SECOND SUPPLEMENT TO THE GIBRALTAR GAZETTE

No. 4626 of 16 October, 2019

LEGAL NOTICE NO.205 OF 2019.

CRIMES ACT 2011

DRUGS (MISUSE) (AMENDMENT) REGULATIONS 2019

In exercise of the powers conferred on it by sections 509, 510 and 529 of the Crimes Act 2011 and all other enabling powers, the Government has made the following Regulations–

Title.

1. These Regulations may be cited as the Drugs (Misuse) (Amendment) Regulations 2019.

Commencement.

2. These Regulations come into operation on the day of publication.

Amendment to the Drugs (Misuse) Regulations 2005.

3.(1) The Drugs (Misuse) Regulations 2005 are amended in accordance with this regulation.

(2) For every instance in which "Drugs (Misuse) Act 1973" or "Drugs "(Misuse) Act" appears, substitute "Crimes Act 2011", with the exception of the first reference to "Regulations made under s. 34 of the Drugs (Misuse) Act".

(3) For every instance in which "section 5" appears with reference to the principal Act, substitute "section 503".

(4) For every instance in which "section 6" appears with reference to the principal Act, substitute "section 504".

(5) For every instance in which "section 7" appears with reference to the principal Act, substitute "section 506".

(6) In sub-regulations 5(1), 5(2), 5(3), 5(4), 10(3), 12(6), 19(3) and 27(4) for "authorisation" substitute "licence".

(7) In sub-regulations 8(3), 9(4), 10(3) and 12(6) for "written authority" substitute "licence".

(8) In sub-regulations 8(3), 9(3), 9(4), 10(2), 10(3), 12(5) and 12(6) for "authority" substitute "licence".

(9) In sub-regulation 2(1)–

(a) for the definition of "authorised as a member of a group" substitute–

> *""authorised as a member of a group" means authorised by virtue of being a member of a class as respects which the Minister has granted a licence in force under and for the purposes of regulations 9(3), 10(2)(a), 10A(2), 12(5) or 12A(4), and "his group licence", in relation to a person who is a member of such a class, means the licence so granted to that class;*";

(b) after the definition of "authorised as a member of a group" insert–

> *""cannabis-based product for medicinal use in humans" means a preparation or other product, not being the substance specified in paragraph 10 of Schedule 2 or a product to which regulation 33 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;*
>
> *(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; and*
>
> *(d) has been approved by the Gibraltar Health Authority, after consultation with medicinal cannabis practitioners, as a product which is safe and effective.*
>
> *"dronabinol" does not include any substance which–*
>
> *(a) has the international non-proprietary name dronabinol (recommended by the World Health Organisation); and*
>
> *(b) is derived from cannabis, cannabis resin or their constituents,*
>
> *and stereoisomers of dronabinol are to be construed accordingly;*";

(c) after the definition of "foreign ship" insert–

> *""Gibraltar Health Authority" means the Gibraltar Health Authority established by section 3 of the Medical (Gibraltar Health Authority) Act 1987;*";

(d) after the definition of "master" insert–

> ""*medicinal cannabis practitioner" means a registered medical practitioner employed by the Gibraltar Health Authority who has completed the relevant training required from time to time by the Gibraltar Health Authority, in respect of the administration of cannabis-based products for medicinal use in humans;*";

(e) for the definition of "principal Act" substitute–

> ""*the principal Act" means the Crimes Act 2011;*".

(10) In regulation 3–

(a) after "which", for "the" substitute "certain"; and

(b) delete "as stated in these Regulations".

(11) In sub-regulation 4(1)–

(a) for "import" substitute "importation"; and

(b) for "export" substitute "exportation".

(12) In sub-regulation 5(1)–

(a) for "written authorisation" substitute "licence";

(b) after "these regulations" insert "for the time being in force"; and

(c) after "conditions attached" insert "to the licence".

(13) After sub-regulation 6(2), insert the following–

> "*(2A) Notwithstanding the provisions of section 504(1)(b) of the principal Act, any person who possesses a drug specified in Schedule 2A which has been supplied by or on the direction of a medicinal cannabis practitioner for the treatment of that person, or of a person whom he represents, may supply that drug to any medicinal cannabis practitioner for the purpose of destruction.*"

(14) In regulation 7–

(a) in the title, after "Schedules 2" insert "2A,"; and

(b) after sub-regulation (4) insert the following–

> "*(5) A medicinal cannabis practitioner may administer to a patient any drug specified in Schedule 2A.*

(6) Any person may administer to a patient any drug specified in Schedule 2A in accordance with the directions of a medicinal cannabis practitioner.

(7) A person shall not administer to a patient, and a person shall not self-administer, a drug specified in Schedule 2A by the smoking of the product.".

(15) In regulation 8–

(a) in the title, after "Schedules 2" insert "2A,"; and

(b) in sub-regulation (2), for "Schedule 2" substitute "Schedules 2 or 2A".

(16) After regulation 10, insert the following–

"*Supply of drugs in Schedule 2A.*

10A.(1) Notwithstanding the provisions of section 504(1)(b) of the principal Act, any drug specified in Schedule 2A may be supplied, or offered for supply, to any person who may lawfully possess it by any of the following persons when acting in their capacity as such-

(a) a medicinal cannabis practitioner;

(b) the head pharmacist of the Gibraltar Health Authority, acting in his capacity as such, or anyone acting under his control;

(c) a public analyst appointed under section 32 of the Food and Drugs Act;

(d) a sampling officer within the meaning of section 34 of the Food and Drugs Act;

(e) a person employed or engaged in connection with a scheme for testing the quality or amount of the drugs, preparations and appliances supplied under the Group Practice Medical Scheme Regulations.

(2) Notwithstanding the provisions of section 504(1)(b) of the principal Act, a person who is authorised as a member of a group may, under and in accordance with the terms of his group licence and in compliance with any conditions attached thereto, supply or offer to supply any drug specified in Schedule 2A to any person who may lawfully possess that drug.".

(17) After regulation 12, insert the following–

"*Possession of drugs in Schedule 2A.*

12A.(1) Notwithstanding the provisions of section 506(1) of the principal Act, for the purpose of acting in his capacity as such, a person specified in one of paragraphs (a) to (e) of regulation 10A(1) may possess any drug specified in Schedule 2A.

(2) Notwithstanding the provisions of section 506(1) of the principal Act and subject to subregulation (3), a person may possess a drug specified in Schedule 2A if –

(a) that person has been diagnosed by a practitioner as suffering from at least one of the conditions specified in Schedule 2B; and

(b) a medicinal cannabis practitioner has supplied or directed the supply of that drug to that person for administration for medical purposes.

(3) Subregulation (2) shall not have effect in the case of a person to whom the drug has been supplied by or on the direction of a medicinal cannabis practioner if-

(a) that person was then being supplied with any controlled drug by or on the direction of another medicinal cannabis practioner and failed to disclose that fact to the first mentioned medicinal cannabis practioner before the supply by him or on his direction; or

(b) that person or any other person on his behalf made a declaration or statement, which was false in any particular, for the purpose of obtaining the supply or direction.

(4) Notwithstanding the provisions of section 506(1) of the principal Act, a person who is authorised as a member of a group may, under and in accordance with the terms of that group licence and in compliance with any conditions attached thereto, possess any drug specified in Schedule 2A.".

(18) In regulation 14–

(a) In sub-regulation (3), after "practitioner" insert "or a medicinal cannabis practitioner"; and

(b) in sub-regulation (5), after sub-paragraph (e) insert "(f) a medicinal cannabis practitioner.".

(19) In sub-regulation 15(1), after "specified in" insert "Schedule 2A,".

(20) In sub-regulation 16(1), after "specified in" insert "Schedule 2A,".

(21) In regulation 17–

(a) in the title, for "14 and 15" substitute "15 and 16";

(b) for "14 or 15" substitute "15 or 16";

(22) In regulation 19–

(a) in the title, for "Schedules 1 and 2" substitute "Schedules 1, 2 and 2A";

(b) for sub-regulation 19(1) substitute–

19.(1) Subject to subregulation (3) and regulation 21, every person authorised by or under regulation 5, 9 or 10A to supply any drug specified in Schedule 1, Schedule 2 or Schedule 2A shall-

(a) keep a register, in accordance with this regulation and regulation 20, and shall enter in it in chronological sequence in the form specified in Part I or Part II of Schedule 6, as the case may require, particulars of every quantity of a drug specified in Schedule 1, Schedule 2 or Schedule 2A obtained by him and of every quantity of such a drug supplied (whether by way of administration or otherwise) by him whether to persons within or outside Gibraltar; and

(b) use a separate register or separate part of the register for entries made in respect of each class of controlled drug, and each of the controlled drugs specified in paragraphs 1 and 3 of Schedule 1, paragraphs 1, 3 and 6 of Schedule 2 and paragraphs 1 and 3 of Schedule 2A, together with its salts and any preparation or other product containing it or any of its salts shall be treated as a separate class, so however that any stereoisomeric form of a drug or its salts shall be classed with that drug.

(23) In regulation 20, in the title for "Schedules 1 and 2", substitute "Schedules 1, 2 and 2A";

(24) In regulation 26–

(a) in sub-regulation (1), after "Schedule 1, 2," insert "2A,";

(b) in sub-regulation (2), after "Schedule 1, 2," insert "2A,"; and

(c) in sub-regulation (3), after "Schedule 1, 2," insert "2A,".

(25) In sub-regulation 29(1), after Schedules 1, 2," insert "2A,".

(26) In regulation 33, for "Crimes Act 2011" substitute "the principal Act".

(27) In Schedule 1, after paragraph 5 insert "6. But paragraphs 1 to 5 do not include a cannabis-based product for medicinal use in humans.".

(28) After Schedule 2, insert the following–

SCHEDULE 2A

Schedule 2A Controlled Drugs

Regulation 3

1. The following substances and products, namely-

Cannabis-based product for medicinal use in humans

2. Any stereoisomeric form of a substance specified in paragraph 1.

3. Any ester or ether of a substance specified in paragraph 1 or 2.

4. Any salt of a substance specified in any of paragraphs 1 to 3.

5. Any preparation or other product containing a substance or product specified in any of paragraphs 1 to 4, not being a preparation specified in Schedule 5.

6. But paragraphs 2 to 6 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.

SCHEDULE 2B

Conditions to which regulation 12A(2)(a) applies

Regulation 12A

1. The following conditions, namely-

(a) moderate to severe muscle spasticity in multiple sclerosis that has failed to respond to standard medications or Sativex whilst under medical supervision;

(b) severe, refractory (treatment-resistant) epilepsy that has failed to respond to standard anticonvulsant medications;

(c) severe and life-altering pain that has failed to respond to standard and rising levels of pain control medications; or

(d) intractable nausea and vomiting associated with chemotherapy, despite the use of standard anti-emetic regimes whilst under medical supervision.

Dated 16th of October, 2019.

N F COSTA,
Minister with responsibility for health.

EXPLANATORY MEMORANDUM

These Regulations amend the Drugs (Misuse) Regulations 2005 to provide for the supply and possession of cannabis-based products for medicinal use in humans by or on the direction of registered medical practitioners employed by the Gibraltar Health Authority who have completed relevant training.

Printed by the Gibraltar Chronicle Printing Limited
Unit 3, New Harbours
Government Printers for Gibraltar,
Copies may be purchased at 6, Convent Place, Price. £0.60