
STATUTORY INSTRUMENTS

2021 No. 1416

The Health Protection (Coronavirus, Restrictions) (Entry to Venues and Events) (England) Regulations 2021

Criteria for entrance and exemptions

- 8.—(1) The criteria referred to in regulation 5(2)(a) are—
- (a) that the person (“P”) has completed a course of doses of—
 - (i) an authorised vaccine, or
 - (ii) a vaccine under the United Kingdom vaccine roll-out overseas, with the final dose of the vaccine having been received before the start of the period beginning with the 14th day before P attends the event or venue,
 - (b) where—
 - (i) P does not satisfy the criteria in sub-paragraph (a), and
 - (ii) P is not exempt under paragraph (2),that P has received a negative result from a qualifying test taken by P, for which the test sample was taken no more than 48 hours before P attends the event or venue.
- (2) A person (“P”) is exempt for the purposes of regulation 5(2)(b) if—
- (a) P has participated, or is participating, in a relevant clinical trial of a vaccine against coronavirus disease, or
 - (b) for clinical reasons P should not be vaccinated with any authorised vaccine.
- (3) For the purposes of paragraph (1)—
- (a) P has completed a course of doses of an authorised vaccine if P has received the complete course of doses 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,
 - (b) P has completed a course of doses of a vaccine under the United Kingdom vaccine roll-out overseas if P has received the complete course of doses of the vaccine as specified in the manufacturer’s guidance for that vaccine,
 - (c) P is deemed to have completed a course of doses of an authorised vaccine if—
 - (i) P 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) P has received a dose of one authorised vaccine and a dose of a different authorised vaccine;

- (d) P is deemed to have completed a course of doses of a vaccine under the United Kingdom vaccine roll-out overseas if—
 - (i) P has received a dose of an authorised vaccine and a dose of a vaccine under the United Kingdom vaccine roll-out overseas, or
 - (ii) P 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.
- (4) For the purposes of paragraph (2), a “relevant clinical trial” means a clinical trial of a vaccine for vaccination against coronavirus which is—
 - (a) 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⁾,
 - (b) a clinical trial regulated in the United States of America by the Food and Drugs Administration, or
 - (c) phase 2 (therapeutic exploratory studies) or phase 3 (clinical efficacy and safety studies) of a clinical trial regulated by an approved regulator, and for these purposes, “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.
- (5) In this regulation—
 - “coronavirus disease” means COVID-19 (the official designation of the disease which can be caused by coronavirus);
 - “crown servant” has the meaning given in section 12(1)(a) to (e) of the Official Secrets Act 1989⁽²⁾;
 - “government contractor” has the meaning given in section 12(2) of the Official Secrets Act 1989;
 - “marketing authorisation” has the meaning given in regulation 3A of the International Travel Regulations;
 - “United Kingdom vaccine roll-out overseas” means the administration of vaccination against coronavirus to—
 - (a) crown servants, government contractors or other personnel posted or based overseas and their dependants under the scheme known as the Foreign, Commonwealth and Development Office staff COVID-19 vaccination programme, or
 - (b) military or civilian personnel, government contractors and their dependants at a military posting overseas, including the British overseas territories, the Channel Islands and the Isle of Man, under the vaccination scheme provided or approved by the UK Defence Medical Services.

(1) S.I. 2004/1031.

(2) 1989 c. 12.