STATUTORY INSTRUMENTS

2021 No. 914

The Health Protection (Coronavirus, International Travel and Operator Liability) (England) (Amendment) (No. 7) Regulations 2021

Amendment of regulation 2A

3.—(1) Regulation 2A (exemptions for vaccinated travellers and others) is amended as follows.

(2) In paragraph (3)—

(a) in sub-paragraph (b), after "United Kingdom" insert "or a relevant country";

(b) after sub-paragraph (b) insert—

"(ba) if the course of doses was received in the United States of America, is ordinarily resident in the United States of America;";

(c) in sub-paragraph (c), for the words "through the NHS COVID pass" to the end substitute—

"through—

(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; or

(iii) the Centers for Disease Control and Prevention vaccination card;";

(d) after sub-paragraph (c), insert—

"(ca) is able to provide proof if required by an immigration officer or the operator of the relevant service on which P travels to England of meeting the requirement in sub-paragraph (ba); and".

(3) In sub-paragraph (b) of paragraph (4), after "participation" insert "if required by an immigration officer or the operator of the relevant service on which P travels to England".

(4) After paragraph (4) insert—

"(4A) P—

(a) has participated or is participating in a clinical trial regulated in the United States of America by the Food and Drugs Administration of a vaccine for vaccination against coronavirus;

(b) is able if required by an immigration officer or the operator of the relevant service on which P travels to England to provide proof of such participation through the Centers for Disease Control and Prevention vaccination card;

(c) has declared on the Passenger Locator Form that P meets the COVID-19 vaccination eligibility criteria for reduced isolation and testing requirements; and

(d) is ordinarily resident in the United States of America and is able to provide proof of that residence if required by an immigration officer or the operator of the relevant service on which P travels to England.".

(5) In sub-paragraph (b) of paragraph (5), at the end insert "or a relevant country".

(6) In paragraph (10)—

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

""authorised vaccine" means a medicinal product for vaccination against coronavirus authorised—

(a) in relation to doses received in the United Kingdom—

(i) for supply in the United Kingdom in accordance with a marketing authorisation, or

(ii) by the licensing authority on a temporary basis under regulation 174 of the Human Medicines Regulations 2012;

(b) in relation to doses received in a relevant country, for supply in that country following evaluation by the relevant regulator for the country;";

(b) for the definition of "marketing authorisation" substitute—

""marketing authorisation"—

(a) in relation to a vaccine authorised for supply in the United Kingdom or in a member State, has the meaning given in regulation 8(1) (general interpretation) of the Human Medicines Regulations 2012;

(b) in relation to a vaccine authorised for supply in a relevant country other than a member State, means a marketing authorisation granted by the relevant regulator for the country;";

(c) after the definition of "NHS Wales" insert—

""relevant country" means a country listed in the first column of the table in paragraph (11);

"relevant regulator", in relation to a relevant country, means the regulator identified in the corresponding row of the second column of the table in paragraph (11), and a reference to a regulator in that table is a reference to the regulatory authority of that name designated as a Stringent Regulatory Authority by the World Health Organization pursuant to the operation of the COVAX Facility(**1**);";

(d) after paragraph (10) insert—

"(11) The table referred to in the definitions of "relevant country" and "relevant regulator" follows—

Relevant country	*Relevant regulator*
a member State	European Medicines Agency
Andorra	European Medicines Agency
Iceland	European Medicines Agency
Lichtenstein	European Medicines Agency
Monaco	European Medicines Agency
Norway	European Medicines Agency
San Marino	European Medicines Agency
Switzerland	Swissmedic

(**1**) A list of the regulatory authorities designated as Stringent Regulatory Authorities has been published by the World Health Organization and is available online athttps://extranet.who.int/pqweb/sites/default/files/documents/Product-Eligibility_COVAX-Facility_Dec2020_0.pdf

Relevant country	*Relevant regulator*
the United States of America	United States Food and Drug Administration
Vatican City State	European Medicines Agency”