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STATUTORY INSTRUMENTS

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**2021 No. 1210**

**The Health Protection (Coronavirus, International  
Travel and Operator Liability) (England)  
(Amendment) (No. 17) Regulations 2021**

**Insertion of regulation 3EA**

7. After regulation 3E insert—

**“Eligible travellers: Non-UK or US clinical trial conditions**

**3EA.—(1) P meets the conditions of this regulation if P—**

- (a) has participated, or is participating in, phase 2 (therapeutic exploratory studies) or phase 3 (clinical efficacy and safety studies) of a clinical trial of a vaccine for vaccination against coronavirus which is regulated by—
  - (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<sup>(1)</sup>,
- (b) if required by an immigration officer or the operator of the relevant service on which P travels to England is able to provide proof of such participation through a participation document, and
- (c) has declared on the Passenger Locator Form that P meets the COVID-19 vaccination eligibility criteria.

(2) For the purposes of this regulation “participation document” means a document in English, French or Spanish issued by a relevant person which confirms—

- (a) P’s full name;
  - (b) P’s date of birth;
  - (c) the name and manufacturer of the vaccine;
  - (d) the country or territory in which the clinical trial is taking, or took, place;
  - (e) the regulatory authority responsible for the regulation of the clinical trial;
  - (f) the phase of the clinical trial in which P is participating or participated.
- (3) For the purposes of paragraph (2) “relevant person” means—
- (a) the competent health authority of the country or territory in which the relevant clinical trial is being, or was, carried out, or
  - (b) the person who is conducting, or conducted, the relevant clinical trial.”.

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(1) The current list national regulators designated as Stringent Regulatory Authorities is available here:<https://www.who.int/initiatives/who-listed-authority-reg-authorities/SRAs>.

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**Changes to legislation:** *There are currently no known outstanding effects for the The Health Protection (Coronavirus, International Travel and Operator Liability) (England) (Amendment) (No. 17) Regulations 2021, Section 7. (See end of Document for details)*

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**Commencement Information**

**II** Reg. 7 in force at 1.11.2021 at 4.00 a.m., see [reg. 1\(2\)](#)

**Changes to legislation:**

There are currently no known outstanding effects for the The Health Protection (Coronavirus, International Travel and Operator Liability) (England) (Amendment) (No. 17) Regulations 2021, Section 7.