

Island of



Guernsey

# Ordinance of the States

**XXXIV**

**2020**

Made ..... 25th August, 2020

Coming into Operation .....28th August, 2020

## **The Prescription Only Medicines (Human) (Bailiwick of Guernsey) (Amendment) Ordinance 2020**

## **The Prescription Only Medicines (Human) (Bailiwick of Guernsey) (Amendment) Ordinance, 2020**

THE STATES, in pursuance of their Resolution of the 25<sup>th</sup> August, 2020<sup>a</sup>, and in exercise of the powers conferred on them by sections 35 and 132 of the Medicines (Human and Veterinary) (Bailiwick of Guernsey) Law, 2008<sup>b</sup>, and all other powers enabling them in that behalf, hereby order:-

### **Amendments to Ordinance of 2009.**

1. The Prescription Only Medicines (Human) (Bailiwick of Guernsey) Ordinance, 2009<sup>c</sup> ("**the principal Ordinance**") is amended as follows.

2. In section 15 of the principal Ordinance –

(a) in subsection (2) –

(i) in paragraph (e), immediately after "Schedule 2", insert  
", or in the case of a designated vaccine, either so specified or prescribed by regulations made by the Committee for Health & Social Care",

(ii) in paragraph (g), immediately after "of it", insert ",

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<sup>a</sup> Article IV of Billet d'Etat No. XVIII of 2020.

<sup>b</sup> Order in Council No. V of 2009; as amended by Ordinance No. XXIV of 2009; No. XLI of 2013; No. IX of 2016.

<sup>c</sup> Ordinance No. XXV of 2009; as amended by No. XXV of 2010; No. IX of 2016.

unless that medicine is a designated vaccine",

(iii) immediately after paragraph (g), insert the following paragraph –

"(ga) in the case of a designated vaccine, the medicine is sold, supplied or administered in accordance with any conditions or requirements specified in the Patient Group Direction under subsection (4)(c)(ii), and",

(b) for subsection (3), substitute –

"(3) In this section –

**"the coronavirus"** means the Severe Acute Respiratory Syndrome Coronavirus 2, the virus causing the disease COVID-19,

**"designated vaccine"** means a medicinal product that, for the time being, is designated by regulations made by the Committee for Health & Social to be used for vaccination or immunisation against the coronavirus, being a medicinal product –

(a) that is authorised by the licensing authority under regulation 174 of the Human Medicines Regulations 2012 on a temporary basis (whether with or without conditions), or

(b) for which a recognised marketing authorisation is in force,

**"excepted person"** means –

- (a) a doctor or dentist, or
- (b) a person lawfully conducting a retail pharmacy business, and

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

- (c) in subsection (4), immediately after paragraph (b), insert "and" and the following paragraph –

"(c) in the case of a designated vaccine –

- (i) is also signed by the Director of Public Health, who may be one of the persons signing the direction for the purposes of paragraph (a), and
- (ii) may include any conditions or requirements relating to the sale, supply or administration of the medicine considered appropriate by the person issuing the direction.", and

- (d) immediately after subsection (5), insert the following subsection –

"(6) Before making any regulations under subsection (2) or (3), the Committee for Health & Social Care shall consult the Policy &

Resources Committee of the States of Guernsey, the Policy and Finance Committee of the States of Alderney and the Medical & Emergency Services Committee of the Chief Pleas."

3. Immediately after section 15 of the principal Ordinance, insert the following section –

**"Protocols relating to coronavirus and influenza vaccinations and immunisations.**

15A. (1) The restrictions imposed by section 35(4) of the Law do not apply to the sale, supply or administration of a designated vaccine or any other medicinal product –

- (a) for parenteral administration, and
- (b) used for vaccination or immunisation against the coronavirus or influenza virus (of any type),

that meets conditions A, B and C.

(2) Condition A is that the sale or supply is made, or the medicinal product administered, while a disease (which may be neither the disease caused by the coronavirus nor influenza) is, or in anticipation of a disease being imminently –

- (a) pandemic, and
- (b) a serious risk or potentially serious risk to human health.

(3) Condition B is that the sale, supply or administration is in accordance with the conditions and requirements of a protocol that is approved by the Committee for Health & Social Care.

(4) Condition C is that the protocol specifies (amongst other matters)—

(a) the classes of persons permitted to administer the medicinal product under the protocol,

(b) the process by which a person of the specified class is designated, and by whom, as a person authorised to administer the medicinal product under the protocol,

(c) requirements as to the recording of the name of a person who, on any particular occasion, administers the medicinal product under the protocol, and

(d) any other conditions or requirements subject to which the sale, supply or administration of the medicinal product is permitted to take place under the protocol.

4. In section 20(1) of the principal Ordinance, insert the following definitions in the appropriate alphabetical order –

""**the coronavirus**"" has the meaning given by section 15(3),"

""**designated vaccine**"" has the meaning given by section 15(3),", and

""occupational health scheme vaccinator" means a person who is employed or engaged by a person operating an occupational health scheme, and who is—

- (a) a registered nurse or registered midwife,
- (b) a registered operating department practitioner, registered paramedic or registered physiotherapist, or
- (c) a pharmacist,".

5. In Schedule 1 to the principal Ordinance –

- (a) in Part II, immediately after paragraph 6, insert the following paragraph –

<p>7(a). The Committee for Health &amp; Social Care, or any person with whom that committee has entered into an arrangement for the sale, supply or administration of a designated vaccine or any other medicinal product,</p>	<p>7(b). A designated vaccine or any other medicinal product used for vaccination or immunisation against the coronavirus or influenza virus (of any type) sold or supplied to a person operating an occupational health scheme mentioned</p>	<p>7(c). The sale or supply of the designated vaccine or other medicinal product is in the course of an occupational health scheme mentioned in entry 7(a) and is made, if not by a doctor, by an occupational health scheme vaccinator</p>
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operating an occupational health scheme, and occupational health scheme vaccinators employed or engaged by them.	in entry 7(a) in response to an order in writing signed by a doctor or an occupational health scheme vaccinator.	acting in accordance with the written directions of a doctor as to the circumstances in which such medicinal products are to be used.",
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and

- (b) in Part III, immediately after paragraph 5, insert the following paragraph –

"5A(a). The Committee for Health & Social Care, or any person with whom that committee has entered into an arrangement for the sale, supply or administration of a designated vaccine or any other medicinal product, operating an	5A(b). A designated vaccine or any other medicinal product used for vaccination or immunisation against the coronavirus or influenza virus (of any type) sold or supplied to a person operating an occupational health scheme mentioned in entry 5A(a) in	5A(c). The administration of the designated vaccine or other medicinal product is in the course of an occupational health scheme mentioned in entry 5A(a), and the individual administering the medicinal product is, if not a doctor, an occupational health
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occupational health scheme, and occupational health scheme vaccinators employed or engaged by them.	response to an order in writing signed by a doctor or an occupational health scheme vaccinator.	scheme vaccinator acting in accordance with the written directions of a doctor as to the circumstances in which such medicinal products are to be used."
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**Extent.**

6. This Ordinance has effect throughout the Bailiwick of Guernsey.

**Citation.**

7. This Ordinance may be cited as The Prescription Only Medicines (Human) (Bailiwick of Guernsey) (Amendment) Ordinance, 2020.

**Commencement.**

8. This Ordinance shall come into force on the 28<sup>th</sup> August, 2020.