make up 71.8%¹⁰¹ of the workforce¹⁰².

<u>Sports</u>

For the sports sector, Covid Status Certification will continue impact on Scottish Rugby home internationals, Scottish Football home internationals, and the home fixtures for all of Rangers, Celtic, Aberdeen, Hearts and Hibernian. The two Dundee clubs may occasionally be affected too. However, for domestic games, one of the Glasgow and Edinburgh clubs will have a home fixture each week and there will be additional domestic and European cup matches where Covid Status Certification is required.

Late night venues with music, alcohol and dancing

It is estimated, based on the Inter-Departmental Business Register 2021 and 2020 Business Register and Employment Survey, that there are 130 businesses under the heading non-charity licensed clubs. Nightclubs and sexual entertainment¹⁰³ businesses in Scotland fall under this classification. These businesses operate across 150 sites (as some businesses may have more than one site) and are estimated to employ around 1,500 people. Over half (56%) of employees working in the sector work part time. It is not possible to separate out sexual entertainment venues from this, though it is understood less than 20 operate in Scotland as of 2015. The vast majority of nightclub and sexual entertainment businesses are small (employing less than 50 people). We currently have no specific data on supply chains for these businesses. It is likely that most of these are based in cities and larger towns although it is not possible to obtain detailed data at this time.

¹⁰¹ Estimate based on a small sample size. This may result in a less precise estimate which should be used with caution.

¹⁰² Source: Annual Population Survey, Jan-Dec 2020, ONS

¹⁰³ As per previous work for Nightclub related BRIAs (e.g. p54-71: The Health Protection (Coronavirus) (Restrictions and Requirements) (Local Levels) (Scotland) Regulations 2020 (legislation.gov.uk) – Nightclub businesses are defined here as non-charity licensed clubs (within Standard Industrial Classification code 56.301). Nightclubs and sexual entertainment businesses in Scotland fall under this classification. The SIC code definition of nightclubs used here does not align perfectly with the definition of nightclubs used in certification regulations. These statistics therefore represent a best estimate.

- Based on the Inter-Departmental Business Register 2021, it is estimated that there are 130 nightclub Businesses in Scotland. These businesses operate across 150 Sites (as some businesses may have more than one site).
- Based on the Business Register and Employment Survey (BRES) 2020, it is estimated that nightclub businesses provide 1,500 Jobs across Scotland.

Late Night Venues – Hybrid Venues

There are potentially premises that might be classed as pubs or restaurants in official statistics that could fall within scope of the Regulations.

Stakeholder estimates suggest that there may be around 300-400 premises across Scotland that operate as 'hybrid' venues (e.g. as pubs or restaurants during the day, and late night venues with music, alcohol and dancing at night). Stakeholders have also suggested there may potentially be up to 1,500 premises that may operate with some of the late night venues with music, alcohol and dancing characteristics (e.g. late opening, dancefloors, loud music).¹⁰⁴ However, it is not currently clear the extent to which all or some of these premises would fall within scope of the Regulations, or the extent to which these may have amended their commercial offer to remove themselves from the scope of Covid Status ertification since October 2021.

• What is the likely cost or benefit to business?

There may be costs to businesses that fall within scope of late night venues with music, alcohol and dancing, and businesses involved in staging live events of sufficient size to fall within scope of the regulations. These include both direct costs associated with compliance with the revised Regulations (additional to those associated with compliance with the existing regulations). The analysis below sets out potential changes as compared to previous Covid Status Certification arrangements, which are described in the previous BRIA¹⁰⁵.

Additional direct costs could arise in the form of affected businesses obtaining stocks of lateral flow devices to provide to customers at point of entrance, should those customers not have proof of vaccination or record of a negative test result in their possession. The extent to which individual businesses may choose to adopt this, and the costs it would involve for individual businesses, are unclear. They would also likely vary across individual businesses and settings. However, this may be adopted by businesses within late night settings and by events venues.

There may continue to be costs associated with lost footfall and revenues from those deterred from entry because of longer wait times or Covid Status Certification requirements in general, with footfall potentially displaced to venues or settings not covered by the Regulations. However, the potential for footfall losses is judged to be lower than circumstances where Covid Status Certification continued without the option of providing a record of a negative test result, as it expands the potential customer base for affected venues; impacts may also be offset to a degree by the additional reassurance to potential customers that other customers within venues will have been fully vaccinated or will have provided evidence of negative test results.

 ¹⁰⁴ Night Time Industries Association (2021), Covid Status Certification: NTIA Scotland Briefing Paper
 ¹⁰⁵ Coronavirus (COVID-19) domestic vaccine certification: business and regulatory impact assessment
 <u>- gov.scot (www.gov.scot)</u>

There may also benefits to affected venues and businesses should this option result in a competitive advantage for settings in scope, as they would be perceived as 'less risky' environments, owing to an absence of unvaccinated people. This may provide reassurance to previously reluctant or risk-averse customers and encourage greater attendance, with positive revenue impacts.

Competition Assessment

• Will the measure directly or indirectly limit the number or range of suppliers?

Unclear. Covid Status Certification overall will potentially discourage some consumers' from attending late night venues with alcohol, dancing and music and live large scale events, and potential displacement to less regulated alternative venues and settings. This may place increased pressure on businesses involved in these activities through reduced footfall and turnover, with consequent pressures on business viability. This pressure may encourage business exit if sufficiently severe and long-lasting. However, inclusion of testing results within Covid Status Certification means this outcome would primarily be influenced by consumers' attitudes towards vaccination and testing, rather than restrictions resulting from certification.

• Will the measure limit the ability of suppliers to compete?

Unclear. The measure primarily impacts on consumers' ability to access venues and live events. However, there may be potential for displacement of unvaccinated consumers to other, less regulated settings. Similarly the displacement of vaccinated customers towards venues operating with Covid Status Certification could occur.

• Will the measure limit suppliers' incentives to compete vigorously?

No. Measure will potentially restrict some consumers' ability to attend late night venues with alcohol, dancing and music and live large scale events, with potential for displacement to other less regulated settings (e.g. pubs) or greater competition for events providers and venues from other geographies. This may strengthen suppliers' incentives to compete across different markets.

• Will the measure limit the choices and information available to consumers?

Yes. Consumer choice of evening and live entertainment among those unwilling to either take up vaccination or provide a record of a negative test results may be reduced in terms of attending late night venues with alcohol, dancing and music and some live events. However, this would be as a consequence of those consumers' decisions around vaccination take-up and testing.

Consumer Assessment

• Does the policy affect the quality, availability or price of any goods or services in a market?

No. The quality of goods and services available to consumers is unlikely to be impacted by the introduction of these regulations. However, the nature of services in different sectors will change as Covid Status Certification is mandatory in some settings and not others.

• Does the policy affect the essential services market, such as energy or water?

No. There is no expected impact on markets for essential services.

• Does the policy involve storage or increased use of consumer data?

Yes. When the original Covid Status Certification was introduced on 1 October there was an interim solution which included increased use of consumer data. On 30 September we launched the <u>NHS Scotland Covid Status App</u> (the "App") for international use. This contained two unique QR codes, one for each dose of the vaccine. This product had been designed for use for international travel and so it is necessary to include full name, date of birth and details of vaccination to meet EU standards. This version of the App was used to demonstrate vaccine status in the settings in scope.

On 20 October, the NHS Scotland Covid Check App, which is used by venues to check QR codes, was updated so that when an international QR code is scanned for domestic purposes only, a green tick or 'certificate not valid' representing someone's vaccination status is displayed, rather than a person's name, date of birth and vaccination details.

In order to further minimise data display, on 21 October, the Covid Status App was updated to include a domestic page. This option simply shows the person's name and a QR code. When the QR code is scanned by the NHS Scotland Covid Check App it shows either a green tick or 'certificate is not valid' representing someone's vaccination status. The domestic App has functionality to hide or display a person's name. The Privacy Notice can be found on NHS Inform: Personal information we process, How we use your data, Your Rights.

Demonstration of a negative LFD or PCR result as reported to the public reporting system will be through the presentation of an original text message or email or a printed text or email.

An update to the NHS Scotland Covid App allowed the added function to register and present record of a negative PCR test in December, with the inclusion of LFD tests to follow in a further iteration.

Similarly, if someone is exempt, the interim solution (an exemption certificate) will state that fact and can be seen by the verifier. It is important to note that the personal data of individuals whose vaccination status is being verified is never stored or transmitted by the NHS Scotland COVID Check App. Once verification is complete, the personal data is deleted.

• Does the policy increase opportunities for unscrupulous suppliers to target consumers?

Unclear. There is a possibility that businesses that are outwith the settings outlined by the policy will adopt Certification. There is also a possibility that even those businesses that are in scope will adopt it for a definition of 'consumer' broader than what is intended (i.e. more than just attendees, for example performers or staff).

The Regulations will mitigate these risks to an extent, as they will clearly define the settings where there will be a legal requirement for businesses to take all reasonable measures to

check vaccination, testing and exemption status. Equally, the Regulations will be clear that that legal requirement will not apply to employees or any person other than the attendees or 'consumers' of the service.

The risks will be further mitigated with sectoral guidance. To support effective implementation consistent with our policy aims, we will provide more information to the sectors where an amendment of Covid Status Certification is mandated about the appropriate implementation, enforcement and handling of exemptions.

Ministers have been clear that Covid Status Certification will not be a requirement for public services or other settings that many people have no option but to attend such as retail, public transport, health services and education. We recognise that some businesses, outside the settings in scope, are asking people for evidence they have been fully vaccinated as a condition of entry or as a condition of employment. Businesses which are not covered by the Government's scheme are required to meet their obligations under all relevant law including data protection, the Equality Act and Human rights in their design and implementation of any such policy. For more information see the Equality and Human Rights Commission Guidance for Employers <u>here</u>.

• Does the policy impact the information available to consumers on either goods or services, or their rights in relation to these?

Yes. Consumers (i.e. attendees of the venues and events in scope) will have information about their rights regarding their personal data. A Privacy Notice has been produced and can be found on <u>NHS Inform</u>. A Data Protection Impact Assessment (DPIA) has been developed and will be published soon.

The Scottish Government has undertaken significant media relations and social media activity through Scottish Government accounts to increase awareness among the public of Certification. This has been supported by paid for advertising activity during September and October that had a reach of 3.32 million adults through radio and digital advertising. Also, information on domestic Covid Status Certification has been added to nhsinform.scot. Promotional materials were distributed to key stakeholders to be used by those businesses and locations where Covid Status Certification is required, these materials have been updated (when needed) in line with changes to the scheme.

• Does the policy affect routes for consumers to seek advice or raise complaints on consumer issues?

No - There is no expected impact on the routes for consumers to seek advice or raise complaints on consumer issues.

Test run of business forms

No statutory forms will be created.

Digital Impact Test

• Does the measure take account of changing digital technologies and markets?

Yes. How we aim to deliver Covid Status Certification takes into account that most businesses and customers use technology and prefer digital solutions that make processes easier. In advance of the launch of the scheme research into public attitudes carried out by YouGov for the Scottish Government, on 24-25 August 2021, (n=1,006 people in Scotland) highlighted attitudes towards the benefits and concerns of a Covid Status certification. Over half of respondents (55%) would download and use a mobile app to prove either vaccination or show a record of a negative test result, with just over one in five (23%) saying they would not use such an app. ¹⁰⁶

The public demonstrate a high awareness of the existing scheme and are generally supportive recognising the benefits it can bring. The overall support is 60%, with around a fifth (20%) opposing it. Opposition to the scheme is down from polling carried out in September, October and November. (YouGov, fieldwork: 14-15 Dec). Among those likely to visit such a venue, 28% are more likely to visit a venue that requires a vaccine certificate, whereas 22% are less likely to do so (14-15 Dec). 65% agree the scheme is a good thing if it helps prevent the return of other strict measures, 15% disagree (14-15 Dec). 52% agree the scheme should be rolled out to other types of events / venues, with 27% disagreeing (14-15 Dec)¹⁰⁷.

Consequently, without losing sight of the paper-based alternatives, we continue to actively promote the use of the digital package (the NHS Scotland Covid Status App and the NHS Scotland Covid Check App) as the most efficient method to operationalise Certification. The latest PHS report¹⁰⁸, published on Wednesday 19 January, showed that the Covid Status App has been downloaded over 2.4 million times up to midnight on 15 January (It is important to note a single user may choose to download the App on multiple devices, so this figure does not represent unique individuals.) and we continue to monitor user activity. Up to midnight on 15 January, more than 1.7 million PDFs have been downloaded since QR codes were introduced on 3 Sept, with over 715,000 printed versions issued.

We continue to monitor user activity¹⁰⁹. In the longer term, we see the NHS Scotland Covid Status App as both an opportunity and a stepping stone that will enable greater digital access to medical data more broadly for Scottish residents.

For those who do not have digital access or would prefer a paper copy, a record of vaccination can still be requested by phoning the Covid-19 Status Helpline on 0808 196 8565. The paper record of vaccination will then be posted to the address that is held on the National Vaccination Service System (NVSS).

• Will the measure be applicable in a digital/online context?

¹⁰⁶ Scottish Government (2021). Coronavirus Fortnightly Tracker Weeks 66-79 – Data Tables from 29 June to 23 September 2021 (Question SG_302_rb_2 on 24-26 August). These figures exclude those who answered: 'Not applicable - would never visit such a venue/attend such an event anyway (20%)'.
¹⁰⁷ Results are taken from questions run on behalf of Scottish Government on the YouGov online omnibus survey. The sample is demographically and geographically representative of adults 18+ across Scotland, with c.1000 responses each week fieldwork is conducted. <u>Public attitudes to coronavirus: tracker - data tables - gov.scot (www.gov.scot)</u>

¹⁰⁸ <u>COVID-19 & Winter Statistical Report (publichealthscotland.scot)</u> page 33.

¹⁰⁹ Public Health Scotland COVID-19 Statistical Report, page 38

No. Although Covid Status Certification will be delivered mainly through digital means, it can only apply in physical settings where there is a risk of transmission of the virus. Therefore, the policy will not apply in a digital context.

• Is there a possibility the measures could be circumvented by digital/online transactions?

No. We do not envisage the policy being circumvented by digital transactions – large events on streaming or any experience of a late night venues with music, alcohol and dancing other than in-person are unlikely to be regarded as comparable substitutes. Therefore, there is no possibility to circumvent the policy digitally.

• Alternatively, will the measure <u>only</u> be applicable in a digital context and therefore may have an adverse impact on traditional or offline businesses?

No. The policy will not be applicable at all in a digital context, so it will not have an adverse impact on traditional business. One of the aims of the policy is to reduce the risk of settings in specified being required to operate under more restrictive protections or closure, therefore, the policy is designed to help, rather than adversely impact, offline businesses.

• If the measure can be applied in an offline <u>and</u> online environment will this in itself have any adverse impact on incumbent operators?

No. As explained, the policy will not be applied in an online environment. Therefore, we do not envisage any adverse impact on incumbent operators of nightclubs or large events.

Legal Aid Impact Test

The policy does not in itself create any new legal rights.

The Regulations include enforcement measures which could in some cases lead to prosecution. These are linked to existing mechanisms within the *Health Protection Coronavirus (Requirements) (Scotland) Regulations 2021.* The intention is not to criminalise individuals in the sense of attendees at the premises and events at which Covid Status Certification is required and at present it is envisaged the policy will have minimal to no impact on Legal Aid.

Enforcement, sanctions and monitoring

The Regulations will set out that not putting in place a reasonable system to restrict entry only to those fully vaccinated or providing a record of a negative LFD test (unless exempt), and the failure to prepare and maintain a compliance plan for the system and other measures to minimise the risk of coronavirus transmission, will be an offence for a person responsible for the premises. Local Authority regulators, like Environmental Health Officers (EHOs) and Trading Standards Officers, are responsible for enforcing the requirements of businesses. We have ensured in the Regulations that Local Authority (LA) officers have the powers that they need to enforce this scheme in a proportionate and risk-based manner.

Businesses which meet the criteria for Covid Status Certification as set out in the Regulations will be required to develop a plan that Local Authority regulators can request to see. In term of compliance monitoring and enforcement, this will be 'front loaded' through pre-event planning and LA officers inspecting plans for venues during the regular working hours in first instance.

For larger events, and more high profile, high risk games, there are likely to be LA officers on site during the event. Intelligence received from Police Scotland and/or complaints by customers/ other traders will be investigated post-event where resourcing permits on a risk/triage basis. A summary of expected activity is as follows:

Pre-event/ night engagement

• SG will share communications that Local Authorities can send out via email to venues and any business as usual direct engagement. The targeted audience for that communication will reflect the premises included and activities affected.

On the day

- Large events/large football games e.g. national team will usually justify Local Authority officer 'boots on ground', while other premises would be on a targeted basis, determined through their risk based approach, engagement with Police Scotland and resourcing by the Local Authority in question.
- At night/weekends some Local Authorities may have Local Authority officers on the ground on some weekends or nights but not routinely. Compliance checks would be planned on a targeted intelligence gathering basis, informed by repeated complaints on a venue.

Post event

- Local Authorities would investigate concerns reported and consider intelligence gathered and take action as necessary taking a 4 E's approach (engage, explain, encourage, enforce).
- Enforcement requires corroborated evidence to initiate formal action, which will be supported by targeted compliance checks based on intelligence.

Police Scotland may have a role, should there be any public disorder or serious criminal offences such as fraud associated with Certification. Effective stewarding and policing activity routinely operates to mitigate disorder and discourages fraudulent activity and the additional costs of Covid Status Certification are not expected to be significant. Any costs can be absorbed as part of Police Scotland's role in respect of live events and other settings in scope.

Implementation, delivery plan and post-implementation review

The Scottish Government is responsible for monitoring and evaluation of the policy. As the regulations have been laid under the Coronavirus Act 2020 there is a requirement to review the regulations every 21 days. The extent to which the policy (Covid Status Certification) is achieving the policy objectives (of reducing the risk of transmission, reducing the risk of serious illness and death thereby alleviating current and future pressure on the NHS, reducing the risk of settings specified in the scheme being required to operate under more restrictive protections, or to close; and increase the protection enjoyed by those using settings covered by the scheme and their contacts) is being monitored in line with this requirement. Monitoring and evaluation will also provide us with further information about other positive and negative effects of the continuation and amendment of the policy. We will also continue to assess whether any less intrusive measures could be introduced to achieve the same combination of policy objectives in respect of the higher risk sectors concerned; if so, the policy will be immediately reviewed.

The Covid Status Certification provisions will expire on 28 February 2022, as with all other Covid measures under the *Health Protection (Coronavirus) (Requirements) (Scotland) Regulations 2021*. Parliamentary approval would be required to extend them further.

Summary and recommendations

The Scottish Government's Strategic Framework includes a package of measures which, taken together, are designed to suppress transmission of the virus. Although daily Covid case numbers are dropping in Scotland, case numbers remain too high, and we still have a large susceptible population which could lead to cases rising again.

This BRIA has set out the relative costs and benefits of an amended Covid Status Certification option, compared against the Covid Status Certification currently in place; both of which have the intended effect of reducing the risk of transmission, reducing the risk of serious illness and death thereby alleviating current and future pressure on the NHS, reducing the risk of settings specified in the scheme being required to operate under more restrictive protections, or to close; and increase the protection enjoyed by those using settings covered by the scheme and their contacts. Our assessment of the options has been informed as much as possible by engagement with the sectors in scope.

A summary of costs and benefits associated with the options is presented below in Table 4:

Measure	Benefits	Costs
Measure Option 1: Retain mandatory Covid Status Certification in higher risk settings, with proof of vaccination <i>or</i> record of a negative test (LFD or PCR result) accepted (current policy).	Sectors in scope continue to be characterised by many of the high risk factors associated with transmission of the virus. Covid Status Certification is an additional means through which we can continue to reduce the risk of transmission. As such, it will mitigate the risk of closure and more restrictive measures, and consequent negative economic impact. This option would result in some public health benefit	These include both direct costs of compliance with the regulations (staffing and infrastructure); local government monitoring and enforcement costs; potential losses of footfall and revenue arising from reduction of customer base for affected venues, particularly among younger demographics; cashflow impacts of requirements to provide refunds for ticketed events; business impact from cancellation or reduced scale of events.
	and would reduce the risk	However, where individuals
	of infection and transmission of the virus and subsequent	have received two doses, vaccine efficacy has been shown to decline over time – particularly in relation to

	hospitalisations and pressure on the NHS.	Omicron - in terms of preventing infection and severe illness. Two doses of vaccine have also been shown to be less beneficial for individuals in terms of reducing risk of harm from the Omicron variant of Covid than having two doses and an additional booster dose. This suggests that, under this option, the public health benefit of current Covid Status Certification arrangements could potentially decrease over time.
Option 2: Retain mandatory Covid Status Certification in higher risk settings and amend the definition of fully vaccinated to include the requirement for a booster vaccination if a person's primary course of MHRA vaccine was more than 120 days ago and amend the definition of late night venue, with proof of vaccination <i>or</i> record of a negative test (LFD or PCR result) accepted.	This option will maintain or increase the public health benefit relative to Option 1, by reflecting the increased protection offered by completion of a primary course of MHRA vaccine and booster if more than 120 days since primary course, particularly against Omicron. It would reduce the risk of infection and transmission of the virus and subsequent hospitalisations and pressure on the NHS, maintain customers options to socialise, providing wider social benefit while offering them increased protection through vaccination and testing.	It is anticipated that there would be limited additional costs on most businesses within scope directly associated with implementing this option, over and above those associated with continued implementation of Covid Status Certification more generally. This option represents an amendment in the definition of fully vaccinated, with the technical functionality to demonstrate expiration and the addition of boosters in the app, PDF and paper certificates. The amendments also seek to clarify the definition of a late night venue, to reduce scope for uncertainty among Local Authorities and businesses affected by certification. There is a risk with this option that those customers who have not completed

	their primary course of MHRA vaccination or had the required booster - if over 120 days - <i>and</i> those that are not yet eligible for certification, due to having their primary completion dose of vaccine or booster within 2 weeks and 10 days respectively, could lead to loss in footfall for businesses.
	Similarly, those customers opting to use paper or PDF versions of certificates may need to request a new paper version or download a new PDF if dated in advance of 13 th December 2021, this again could lead to loss of footfall.
	that confusion amongst customers could lead to a loss of footfall as updated proof of vaccination and boosters may not have been acquired.

Table 1. Summary table.

We conclude that Option 2 – the retention of mandatory Covid Status Certification in higher risk settings (current policy) and amendment of the definition of fully vaccinated to include the requirement for a booster vaccination if a person's primary course of MHRA vaccine was more than 120 days ago and amendment to the definition of late night venue is a necessary and proportionate response which, alongside an effective baseline of public health protections, will best meet our policy objectives. Continued monitoring and evaluation will inform implementation as well as regular review (at least once every 21 days) of the Regulations to determine whether any less intrusive alternative measures could be introduced to achieve the same combination of policy objectives in respect of the higher risk sectors concerned.

Declaration and publication

Sign-off for BRIA:

I have read the Business and Regulatory Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the measures set out in the regulations and guidance. I am satisfied that business impact has been assessed with the support of businesses in Scotland.

Signed: John Swinney

Date: 24/01/2022

Minister's name: John Swinney MSP Minister's title: Deputy First Minister and Cabinet Secretary for Covid-19 Recovery

Annex A Stakeholders and sectors engaged

Business Organisations including Scottish Chamber of Commerce and Federation of **Small Businesses** Hospitality, including Scottish Wedding Industry Alliance Tourism Events, including the Events Industry Advisory Group and wider, individual enterprises and industry members. Performing arts / arts venues Higher education Disability organisations Police Trade Unions, including the STUC Night time economy Local Government (Environmental Health Officers) Sporting organisations (Football, Rugby, Horse Racing) Music Industry Legal specialists Agriculture Rural Cinema. Theatre Music Museums Leisure