STATUTORY INSTRUMENTS

2022 No. 72

The Health Protection (Coronavirus, Restrictions) (Self-Isolation) (England) (Amendment) Regulations 2022

Amendments to the Health Protection (Coronavirus, Restrictions) (Self-Isolation) (England) Regulations 2020

2.—(1) The Health Protection (Coronavirus, Restrictions) (Self-Isolation) (England) Regulations 2020 are amended as follows.

(2) In regulation 2(2)(h), omit "or (b)".

(3) In regulation 2B—

(a) in paragraph (6)—

(i) for sub-paragraph (a), substitute—

"(a) the person ("NP")—

(i) has completed a course of doses of—

(aa) an authorised vaccine, or

(bb) a vaccine under the United Kingdom vaccine roll-out overseas,

and the relevant day is more than 14 days after the day on which NP completed that course of doses, and

(ii) is able to provide proof that the requirement in paragraph (i) is satisfied to a relevant person or an authorised person upon request,";

(ii) for sub-paragraph (b), but not the "or" at the end of that sub-paragraph, substitute—

"(b) NP—

(i) has participated, or is participating, in a relevant clinical trial of a vaccine for vaccination against coronavirus, and

(ii) is able to provide proof of such participation to a relevant person or an authorised person upon request,";

(iii) for sub-paragraph (c), substitute—

"(c) NP—

(i) has been advised by a registered medical practitioner that for clinical reasons NP should not be vaccinated with an authorised vaccine, and

(ii) is able to provide proof of such advice through a relevant document if required to do so by a relevant person or an authorised person.";

(b) in paragraph (7) for the words from "specified" to the end of the paragraph, substitute—

"—

(a) specified—

(i) in the summary of product characteristics approved as part of the marketing authorisation for the authorised vaccine, or

(ii) in the instructions for usage approved as part of the authorisation by the licensing authority on a temporary basis under regulation 174 (supply in response to spread of pathogenic agents etc) of the Human Medicines Regulations 2012 for the authorised vaccine, or

(b) of a vaccine under the United Kingdom vaccine roll-out overseas as specified in the manufacturer's guidance for that vaccine.";

(c) for paragraph (7A), substitute—

"(7A) For the purposes of paragraph (6)(a)—

(a) "the relevant day" means—

(i) where the person who has tested positive for coronavirus with whom NP has had close contact ("C") is a member of the same household as NP—

(aa) the date which C reported to a relevant person as the date on which symptoms first developed, or

(bb) if C has no symptoms of coronavirus, the day on which C took the test for coronavirus which resulted in a positive result, or

(ii) in any other case, the day on which NP had the close contact which resulted in the notification described in paragraph (1);

(b) proof that the requirement in paragraph (6)(a)(i)(aa) has been satisfied must be provided by—

(i) the NHS COVID pass, or equivalent from NHS Scotland, NHS Wales or the Department of Health in Northern Ireland,

(ii) the EU Digital COVID Certificate,

(iii) a North American Certificate,

(iv) a COVID-19 vaccination certificate issued by an approved third country or territory and considered by the European Commission to be equivalent to an EU Digital COVID Certificate issued in accordance with Regulation (EU) 2021/953,

(v) the Centers for Disease Control and Prevention vaccination card, or

(vi) a vaccine certificate,

and for these purposes, "NHS COVID pass", "NHS Scotland", "NHS Wales", the "EU Digital COVID Certificate", "North American Certificate" and "vaccine certificate" have the same meanings as in Part 1B of the International Travel Regulations.";

(d) after paragraph (7A), insert—

"(7AA) For the purposes of paragraph (6)(b)—

(a) "a relevant clinical trial" means—

(i) a clinical trial carried out in the United Kingdom in accordance with the requirements of the Medicines for Human Use (Clinical Trials) Regulations 2004(**1**),

(ii) a clinical trial regulated in the United States of America by the Food and Drugs Administration, or

(**1**) S.I. 2004/1031.

(iii) phase 2 (therapeutic exploratory studies) or phase 3 (clinical efficacy and safety studies) of a clinical trial regulated by an approved regulator;

(b) proof of participation in a relevant clinical trial referred to in sub-paragraph (a)(ii) or (iii) must be provided through—

(i) a vaccination card issued by the Centers for Disease Control and Prevention, in the case of a clinical trial referred to in sub-paragraph (a)(ii), or

(ii) a participation document, in the case of a clinical trial referred to in sub-paragraph (a)(iii).

(7AB) In paragraph (7AA)—

(a) "approved regulator" means—

(i) the European Medicines Agency, or

(ii) a regulatory authority (other than such an authority in the United Kingdom or the United States of America) which is designated as a Stringent Regulatory Authority by the World Health Organization;

(b) "participation document" means a document in English, French or Spanish issued by the competent health authority of the country or territory in which the relevant clinical trial is being, or was, carried out, or the person who is conducting, or conducted, the relevant clinical trial, which confirms—

(i) NP's full name;

(ii) NP's date of birth;

(iii) the name and manufacturer of the vaccine;

(iv) the country or territory in which the clinical trial is taking, or took, place;

(v) the regulatory authority responsible for the regulation of the clinical trial;

(vi) the phase of the clinical trial in which NP is participating or participated.";

(e) for paragraph (7B), substitute—

"(7B) For the purposes of this regulation—

(a) NP is deemed to have completed a course of doses of an authorised vaccine if—

(i) NP has received at least 2 doses of any of the vaccines referred in sub-paragraph (c)(ii) of the definition of "authorised vaccine" in regulation 3A(2) of the International Travel Regulations, or

(ii) NP has received a dose of one authorised vaccine and a dose of a different authorised vaccine;

(b) NP is deemed to have completed a course of doses of a vaccine under the United Kingdom vaccine roll-out overseas if—

(i) NP has received a dose of an authorised vaccine and a dose of a vaccine under the United Kingdom vaccine roll-out overseas, or

(ii) NP has received a dose of one vaccine under the United Kingdom vaccine roll-out overseas, and a dose of a different vaccine under the United Kingdom vaccine roll-out overseas.";

(f) in paragraph (8)—

(i) before the definition of "authorised vaccine", insert–

""authorised person" has the meaning given in regulation 12(12);";

(ii) for the definition of "authorised vaccine" substitute—

""authorised vaccine" has the same meaning as in Part 1B of the International Travel Regulations;";

(iii) after the definition of "clinical trial", insert—

""the International Travel Regulations" means the Health Protection (Coronavirus, International Travel and Operator Liability) (England) Regulations 2021(**2**);";

(iv) for the definition of "marketing authorisation", substitute—

""marketing authorisation" has the same meaning as in Part 1B of the International Travel Regulations;";

(v) at the end insert—

""relevant document" means—

(a) a letter issued by the NHS in response to an NHS COVID pass medical exemptions application,

(b) a certification in paper or electronic form issued by NHS Scotland, or

(c) a maternity certificate which satisfies the requirements of—

(i) regulation 2(3) of the Social Security (Medical Evidence) Regulations 1976(**3**), or

(ii) regulation 2 of the Statutory Maternity Pay (Medical Evidence) Regulations 1987(**4**);

"United Kingdom vaccine roll-out overseas" has the same meaning as in Part 1B of the International Travel Regulations.".

(4) In regulation 2D(2), in the opening words, for "2B(2)(a)" substitute "2B(2)".

(5) In regulation 9(1)(a), for "4" substitute "9".

(6) In regulation 19(1), for "16th August 2021", both times it occurs, substitute "27th January 2022".

(**2**) S.I. 2021/582. Part 1B was inserted by S.I. 2021/1107, and amended by S.I. 2021/1130, 1179, 1210, 1213, 1289, 1339, 1449, 1463 and S.I. 2022/11.
(**3**) S.I. 1976/615. Regulation 2(3) has been amended by S.I. 1987/409 and 2001/2931.
(**4**) S.I. 1987/235. Regulation 2 has been amended by S.I. 2001/2931.