

GUERNSEY STATUTORY INSTRUMENT

2021 No.

**The Emergency Powers (Coronavirus) (Vaccine)
(Limitation of Liability) (No. 4) (Bailiwick of Guernsey)
Regulations, 2021**

<i>Made</i>	<i>1st April, 2021</i>
<i>Coming into operation</i>	<i>2nd April, 2021</i>
<i>Laid before the States</i>	<i>, 2021</i>

WHEREAS there are one or more persons within the Bailiwick, or who may enter the Bailiwick, who may be infected with Severe Acute Respiratory Syndrome Coronavirus 2, resulting in the occurrence of an emergency within the meaning of the Civil Contingencies (Bailiwick of Guernsey) Law, 2012^a;

AND WHEREAS one or more persons within the Bailiwick have died after being infected with Severe Acute Respiratory Syndrome Coronavirus 2;

AND WHEREAS there has been a recent surge of infections of several different variants of Severe Acute Respiratory Syndrome Coronavirus 2 in Europe;

^a Order in Council No. XIV of 2012; amended by Ordinance No. IX of 2016; and No. II of 2017.

AND WHEREAS the States of Guernsey Committee for Health & Social Care considers that, for the purposes of controlling or mitigating the emergency referred to above, it is appropriate and proportionate to carry out a voluntary mass vaccination programme throughout the Bailiwick, using vaccines that have been temporarily authorised by the licensing authority in the United Kingdom,

AND WHEREAS the Civil Contingencies Authority ("**the Authority**") (having consulted the Medical Officer of Health in respect of the risk to public health created thereby and by the spread of Severe Acute Respiratory Syndrome Coronavirus 2, the virus causing the disease COVID-19, and in respect of the measures necessary to prevent or slow the spread of infection) is satisfied that the conditions set out in section 13 of the Law are satisfied, and that the following regulations contain only provisions which are appropriate for and proportionate to the purpose of preventing, controlling or mitigating the emergency referred to above;

AND WHEREAS the Authority is satisfied that the effect of the following regulations is in due proportion to that emergency, and that they are compatible with the Convention rights within the meaning of section 1 of the Human Rights (Bailiwick of Guernsey) Law, 2000^b;

NOW THEREFORE THE AUTHORITY, in exercise of the powers conferred upon it by sections 12(1), 14 and 19 of the Law, and of all other powers enabling it in that behalf, hereby makes the following regulations: –

^b Order in Council No. XIV of 2000; amended by No. I of 2005; Ordinance No. XXXVII of 2001; No. XXXIII of 2003; No. XX of 2015; No. IX of 2016; No. XXVI of 2018; and G.S.I. No. 27 of 2006.

Application of these Regulations.

1. (1) These Regulations apply where –
 - (a) the UK licensing authority has authorised a medicinal product on a temporary basis (whether with or without conditions) under regulation 174 of the Human Medicines Regulations 2012^c,
 - (b) the Committee has designated the medicinal product to be used for vaccination or immunisation against the coronavirus under regulations made under section 15(2) and (3) of the Prescription Only Medicines (Human) (Bailiwick of Guernsey) Ordinance, 2009^d,
 - (c) a medicinal product falling within the description or class of the designated vaccine has been sold, supplied or administered by or on behalf of, or under arrangements made by, any person in accordance with–
 - (i) a Patient Group Direction approved or consented to by the Committee, or
 - (ii) a protocol,

^c UK S.I. 2012 No. 1916.

^d Ordinance No. XXV of 2009; as amended by No. XXV of 2010; No. IX of 2016; No. XXXIV of 2020.

- (d) any person dies or suffers any personal injury as a result of the person receiving the relevant medicinal product administered in accordance with the Patient Group Direction or (as the case may be) protocol, and
- (e) any person (whether the person referred to in subparagraph (d) or any other person) suffers or incurs any loss or damage arising out of or in connection with the death or personal injury.

(2) In paragraph (1)(a), "**UK licensing authority**" means the licensing authority within the meaning given by regulation 6(2) of the Human Medicines Regulations 2012.

Limitation of liability.

2. (1) Where these Regulations apply and a court determines in any civil proceedings that a responsible person is liable to any other person in respect of any loss or damage falling within regulation 1(1)(e), the maximum aggregate amount of damages and costs that may be awarded against the responsible person in respect of all such losses and damages is £120,000.00 in respect of any one person who died or suffered personal injury.

(2) Paragraph (1) –

- (a) is subject to regulation 3, and
- (b) does not apply so as to limit an award of damages on the ground that any action or omission of the responsible person was unlawful as a result of section 6(1) of the Human Rights (Bailiwick of Guernsey) Law, 2000.

(3) In paragraph (1), "**damages and costs**" includes all liabilities, costs, expenses, damages and losses, including but not limited to any direct, indirect or consequential losses, loss of profit, loss of reputation and all interest, penalties and legal costs and all other professional costs and expenses.

Time of sale, supply or administration.

3. Regulation 2(1) applies only in respect of a relevant medicinal product sold, supplied or (as the case may be) administered in any particular circumstances (including to any age group) –

- (a) at any time on or after the 15th December, 2020, and
- (b) if the designated vaccine is given a United Kingdom marketing authorisation or a European Union marketing authorisation, for administration in those circumstances, within the meaning given by regulations 12 and 13(1), respectively, of the Medicines (Human) (Exemptions and Recognition of Marketing Authorisations) (Bailiwick of Guernsey) (Bailiwick of Guernsey) Regulations, 2009^e, before it is given either marketing authorisation concerned.

Relationship with the European Communities (Coronavirus Vaccine) (Immunity from Civil Liability) (Guernsey) Ordinance, 2020 and any equivalent enactment.

4. Nothing in these Regulations limits the effect of the European Communities (Coronavirus Vaccine) (Immunity from Civil Liability) (Guernsey)

^e G.S.I. No. 63 of 2009.

Ordinance, 2020 or any equivalent Ordinance or other enactment having effect in Sark or Alderney.

Interpretation.

5. In these Regulations, unless the context requires otherwise –

"**the Committee**" means the States of Guernsey Committee for Health & Social Care,

"**the coronavirus**" has the meaning given by section 15(3) of the Prescription Only Medicines (Human) (Bailiwick of Guernsey) Ordinance, 2009,

"**designated vaccine**" means the medicinal product designated in accordance with regulation 1(1)(b),

"**medicinal product**" has the meaning given by section 133 of the Medicines (Human and Veterinary) (Bailiwick of Guernsey) Law, 2008^f,

"**Patient Group Direction**" has the meaning given by section 15(4) of the Prescription Only Medicines (Human) (Bailiwick of Guernsey) Ordinance, 2009,

"**personal injury**" includes any disease and any impairment of a person's physical or mental condition,

^f Order in Council No. V of 2009; as amended by Ordinance No. XXIV of 2009; No. XLI of 2013; No. IX of 2016.

"**protocol**" means any protocol for the sale, supply or administration of the designated vaccine approved under or for the purposes of section 15A of the Prescription Only Medicines (Human) (Bailiwick of Guernsey) Ordinance, 2009,

"**relevant medicinal product**" means the medicinal product sold, supplied or (as the case may be) administered in accordance with regulation 1(1)(c), and

"**responsible person**" –

- (a) means the person –
 - (i) by or on whose behalf the relevant medicinal product was sold, supplied or (as the case may be) administered in circumstances falling within regulation 1(1)(c), or
 - (ii) who made the arrangements under which the relevant medicinal product was sold, supplied or (as the case may be) administered in circumstances falling within regulation 1(1)(c), and
- (b) for the avoidance of doubt, includes (but is not limited to) –
 - (i) the States of Guernsey, and
 - (ii) the Committee.

Revocation.

6. The Emergency Powers (Coronavirus) (Vaccine) (Limitation of Liability) (No. 3) (Bailiwick of Guernsey) Regulations, 2021⁸ are revoked.

Extent.

7. These Regulations apply throughout the Bailiwick of Guernsey.

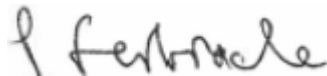
Citation.

8. These Regulations may be cited as the Emergency Powers (Coronavirus) (Vaccine) (Limitation of Liability) (No. 4) (Bailiwick of Guernsey) Regulations, 2021.

Commencement

9. These Regulations shall come into force on the 2nd April, 2021.

Dated this 1st day of April, 2021



P.T.R. FERBRACHE
Chairman of the Civil Contingencies Authority
For and on behalf of the Authority

⁸ G.S.I. No. 20 of 2021.

EXPLANATORY NOTE
(This note is not part of the Regulations)

These Regulations are emergency regulations made by the Civil Contingencies Authority under Part 3 of the Civil Contingencies (Bailiwick of Guernsey) Law, 2012 ("the Law"). They are made on the occurrence of an emergency, within the meaning of the Law, in the Bailiwick, arising from the urgent need to prevent, control or mitigate the spread of the virus Severe Acute Respiratory Syndrome Coronavirus 2 and the disease caused thereby, COVID-19 (referred to together in these regulations as coronavirus). They are prefaced with a statement by the Civil Contingencies Authority, as required by section 12(2) of the Law. COVID-19 was made a notifiable disease for the purposes of the Public Health Ordinance, 1936 on 10th February 2020.

These Regulations apply where a vaccine against the coronavirus has been temporarily authorised under the UK's Human Medicines Regulations, 2012 and designated under regulations made under the Prescription Only Medicines (Human) (Bailiwick of Guernsey) Ordinance, 2009, and the vaccine is sold, supplied or administered in accordance with a Patient Group Direction or protocol approved or consented to by the States of Guernsey Committee for Health & Social Care. They only apply to a vaccine administered on or after the 15th December, 2020 (the date on which the Emergency Powers (Coronavirus) (Vaccine) (Limitation of Liability) (Bailiwick of Guernsey) Regulations, 2020 came into force) and before the vaccine receives either a UK marketing authorisation or a European Medicines Agency marketing authorisation for administration in the circumstances concerned.

Where these Regulations apply they will limit the aggregate amount of damages and costs that may be awarded by any court in respect of death or personal injury suffered by any one person receiving the vaccine administered in accordance with the Patient Group Direction or protocol.

These Regulations revoke (and replace) the Emergency Powers (Coronavirus) (Vaccine) (Limitation of Liability) (No. 3) (Bailiwick of Guernsey) Regulations, 2021.

These Regulations will come into force on the 2nd April, 2021 and shall have temporary effect only in accordance with the provisions of section 16 (duration and scrutiny of emergency regulations) of the Law.