SCOTTISH STATUTORY INSTRUMENTS

2021 No. 322

The Health Protection (Coronavirus) (International Travel and Operator Liability) (Scotland) Regulations 2021

[F1PART 1A

Eligible vaccinated arrivals

Textual Amendments

F1 Pt. 1A substituted for reg. 3 (17.12.2021) by The Health Protection (Coronavirus) (International Travel and Operator Liability) (Scotland) Amendment (No. 13) Regulations 2021 (S.S.I. 2021/478), regs. 1, **4** (with regs. 14, 15)

Interpretation of Part

3.—(1) In this Part—

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

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

(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 (supply in response to spread of pathogenic agents etc.) of the Human Medicines Regulations 2012,

(b) in relation to doses received in a relevant country listed in the table in paragraph (2), is authorised for supply in that country following evaluation by the relevant regulator for that country,

(c) in relation to doses received in any other country or territory (including a relevant country listed in schedule 1A (relevant countries)), is authorised in the United Kingdom in accordance with head (i) or (ii) of paragraph (a),

"clinical trial" has the meaning given in regulation 2(1) of the Medicines for Human Use (Clinical Trials) Regulations 2004 (interpretation),

"Crown servant" has the meaning given in section 12(1)(a) to (e) of the Official Secrets Act 1989,

"government contractor" has the meaning given in section 12(2) of the Official Secrets Act 1989,

"the licensing authority" has the meaning given in regulation 6(2) (the licensing authority and the Ministers) of the Human Medicines Regulations 2012,

"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 listed in the table in paragraph (2) other than a member State, means a marketing authorisation granted by the relevant regulator for the country,

"medicinal product" has the meaning given in regulation 2 (medicinal products) of the Human Medicines Regulations 2012,

"NHS COVID pass" means the COVID-19 records available on the NHS smartphone app developed and operated by the Secretary of State, through NHS.uk or in a COVID-19 post-vaccination status letter obtained from the NHS,

"NHS England" means the health service continued under section 1(1) of the National Health Service Act 2006,

"NHS Scotland" means the health service continued under section 1(1) of the National Health Service (Scotland) Act 1978,

"NHS Wales" means the health service continued under section 1(1) of the National Health Service (Wales) Act 2006,

"North American Certificate" means, in relation to a state, district or province listed in the table in paragraph (6), the certificate identified in the corresponding row of the second column of that table,

"relevant country" means a country, territory or part of a country or territory listed in the first column of the table in paragraph (2) or a country, territory or part of a country or territory listed in schedule 1A (relevant countries),

"relevant regulator", in relation to a relevant country listed in the table in paragraph (2), means the regulator identified in the corresponding row of the second column of the table in paragraph (2), 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 Organisation pursuant to the operation of the COVAX Facility[F2],

"United Kingdom vaccine roll-out overseas" means the administration of vaccine 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,

"vaccine certificate" in relation to a passenger ("P"), means a certificate in English, French or Spanish issued by the competent health authority of a relevant country, other than a European country listed in the table in paragraph (2) or the United States of America, which contains—

(a) P's full name,

(b) P's date of birth,

(c) the name and manufacturer of the vaccine that P received,

(d) the date that P received each dose of the vaccine, and

(e) details of either the identity of the issuer of the certificate or the country of vaccination, or both,

"WHO List vaccine" means a vaccine which is—

(a) listed in lines 10, 11 or 13 of the Guidance Document "Status of COVID-19 Vaccines within WHO EUL/PQ evaluation process" published by the World Health Organisation on 11 November 2021[F3], and

(b) authorised or certified in a country or territory, or part of a country or territory, listed in schedule 1A.

(2) 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
Australia	The Therapeutic Goods Administration
Canada	Health Canada
Iceland	European Medicines Agency
Liechtenstein	European Medicines Agency
Monaco	European Medicines Agency
Norway	European Medicines Agency
San Marino	European Medicines Agency
Switzerland	Swissmedic
the United States of America	United States Food and Drug Administration
Vatican City State	European Medicines Agency

(3) Where a course of doses of an authorised vaccine or of a WHO List vaccine has been administered to a person ("P") by a person acting on behalf of the United Nations and authorised to administer the vaccination in that capacity, P is to be treated as if they have received those doses in a relevant country listed in schedule 1A, and any reference to doses received in a relevant country, or to the competent health authority of a relevant country in these Regulations is to be construed as a reference to doses administered by the United Nations, and to the person acting on behalf of the United Nations.

(4) For the purposes of this Part, a child is to be treated as making a declaration on the Passenger Locator Form, and possessing any evidence required, if that declaration is made, and that evidence possessed, by a person who is travelling with, and has responsibility for, that child.

(5) For the purpose of this Part the following countries and territories are approved third countries or territories—

Albania,

Armenia,

Faroe Islands,

Israel,

Morocco,

North Macedonia,

Panama,

Turkey,

Ukraine.

(6) The table referred to in the definition of "North American Certificate" in paragraph (2) follows—

State, District or Province	*Certificate Name*
California	Digital COVID-19 Vaccine Record
New York	Excelsior Pass Plus
Washington State	WA Verify

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F2 A list of the national regulatory authorities designated as Stringent Regulatory Authorities has been published by the World Health Organization and is available online at Product-Eligibility_COVAX-Facility_Dec2020_0.pdf (who.int).

F3 https://extranet.who.int/pqweb/sites/default/files/documents/Status_COVID_VAX_11Nov2021.pdf

Eligible vaccinated arrivals

3A. A person ("P") is an eligible vaccinated arrival if P—

(a) is not a red list arrival, and

(b) meets any of the descriptions in regulations 3B to 3H.

Eligible vaccinated arrivals: vaccination conditions

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

(a) has completed a course of doses of an authorised vaccine or a WHO List vaccine with the final dose having been received before the start of the period beginning with the 14th day before the date of P's arrival in Scotland,

(b) is able to provide proof, if requested to do so by an immigration officer or the operator of the relevant service on which P travels to Scotland, of meeting the requirement in sub-paragraph (a), through—

(i) certification in paper or electronic form issued by NHS Scotland, or equivalent certification issued by NHS England, NHS Wales or the Department of Health in Northern Ireland, including through the NHS COVID pass,

(ii) the EU Digital COVID certificate,

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

(iv) a vaccine certificate,

(v) a North American Certificate, or

(vi) a certificate of COVID-19 records issued by an approved third country or territory, and

(c) has declared on P's Passenger Locator Form that P meets the COVID-19 vaccination eligibility criteria.

(2) For the purposes of this regulation—

(a) P has completed a course of doses 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 a WHO List vaccine, as the case may be, 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) if P has received a dose of one authorised vaccine or one WHO List vaccine and a dose of a different authorised vaccine or WHO List vaccine, P is deemed to have completed a course of doses of an authorised vaccine.

Eligible vaccinated arrivals: UK clinical trial conditions

3C. P meets the conditions of this regulation if P—

(a) has participated, or is participating, in a clinical trial of a vaccine for vaccination against coronavirus carried out in accordance with the requirements of the Medicines for Human Use (Clinical Trials) Regulations 2004,

(b) is able to provide proof of such participation if requested to do so by an immigration officer or the operator of the relevant service on which P travels to Scotland, and

(c) has declared on P's Passenger Locator Form that P meets the COVID-19 vaccination eligibility criteria.

Eligible vaccinated arrivals: US clinical trial conditions

3D. P meets the conditions of this regulation if 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 requested to do so by an immigration officer or the operator of the relevant service on which P travels to Scotland, to provide proof of such participation through the Centers for Disease Control and Prevention vaccination card, and

(c) has declared on the Passenger Locator Form that P meets the COVID-19 vaccination eligibility criteria.

Eligible vaccinated arrivals: Non-UK or US clinical trial conditions

3E.—(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[F4],

(b) is able, if requested to do so by an immigration officer or the operator of the relevant service on which P travels to Scotland, 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.

Textual Amendments

F4 The current list national regulators designated as Stringent Regulatory Authorities is available here: https://www.who.int/initiatives/who-listed-authority-reg-authorities/SRAs.

Eligible vaccinated arrivals: UK clinical exemptions conditions

3F. P meets the conditions of this regulation if P—

(a) is a person who cannot be vaccinated against coronavirus for medical reasons with an authorised vaccine or a WHO List vaccine,

(b) is able to provide proof of that if requested to do so by an immigration officer or the operator of the relevant service on which P travels to Scotland, and

(c) has declared on P's Passenger Locator Form that P meets the COVID-19 vaccination eligibility criteria.

Eligible vaccinated arrivals: age conditions

3G. P meets the conditions of this regulation if P is under the age of 18 years upon arrival in Scotland.

Eligible vaccinated arrivals: UK vaccine rollout overseas conditions

3H.—(1) P meets the conditions of this regulation if P is either—

(a) a person who—

(i) has completed a course of doses of a vaccine under the United Kingdom vaccine roll-out overseas, with the final dose having been received before the start of the period beginning with the 14th day before the date of P's arrival in Scotland,

(ii) is able to provide proof, if requested to do so by an immigration officer or the operator of the relevant service on which P travels to Scotland, of meeting the requirement in head (i), and

(iii) has declared on P's Passenger Locator Form that P meets the COVID-19 vaccination eligibility criteria.

(2) For the purposes of this regulation—

(a) P has completed a course of doses of a 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 a WHO List vaccine, as the case may be, 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 WHO List vaccine,

(b) where P has received a dose of an authorised vaccine or WHO List vaccine and a dose of a vaccine under the United Kingdom vaccine roll-out overseas, P is deemed to have completed a course of doses of a vaccine under the United Kingdom vaccine roll-out overseas,

(c) where 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, P is deemed to have completed a course of doses of a vaccine under the United Kingdom vaccine roll-out overseas.

(3) Where P is a person described in paragraph (2)(b), the proof which P provides for the purposes of paragraph (1)(a)(ii) must include proof of having received the dose of an authorised vaccine or WHO List vaccine through—

(a) certification in paper or electronic form issued by NHS Scotland, or equivalent certification issued by NHS England, NHS Wales or the Department of Health in Northern Ireland, including through the NHS COVID pass,

(b) the EU Digital COVID certificate,

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

(d) a vaccine certificate,

(e) a North American Certificate,

(f) a certificate of COVID-19 records issued by an approved third country or territory.]

Status:
Point in time view as at 17/12/2021.

Changes to legislation:
There are currently no known outstanding effects for the The Health Protection (Coronavirus) (International Travel and Operator Liability) (Scotland) Regulations 2021, PART 1A.