

Mr W J Abel Chairman Policy and Finance Committee States of Alderney PO Box 1001 Alderney GY9 3AA

20th August 2021

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Le Vauquiedor Office

Rue Mignot

Dear Mr Abel

# THE MEDICINES (HUMAN AND VETERINARY) (BAILIWICK OF GUERNSEY) LAW (AMENDMENT) ORDINANCE, 2021

Further to my recent correspondence, I am pleased to attach 'The Medicines (Human and Veterinary) (Bailiwick of Guernsey) Law (Amendment) Ordinance, 2021' ('the Ordinance'), which was made by the Policy & Resources Committee on 17<sup>th</sup> August 2021 using the powers conferred to it by Article 66A(1) of the Reform (Guernsey) Law, 1948. Prior to the Committee *for* Health & Social Care making Regulations to commence the Ordinance, confirmation of its approval from the States of Alderney is required.

The Ordinance will replace the need for regulations to be made by the Civil Contingencies Authority (CCA) every 30 days, as at present, which limit the liability of the States of Guernsey to £120,000, should a vaccine recipient suffer any significant adverse consequences having been administered a COVID-19 vaccine with temporary authorisation.

The Ordinance will remain in place until the proposed amendments to The Medicines (Human and Veterinary) (Bailiwick of Guernsey) Law, 2008 are passed by the States and subsequently approved by Privy Council, at which point it would be repealed. This achieves the aim of placing the existing emergency regulations of the CCA on a more robust statutory footing at the earliest opportunity, initially through the Ordinance and later through changes to the primary Law.

The Committee's wider recommendations for amendments to the Medicines Law have been the subject of separate correspondence and the Policy Letter will be finalised shortly.

I should be grateful if the enclosed Ordinance could be scheduled for consideration of approval by the States of Alderney at the earliest opportunity.

Should any further information or assistance be required, Amy Taylor, Policy Officer, Office of the Committee for Health & Social Care, would be pleased to assist. Amy may be contacted by e-mail at: <a href="mailto:amy.taylor@gov.gg">amy.taylor@gov.gg</a>

Yours sincerely,

**Deputy Al Brouard** 

President

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# The Medicines (Human and Veterinary) (Bailiwick of Guernsey) Law (Amendment) Ordinance, 2021

THE STATES POLICY & RESOURCES COMMITTEE, in exercise of the powers conferred on the States by section 131 of the Medicines (Human and Veterinary) (Bailiwick of Guernsey) Law, 2008<sup>a</sup> and all other powers enabling them in that behalf, and on the Committee by Article 66A(1) of the Reform (Guernsey) Law, 1948<sup>b</sup>, hereby order:-

## Amendment of the Law of 2008.

- 1. (1) The Medicines (Human and Veterinary) (Bailiwick of Guernsey)
  Law, 2008 ("the Law") is amended as follows.
- (2) Immediately after Part VII of the Law, insert the Part set out in the Schedule to this Ordinance.

#### Citation.

2. This Ordinance may be cited as the Medicines (Human and Veterinary)
(Bailiwick of Guernsey) Law (Amendment) Ordinance, 2021.

#### Commencement.

3. This Ordinance shall come into force on a date to be appointed by regulations made by the States of Guernsey Committee for Health & Social Care.

<sup>&</sup>lt;sup>a</sup> Order in Council No. V of 2009; amended by Ordinance No. XXIV of 2009; No. XLI of 2013; No. IX of 2016; and G.S.I. No. 39 of 2019.

Ordres en Conseil Vol. XIII, p. 288; amended by Order in Council No. XVII of 2015; there are other amendments not relevant to this Ordinance.

#### **SCHEDULE**

Section 1(2)

#### PART TO INSERT AFTER PART VII OF THE LAW

#### "PART VIIA

#### LIMITATION OF LIABILITY FOR CORONAVIRUS VACCINATIONS

# **Application of this Part.**

- 107A. (1) This Part applies where, at any time before or after this Part comes into force
  - (a) the Committee for Health & Social Care designates a 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 Ordinance,
  - (b) a medicinal product falling within the description or class of the designated vaccine is sold, supplied or administered under –
    - (i) a Patient Group Direction approved or consented to by the Committee for Health & Social Care, or
    - (ii) a protocol,
  - (c) a person dies or suffers any personal injury as a result of receiving the relevant medicinal product administered

under the Patient Group Direction or (as the case may be) protocol,

- (d) any person (whether the person referred to in paragraph(c) or any other person) suffers or incurs any loss or damage arising out of or in connection with the death or personal injury, and
- (e) any person brings civil proceedings against any other person in respect of the loss or damage referred to in paragraph (d).

### (2) In this Part -

"the coronavirus" has the meaning given by section 15(3) of the Prescription Only Medicines Ordinance,

"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,

"designated vaccine" means any medicinal product designated in accordance with subsection (1)(a),

"loss or damage" includes damages and costs,

"Patient Group Direction" has the meaning given by section 15(4) of the Prescription Only Medicines Ordinance, "the Prescription Only Medicines Ordinance" means 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 subsection (1)(b), and

"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 Ordinance.

### Limitation of liability.

107B. (1) Where this Part applies and, after this Part comes into force, a court determines in those civil proceedings that a responsible person is liable to any other person in respect of that loss or damage, 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) Subsection (1) -

- (a) is subject to sections 107C and 107D,
- (b) does not limit or affect the application of any Immunity
  Ordinance, and
- (c) 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 this section -

# "Immunity Ordinance" means -

- (a) the European Communities (Coronavirus Vaccine)(Immunity from Civil Liability) (Guernsey) Ordinance,2020,
- (b) the European Communities (Coronavirus Vaccine)(Immunity from Civil Liability) (Alderney) Ordinance,2020, or
- (c) the European Communities (Coronavirus Vaccine)
  (Immunity from Civil Liability) (Sark) Ordinance, 2020,

# "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, or
  - (ii) who made the arrangements under which the relevant medicinal product was sold, supplied or (as the case may be) administered, and
- (b) for the avoidance of doubt, includes (but is not limited to)
  - (i) the States of Guernsey, and

(ii) the Committee for Health & Social Care.

# Time of sale, supply or administration.

107C. Section 107B(1) does not apply if the relevant medicinal product was sold, supplied or (as the case may be) administered before the 15th December, 2020.

# Disapplication where designated vaccine is given a marketing authorisation.

- 107D. (1) Section 107B(1) does not apply in relation to a relevant medicinal product falling within the description or class of a designated vaccine if
  - (a) after its designation in accordance with section 107A(1)(a), the designated vaccine is given a UK marketing authorisation or European Union marketing authorisation, and
  - (b) the relevant medicinal product was sold, supplied or (asthe case may be) administered -
    - (i) in circumstances for which the marketing authorisation concerned was given, and
    - (ii) after that marketing authorisation was given.
  - (2) In subsection (1) –

"European Union marketing authorisation" means an authorisation to market a medicinal product for human use in the European Union granted by the European Medicines Agency under Regulation (EEC) No. 2309/1993 of the European Parliament and Council laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary

use and establishing a European Agency for the Evaluation of Medicinal Products, or any related legislation, and

"UK marketing authorisation" has the meaning given by regulation 8(1) of the Human Medicines Regulations 2012 (UK S.I. 2012 No. 1916).".