GUERNSEY STATUTORY INSTRUMENT

2019 NO. 67

The Misuse of Drugs (Modification) Order, 2019

Made	*1st May, 2019*
Coming into operation	*1st June, 2019*
Laid before the States	*, 2019*

THE COMMITTEE *FOR* HEALTH & SOCIAL CARE, in exercise of the powers conferred on it by sections 6, 9, 21 and 30 of the Misuse of Drugs (Bailiwick of Guernsey) Law, 1974[a], section 1(2) of the Misuse of Drugs (Amendment) (Bailiwick of Guernsey) Law, 2000[b] and all other powers enabling it in that behalf, hereby orders: -

Amendment of the 1997 Ordinance.

1. The Misuse of Drugs (Bailiwick of Guernsey) Ordinance, 1997[c] ("**the Ordinance**") is amended as follows.

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a Ordres en Conseil Vol. XXIV, p. 273; amended by Vol. XXVIII, p. 307; Vol. XXXI, pp. 47 and 278; Vol. XXXIII, p. 217; Vol. XXXIV, p. 172; Vol. XXXVI, p. 396; Order in Council Nos. III and No. VII of 2000; Nos. IV and XIII of 2006; Recueil d'Ordonnances Tome XX, p. 271; Tome XXII, p. 483; Tome XXIV, p. 477; Tome XXV, pp. 38 and 325; Ordinance No. XXXIII of 2003; No. XLIII of 2010; No. XXV of 2011; No. XXII of 2015; No. IX of 2016; G.S.I. No. 19 of 1997; No. 5 of 2004; No. 42 of 2006; No. 20 of 2008; Nos. 22, 33 and 82 of 2010; No. 44 of 2012; No. 54 of 2013; No. 79 of 2014; No. 93 of 2015.

b Order in Council No. III of 2000.

c Recueil d'Ordonnances Tome XXVII, p. 247; amended by Ordinance No. XXXIII of 2003; No. XXV of 2009; No. XXII of 2015; No. IX of 2016; G.S.I. No. 5 of 2004; No. 42 of 2006; No. 20 of 2008; Nos. 22, 33, 82 and 98 of 2010; No. 44 of 2012; No. 79 of 2014; No. 93 of 2015; Nos. 1, 10 and 36 of 2018.

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

""**cannabis-based product for medicinal use in humans**" means a preparation or other product, other than one to which paragraph 10 of Schedule 2 applies, which—

(a) is or contains cannabis, cannabis resin, cannabinol or a cannabinol derivative (not being dronabinol or its stereoisomers),

(b) is produced for medicinal use in humans, and—

(c) is —

(i) a medicinal product, or

(ii) a substance or preparation for use as an ingredient of, or in the production of an ingredient of, a medicinal product,",

""**dronabinol**" excludes any substance which is derived from cannabis, cannabis resin or their constituents, and stereoisomers of dronabinol are to be construed accordingly,", and

""**specialist medical practitioner**" means a medical practitioner who –

(a) is included in the register of specialist medical practitioners kept under section 34D of the Medical Act 1983 (the Specialist Register), and

(b) is a registered practitioner within the meaning of –

(i) in the case of a practitioner practising in Guernsey or Alderney, the Regulation of Health Professions (Medical Practitioners) (Guernsey and Alderney) Ordinance, 2015, and

(ii) in the case of a practitioner practising in Sark, the Regulation of Health Professions (Medical Practitioners) (Sark) Ordinance, 2017,".

3. In section 5(2) of the Ordinance, immediately before "supplied", insert "lawfully".

4. In section 6A of the Ordinance –

(a) in subsection (1), for "subsection (2)", substitute "subsections (1A) and (2)", and

(b) immediately after subsection (1), insert the following subsection –

"(1A) Subsection (1) does not apply to a cannabis-based product for medicinal use in humans.".

5. In section 6 of the Ordinance –

(a) immediately after subsection (3), insert the following subsection –

"(3A) None of subsections (2), (2A) or (3) applies to a cannabis-based product for medicinal use in humans unless

the product is administered in accordance with a prescription or direction given by a specialist medical practitioner in compliance with section 14A(1).", and

(b) immediately after subsection (6), insert the following subsection –

"(6A) None of subsections (4), (5) or (6) applies to a cannabis-based product for medicinal use in humans.".

6. In section 7 of the Ordinance –

(a) in the proviso at the end of subsection (2) –

(i) at the end of subparagraph (ii), for the full stop, substitute ", or", and

(ii) immediately after subparagraph (ii), insert the following subparagraph –

"(iii) a person to supply a cannabis-based product for medicinal use in humans in contravention of section 14A(2).", and

(b) immediately after subsection (5), insert the following subsection –

"(5A) Neither subsection (3) nor (5) applies to a cannabis-based product for medicinal use in humans.".

7. In section 9 of the Ordinance –

(a) immediately after subsection (1), insert the following subsection –

"(1A) Nothing in subsection (1)(a) authorises a person specified in section 7(2)(h), (i) or (j) to have in his possession a cannabis-based product for medicinal use in humans.",

(b) immediately after subsection (2), insert the following subsection –

"(2A) Nothing in subsection (2) authorises a person to have in his possession a cannabis-based product for medicinal use in humans for administration for medical or dental purposes except for administration in accordance with a prescription or direction given by a specialist medical practitioner in compliance with section 14A(1).", and

(c) immediately after subsection (5), insert the following subsection –

"(5A) Neither subsection (3) nor (5) applies to a cannabis-based product for medicinal use in humans.".

8. Immediately after section 14 of the Ordinance, insert the following section –

"**Orders, supply and use of cannabis-based products for administration.**

14A. (1) A person shall not order (whether by issuing a prescription or otherwise) a cannabis-based product for medicinal use in humans for administration, unless that product is —

(a) a special medicinal product that is for use in accordance with a prescription or direction of a specialist medical practitioner, or

(b) a medicinal product with a marketing authorisation.

(2) A person shall not supply a cannabis-based product for medicinal use in humans by way of or for the purpose of the administration of that product, unless the supply—

(a) is pursuant to an order that complies with subsection (1), and

(b) is —

(i) in the case of a product that is a special medicinal product, for use in accordance with a prescription or direction of a specialist medical practitioner, or

(ii) of a medicinal product with a marketing authorisation.

(3) A person shall not self-administer a cannabis-based product for medicinal use in humans by the smoking of the product.

(4) Nothing in this section has effect in relation to the order or supply of a cannabis-based product for medicinal use in humans for administration to animals for research purposes.

(5) In this section –

"**marketing authorisation**" has the meaning given by section 136(1) of the Medicines (Human and Veterinary) (Bailiwick of Guernsey) Law, 2008,

"**special medicinal product**" has the meaning given by Schedule 2A, and

"**specialist medical practitioner**" means a medical practitioner who –

(a) is included in the register of specialist medical practitioners kept under section 34D of the Medical Act 1983 (the Specialist Register),

(b) is a registered practitioner within the meaning of –

(i) in the case of an order made or issued or supply carried out in Guernsey or Alderney, the Regulation of Health Professions (Medical Practitioners) (Guernsey and Alderney) Ordinance, 2015, and

(ii) in the case of an order made or issued or supply carried out in Sark, the Regulation of Health Professions (Medical Practitioners) (Sark) Ordinance, 2017, and

(c) prior to making or issuing an order or (as the case may be) supplying the product –

(i) has given written notice to the States of Guernsey Committee *for* Health & Social Care that the medical practitioner intends, in his or her practice, to prescribe or direct the administration or use in one or more human beings of cannabis-based products for medicinal use in humans, and

(ii) has not revoked the written notice by a further written notice to that committee.".

9. In Schedule 1 to the Ordinance, immediately after paragraph 5, insert the following paragraph –

"**6.** But paragraphs 1 to 5 do not include a cannabis-based product for medicinal use in humans.".

10. In Schedule 2 to the Ordinance –

(a) in the heading of the schedule, immediately after "14,", insert "14A,",

(b) in paragraph 1, insert in the appropriate alphabetical order –

"Cannabis-based product for medicinal use in humans", and

(c) immediately after paragraph 5, insert the following paragraph –

"5A. But paragraphs 2 to 5 only apply in respect of a cannabis-based product for medicinal use in humans if the cannabis-based product that would, as a consequence of paragraphs 2 to 5, be specified in this Schedule but for the operation of this paragraph, is produced for medicinal use in humans.".

11. Immediately after Schedule 2 to the Ordinance, insert the schedule in the Schedule to this Order.

12. In Schedule 5 to the Ordinance, for paragraph 10(b), substitute the following subparagraph –

"(b) in aggregate and by weight, contains not more than 3% cannabinol and cannabinol derivatives relative to its cannabidiol content,".

Citation.

13. This Order may be cited as the Misuse of Drugs (Modification) Order, 2019.

Commencement.

14. This Order comes into force on the 1st June, 2019.

Dated this 1st day of May, 2019

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Deputy Heidi Soulsby

President of the Committee *for* Health & Social Care

For and on behalf of the Committee

SCHEDULE

Article 11

SCHEDULE TO BE INSERTED AFTER SCHEDULE 2 TO THE MISUSE OF DRUGS (BAILIWICK OF GUERNSEY) ORDINANCE, 1997

"SCHEDULE 2A

Section 14A(5)

MEANING OF "SPECIAL MEDICINAL PRODUCT"

(1) A special medicinal product means a medicinal product that —

(a) is supplied in response to an unsolicited order,

(b) is manufactured and assembled in accordance with the specification of a specialist medical practitioner, and

(c) is for use by a patient for whose treatment that specialist medical practitioner is directly responsible in order to fulfil the special needs of that patient,

where the following conditions are met.

(2) Condition A is that the medicinal product is supplied—

(a) to a specialist medical practitioner, or

(b) for use under the supervision of a specialist medical practitioner in a hospital, a nursing home or the premises of any person providing medical services under a contract for services agreed between the person and the Committee.

(3) Condition B is that no advertisement relating to the medicinal product is issued by any person.

(4) Condition C is that—

(a) the manufacture and assembly of the medicinal product are carried out under such supervision, and

(b) such precautions are taken,

as are adequate to ensure that the medicinal product meets the specification of the specialist medical practitioner who requires it.

(5) Condition D is that written records of the manufacture or assembly of the medicinal product in accordance with condition C are maintained and are available to the Committee on request.

(6) Condition E is that if the medicinal product is manufactured or assembled in the Bailiwick or imported into the Bailiwick from a country or territory that is neither a Member State of the European Union nor (if the United Kingdom is no longer a Member State of the European Union) the United Kingdom, it is manufactured, assembled or imported by the holder of a manufacturer's licence that relates specifically to the manufacture, assembly or importation of special medicinal products.

(7) Condition F is that if the product is imported from a Member State of the European Union (or, if the United Kingdom is no longer a Member State of the European Union) the United Kingdom —

(a) it is manufactured or assembled in the country or territory from which it is imported by a person who is the holder of an authorisation in relation to its manufacture or assembly in accordance with –

(i) the provisions of the 2001 Directive as implemented in that country or territory, or

(ii) if manufactured or assembled in the United Kingdom and the United Kingdom is no longer a Member State of the European Union, equivalent provisions in force in the United Kingdom, or

(b) it is manufactured or assembled as an investigational medicinal product in the country or territory concerned by the holder of an authorisation in relation to its manufacture or assembly in accordance with –

(i) Article 13 of the Clinical Trials Directive as implemented in that country or territory, or

(ii) if so manufactured or assembled in the United Kingdom and the United Kingdom is no longer a Member State of the European Union, equivalent provisions in force in the United Kingdom,

and it is imported by the Committee or the holder of a wholesale dealer's licence in relation to the product in question.

(8) Condition G is that if the product is distributed by way of wholesale dealing by a person ("P"), who has not, as the case may be, manufactured, assembled or imported the product in accordance with paragraph (6) or (7)(a), P must be either the Committee or the holder of a wholesale dealer's licence in relation to the product in question.

(9) In this schedule –

"**advertisement**" has the meaning given by section 72 of the Medicines (Human and Veterinary) (Bailiwick of Guernsey) Law, 2008, and

"**manufacturer's licence**" has the meaning given by section 8(2) of the Medicines (Human and Veterinary) (Bailiwick of Guernsey) Law, 2008.

EXPLANATORY NOTE

(This note is not part of the Order)

This Order amends the Misuse of Drugs (Bailiwick of Guernsey) Ordinance, 1997 ("**the Ordinance**") to allow the wider use of cannabis-based products for medicinal use in humans, essentially for medical purposes.

Article 2 of this Order inserts in section 1(1) of the Ordinance definitions of "**cannabis-based product for medicinal use in humans**", "**dronabinol**" and "**specialist medical practitioner**".

Articles 3, 4, 5, 6 and 7 of this Order amend sections 5, 6A, 6, 7 and 9 of the Ordinance respectively, to modify the application of those provisions of the Order to cannabis-based product for medicinal use in humans.

Article 8 of this Order inserts a new section 14A in the Ordinance, which contains provisions that restrict the ordering, supply and administration of cannabis-based product for medicinal use in humans, over and above the controls generally imposed in relation to drugs specified in Schedule 2 to the Ordinance.

This new section 14A of the Ordinance specifies requirements for the order and supply of these products for the purpose of administration (whether to humans or animals) and their use. The order (by prescription, direction or otherwise) must be for: (a) a special medicinal product (within the meaning of the new Schedule 2A to the Ordinance) for use in accordance with the prescription or direction of a specialist medical practitioner; or (b) a medicinal product with a marketing authorisation. Any supply of these products, by administration or for the purpose of administration, must be pursuant to such an order. Additionally, a person is restricted from self-administration of a cannabis-based product for medicinal use in humans by way of smoking. An exception is, however, created for the order and supply of such products for administration to animals for research purposes.

Article 9 of this Order inserts a new paragraph 6 in Schedule 1 to the Ordinance. The new paragraph excludes cannabis-based products for medicinal use in humans from the list of drugs specified in that schedule.

Article 10 of this Order amends Schedule 2 to the Ordinance to list in that schedule cannabis-based products for medicinal use in humans, as well as stereoisomers, esters, salts, and other preparations or products containing such products, where these are produced for medicinal use in humans.

The effect of articles 9 and 10 of this Order is to transfer cannabis-based products for medicinal use in humans, as well as stereoisomers, etc. of such products from Schedule 1 to Schedule 2 to the Ordinance. A synthetic version of a constituent of cannabis, dronabinol, was already listed in Schedule 2 to the Ordinance, and the new definition of dronabinol was inserted (by article 2 of this Order) to ensure its position is unchanged.

Article 11 of this Order inserts a new Schedule 2A in the Ordinance. This new schedule defines "special medicinal product" for the purposes of the new section 14A of the Ordinance.

Article 12 of this Order amends paragraph 10(b) of Schedule 5 to the Ordinance to clarify the maximum content of cannabinol and cannabinol derivatives which a cannabidiol preparation is allowed to have before it falls outside Schedule 5.

Articles 13 and 14 are the citation and commencement provisions respectively.

This Order will come into force on the 1st June, 2019.