

EXPLANATORY MEMORANDUM TO

THE HEALTH PROTECTION (CORONAVIRUS, RESTRICTIONS) (SELF-ISOLATION) (ENGLAND) (AMENDMENT) (NO. 5) REGULATIONS 2021

2021 No. 1382

1. Introduction

- 1.1 This explanatory memorandum has been prepared by the Department of Health and Social Care ('DHSC') and is laid before Parliament by Command of Her Majesty.
- 1.2 This memorandum contains information for the Joint Committee on Statutory Instruments.

2. Purpose of the instrument

- 2.1 This instrument makes provision to align exemptions in the Health Protection (Coronavirus, Restrictions) (Self- Isolation) (England) Regulations 2020 (the "Self-Isolation Regulations") with equivalent provisions in The Health Protection (Coronavirus, International Travel and Operator Liability) (England) Regulations 2021 (the "International Travel Regulations"), specifically in relation to treatment of individuals who are fully vaccinated.
- 2.2 The amendments expand the exemptions to self-isolation following close contact with a positive case to those who are fully vaccinated with a vaccine recognised for the purposes of the International Travel Regulations. The International Travel Regulations recognise vaccines administered overseas which are regulated by the European Medicines Agency, Swissmedic, United States Food and Drug Administration, the Therapeutic Goods Administration in Australia and Health Canada, or which are listed on the World Health Organization (WHO) emergency use list.
- 2.3 The amendments also expand the exemption from self-isolation to close contacts who are taking part or have taken part in clinical trials regulated by a WHO-approved stringent regulatory authority, in alignment with the International Travel Regulations. They update the Self-Isolation Regulations to include more detail around the evidence required for a contact of a positive case to demonstrate that they are medically unable to be vaccinated and therefore exempt from self-isolation.
- 2.4 The expanded criteria do not currently apply to individuals who have been notified that they are close contacts of a suspected or confirmed case of the Omicron variant.

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

- 3.1 This instrument is made under the emergency procedure set out in section 45R of the Public Health (Control of Disease) Act 1984 (c.22) ("the 1984 Act"). This instrument is made without a draft having been laid and approved by a resolution of each House of Parliament. It is the opinion of the Secretary of State that, by reason of urgency, it is necessary to make this instrument without a draft being so laid and approved.
- 3.2 The instrument was made on 8 December 2021, laid on 8 December 2021 and published on www.legislation.gov.uk later that day. The regulations cease to have effect at the end of the period of 28 days beginning with the day on which the

instrument is made unless, during that period, the instrument is approved by a resolution of each House of Parliament.

- 3.3 This instrument (with the exception of regulation 2(3)(a)(iii)) comes into force on 9 December 2021. Regulation 2(3)(a)(iii) will come into force on 18 January 2022. The Self-Isolation Regulations which this instrument amends will expire at the end of 24 March 2022.

4. Extent and Territorial Application

- 4.1 The territorial extent of this instrument is England and Wales.
4.2 The territorial application of this instrument is England.

5. European Convention on Human Rights

- 5.1 The Secretary of State for Health and Social Care, Sajid Javid MP, has made the following statement regarding Human Rights:

“In my view the provisions of the Health Protection (Coronavirus, Restrictions) (Self-Isolation) (England) (Amendment) (No. 5) Regulations 2021 are compatible with the Convention rights.”

6. Legislative Context

Background

- 6.1 The 1984 Act, and regulations made under it, provide a legislative framework for health protection in England and Wales.
- 6.2 Part 2A of the 1984 Act, as inserted by the Health and Social Care Act 2008, provides a legal basis to protect the public from threats arising from infectious diseases, or contamination from chemicals or radiation. Part 2A includes powers to impose restrictions or requirements on people, and in relation to things and premises. Overall, the amended 1984 Act sets out a framework for health protections which requires much of the detailed provisions to be delivered through regulations.
- 6.3 Section 45C of the 1984 Act provides a power for the appropriate Minister to make regulations to prevent, protect against, control or provide a public health response to the incidence or spread of infection or contamination in England and Wales. The threat of infection or contamination can come from outside England and Wales.
- 6.4 A number of regulations under section 45C of the 1984 Act have been made, including regulations relating to severe acute respiratory syndrome Coronavirus 2 (SARSCoV-2) (“COVID-19”).
- 6.5 In particular, The Health Protection (Coronavirus, Restrictions) (Self-Isolation) (England) Regulations 2020 imposed requirements on people who are notified of a legal obligation to self-isolate. This plays a key role in slowing or preventing a rise in the rate of reproduction (R) of COVID-19. The instrument required persons who have been notified, other than through the NHS COVID-19 app, that they have tested positive for coronavirus or have been identified as a close contact of someone who has tested positive, to self-isolate for a specified period.
- 6.6 The Health Protection (Coronavirus, Restrictions) (Self-Isolation) (England) (Amendment) Regulations 2021, which came into force on 19 July 2021, made

amendments to the legal duty to self-isolate. The following amendments to the Self-Isolation Regulations were included:

- From 19 July 2021, a person can leave self-isolation to post an antibody test.
- From 16 August 2021, a person is not required to self-isolate if they are notified that they have been in close contact with a person who has tested positive, if the person:
 - has completed a course of an authorised vaccine administered in the UK; or,
 - has participated or is participating in an authorised clinical trial of a coronavirus vaccine; or,
 - can evidence that they are unable to be vaccinated for clinical reasons.
- An approved vaccination was defined under Regulation 2(8). “Completing a course” means that the person is more than 14 days post-completion of their vaccine course as at the date they had close contact.
- A removal of the duty on a child under the age of 18 to self-isolate where they are notified that they have been in close contact with a person who has tested positive.

6.7 The Health Protection (Coronavirus, Restrictions) (Self-Isolation) (England) (No. 3) Regulations 2021, which came into force on 27 September 2021 extended the Self-Isolation Regulations until 24 March 2022, and made the following amendments:

- clarified when a household contact will be exempt from self-isolation due to being fully vaccinated;
- extended the exemption from the duty to self-isolate for fully vaccinated persons to those who have received doses of two different Medicines and Healthcare Products Regulatory Agency (MHRA) authorised vaccines in the UK; and,
- clarified the requirements on those taking part in a testing scheme, in a situation where they test positive with a lateral flow test, but receive a subsequent negative confirmatory PCR test result.

6.8 The Health Protection (Coronavirus, Restrictions) (Self-Isolation) (England) (Amendment) (No.4) Regulations 2021, which came into force on 30 November 2021, included the following amendments in response to the emergence of the Omicron variant:

- To make specific provision in relation to self-isolation where a relevant person notifies an individual that they are a close contact of a case suspected or confirmed as having the Omicron (B.1.1.529) variant of COVID-19;
- In the case of a person being notified that they are a close contact of a suspected or confirmed case of the Omicron variant, the existing provisions exempting close contacts from self-isolation providing they have completed a full course of an authorised vaccine, have participated in a clinical vaccine trial, are medically unable to be vaccinated or are under the age of 18, do not apply;
- The affected individuals cannot benefit from the exemption from the requirement to self-isolate which otherwise applies to participants in an approved daily contact testing scheme.

- 6.9 In accordance with section 45R of the 1984 Act, the Secretary of State is of the opinion that, by reason of urgency, it is necessary to make this instrument without a draft having been laid before, and approved by a resolution of, each House of Parliament.

Legislative Changes

- 6.10 Regulation (2)(2) omits a superfluous cross reference in regulation 2(2)(h) of the Self-Isolation Regulations as regulation 2B(1)(b) no longer exists.
- 6.11 Regulation 2(3)(a) amends regulation 2B(6) of the Self-Isolation Regulations to extend the application of the provision exempting fully vaccinated close contacts from the requirement to self-isolate. It omits references which limit the application of the exemption to vaccines administered in the UK and incorporates a new term of “authorised vaccine” which covers vaccines administered overseas. It also includes the United Kingdom vaccine rollout overseas within the exemption.
- 6.12 Regulation 2(3)(a) also amends regulation 2B(6) of the Self-Isolation Regulations to extend the application of the provision exempting close contacts who are or have been participants in clinical trials from the requirement to self-isolate where those trials are governed by approved regulators.
- 6.13 Regulation 2(3)(a) also amends the provision under regulation 2B(6) of the Self-Isolation Regulations which allows a close contact to be exempt from self-isolation if they cannot be vaccinated for clinical reasons. It clarifies the type of evidence that is required to prove a person is subject to this exemption. This provision will not come into force until 18 January 2022.
- 6.14 Regulation 2(3)(b) amends regulation 2B(7) of the Self-Isolation Regulations to clarify what “a complete course of doses” means for the purposes of paragraph (6) of regulation 2B.
- 6.15 Regulation 2(3)(c) inserts a new paragraph 7A into regulation 2B of the Self-Isolation Regulations which sets out the definition of “relevant day” and outlines the documents which can be used to prove that an individual is fully vaccinated. The documents are the same as are recognised under the International Travel Regulations. Regulation 2(3)(d) inserts new paragraphs 7AA and 7AB into regulation 2B of the Self-Isolation Regulations. Paragraph 7AA sets out which clinical trials for COVID-19 vaccines are recognised under the Self-Isolation Regulations for the purposes of exemption from self-isolation as a close contact. This includes those regulated by the Food and Drug Administration in the USA, the European Medicines Agency, or a Stringent Regulatory Authority as designated by the WHO. Paragraph 7AB outlines the type of evidence of participation in clinical trials that these close contacts will be required to provide to an authorised person when requested.
- 6.16 Regulation 2(3)(e) inserts a new paragraph 7B into regulation 2B of the Self-Isolation Regulations. Paragraph 7B sets out what criteria must be satisfied for an individual to have completed a course of doses of an authorised vaccine for the purposes of exemption from self-isolation if identified as a close contact.
- 6.17 Regulation 2(3)(f) inserts the definitions of “authorised person”, “authorised vaccine”, “the International Travel Regulations”, “marketing authorisation” and “relevant document”. The new definition of “authorised vaccine” cross refers to the International Travel Regulations. The International Travel Regulations recognise vaccines administered overseas, which are regulated by the European Medicines

Agency, Swissmedic, United States Food and Drug Administration, the Therapeutic Goods Administration in Australia and Health Canada, or which are listed on the WHO emergency use list.

- 6.18 Regulations 4 and 5 also make minor updates to the Self-Isolation Regulations to address cross-referencing errors which have emerged due to previous amendments.
- 6.19 Regulation 6 amends the transitional provision in regulation 19 of the Self-Isolation Regulations. It enables those self-isolating on 9 December 2021 who will become exempt from self-isolation as a result of these amendments to cease self-isolating on that date.

7. Policy background

What is being done and why?

- 7.1 These changes are intended to provide greater consistency across the Self-Isolation Regulations and the International Travel Regulations. They mean that a person who has been vaccinated outside the UK will be exempt from self-isolation if identified as a close contact of a positive COVID-19 case if their vaccine status is recognised for the purposes of international travel rules. This exemption does not currently apply to contacts of a confirmed or suspected case of the Omicron variant.

Exemption from self-isolation for close contacts who have been fully vaccinated outside the UK

- 7.2 The Self-Isolation Regulations currently exempt close contacts from self-isolation if they have completed a course of MHRA-approved vaccines in the UK (including doses of two different vaccines).
- 7.3 Self-isolation can help break chains of COVID-19 transmission. However, given the significant burden it can place on individuals, particularly in terms of their mental and physical wellbeing, it should only be used where it is necessary and proportionate to do so. Evidence suggests there is little difference between vaccines currently on the WHO EUL list in reducing transmission and that most vaccines offer good individual protection against hospitalisation and death.
- 7.4 This amendment expands the exemption to self-isolation for fully vaccinated close contacts to include those considered fully vaccinated under the International Travel Regulations. The International Travel Regulations recognise vaccines administered overseas, which are regulated by the European Medicines Agency, Swissmedic, United States Food and Drug Administration, the Therapeutic Goods Administration in Australia and Health Canada, or which are listed on the WHO emergency use list. These vaccines need to have been administered in a country whose vaccination programme is recognised under the International Travel Regulations and the individual must be able to provide recognised proof of vaccination if requested by a constable, police community support officer or a relevant person (as defined in the Self-Isolation Regulations).

Exemption to self-isolation for participants in clinical vaccine trials to include those who have participated in trials regulated by a WHO-approved authority

- 7.5 The Self-Isolation Regulations currently provide an exemption from self-isolation for close contacts who are taking part or have taken part in an MHRA-approved vaccine trial in the UK.

- 7.6 The International Travel Regulations treat those taking part in certain clinical trials overseas as equivalent to individuals who are fully vaccinated. This amendment extends the exemption to self-isolation to close contacts taking part in the same range of clinical trials overseas.

Clarification of the process around exemption to self-isolation for close contacts who are medically unable to be vaccinated.

- 7.7 The Self-Isolation Regulations currently provide an exemption from self-isolation for close contacts who can evidence that they are clinically unable to be vaccinated. However, the current regulations do not include detail as to the type of evidence required and how this exemption should be obtained. The NHS COVID Pass system is used for obtaining and proving a medical exemption to vaccination; however, this process was previously only outlined in guidance.
- 7.8 As the International Travel Regulations define these processes in legislation, this amendment provides the same detail in the Self-Isolation Regulations. This provision will not come into force until 18 January 2022 to allow affected individuals time to obtain the necessary proof through the required means.

8. European Union Withdrawal and Future Relationship

- 8.1 This instrument does not relate to withdrawal from the European Union / trigger the statement requirements under the European Union (Withdrawal) Act 2018.

9. Consolidation

- 9.1 This instrument does not consolidate any legislation.

10. Consultation outcome

- 10.1 There has been no public consultation in relation to this instrument.

11. Guidance

- 11.1 The Government has published guidance in relation to COVID-19 at www.gov.uk/coronavirus and this guidance will include updated information in relation to the amendments.

12. Impact

- 12.1 An Impact Assessment has not been prepared for this instrument because it is a temporary measure which is part of the Government's response to COVID-19. As this instrument will cease to have effect after 6 months, an Impact Assessment is not required and would be disproportionate. This extension falls under the Civil Contingencies Exclusion of the Better Regulation Framework and the Better Regulation Executive will not seek to enforce the current administrative requirement for validating impacts for temporary emergency COVID-19 legislation in advance of the wider reform of the Better Regulation Framework.

13. Regulating small business

- 13.1 This instrument does not apply to activities that are undertaken by small businesses.

14. Monitoring & review

- 14.1 The Health Protection (Coronavirus, Restrictions) (Self-Isolation) (England) (Amendment) Regulations 2021 that this instrument establishes will expire and cease to have effect at the end of 24 March 2022.

15. Contact

- 15.1 Sophie George (Sophie.George@DHSC.gov.uk), Head of COVID-19 Self-Isolation Policy Team at the UK Health Security Agency, can be contacted with any queries regarding the instrument.
- 15.2 Ben Dyson (Ben.Dyson@DHSC.gov.uk), Director of Cross Cutting Policy and Parliamentary & Public Accountability at the UK Health Security Agency, can confirm that this Explanatory Memorandum meets the required standard.
- 15.3 Sajid Javid MP, the Secretary of State at the Department of Health and Social Care, can confirm that this Explanatory Memorandum meets the required standard.