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S.I. 25 of 2020

MISUSE OF DRUGS ACT

(Act 5 of 2016)

Misuse of Drugs (Cannabidiol-based Products for Medical Purposes)Regulations 2020

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S.I. 25 of 2020

MISUSE OF DRUGS ACT

(Act 5 of 2016)

Misuse of Drugs (Cannabidiol-based Products for Medical Purposes) Regulations, 2020

In exercise of the powers conferred by section 54(2)(a) of the Misuse of Drugs Act, 2016, the Minister responsible for home affairs, in consultation with the Minister responsible for health, makes the following regulations —

PART I
PRELIMINARY

Citation and commencement

1. These regulations may be cited as theMisuse of Drugs (Cannabidiol-based Products for Medical Purposes) Regulations, 2020, and shall come into operation on 1 July 2020.

Interpretation

2. In these regulations, unless otherwise expressly provided or the context otherwise requires —

"Act" means the Misuse of Drugs Act, 2016;

"Agency" means the Health Care Agency established under the Health Care Agency Act, 2013;

"Authority" means the Public Health Authority established under the Public Health Authority Act, 2013;

"cannabidiol" or "CBD" means a substance found in the cannabis plant which;

(a) contains cannabidiol; or

(b) either —

(i) does not contain a specified substance; or

(ii) contains specified substances in an amount that is no more that 2% of the sum of the amount of cannabidiol in the product; and

(c) does not contain any other controlled drug; and

(d) does not contain any other psychoactive substance or new psychoactive substance as defined in section 2 of the Act.

For the avoidance of any doubt, cannabidiol reacts with specific receptors in the human body to give a therapeutic effect and shall not include any form of cannabisthat gives a psychoactive effect;

"caregiver" means —

(a) a person, other than a minor, who is designated as a caregiver by a patient under regulation 15; or

(b) the parent or custodian of a minor who is a patient;

"Commissioner" means the Public Health Commissioner appointed under the Public Health Authority Act, 2013;

"Council" means the Seychelles Medical and Dental Council established under the Medical Practitioners and Dentists Act, Cap 126;

"cultivate" growing cannabis, sowing or scattering the seed produced by the cannabis plant, planting cannabis plant or any part thereof, nurturing or

tending the plant or harvesting the flowers, leaves or seeds or the whole or any part of the cannabis plant and includes cultivation by enhanced indoor means as defined by section 2 of the Act;

"custodian" means a person, other than a parent of a minor, who —

(a) has the actual custody of a child; or

(b) is guardian of a child;

"medical certification" means a document submitted by a Specialist to the Authority, in respect of a patient, in accordance with regulation 7;

"medical practitioner" means a person registered as a medical practitioner under the Medical Practitioners and Dentists Act, Cap 126;

"medicinal cannabis" means a product produced or manufactured from cannabidiol that is intended for use or consumption other than by smoking, including but not limited to edible products, ointments, tinctures and there is medical testimonial or scientific evidence that such a product can treat a qualifying medical condition;

"medicinal cannabis permit" or "permit" means a document issued by the Authority to a patient or caregiver, as applicable, who is registered under regulation 11, which —

(a) attests to the validity of the identity of the patient or caregiver to whom the permit is issued; and

(b) authorizes the patient or caregiver, subject to

these regulations, to obtain, possess, store, administer or use medicinal cannabis;

"minor" means a person under the age of 18 years;

"patient" means any person in Seychelles who suffers from a qualifying medical condition;

"pharmacy" or "authorized pharmacy" means a pharmacy under the control and supervision of the Agency, or a pharmacy that is given written authorization, to dispense medicinal cannabis on such conditions that the Agency may specify;

"qualifying medical condition" means a serious illness or condition that is likely to result, or continue to result in, a significant reduction in the quality of life of a person, whether from the symptoms of the illness or condition or from treatment for the symptoms of the illness or condition as determined under Schedule 1;

"smoke" means inhaling, exhaling or handling ignited or heated cannabis of any form or type;

"Specialist" means a medical practitioner who has special training, experience or academic qualifications in a specialityin relation to a qualifying medical condition and is qualified to submit to the Authority, in respect of a patient, a medical certification for the approval to prescribe medicinal cannabis to treat a patient, where the patient has been diagnosed by the medical practitioner with a specific qualifying medical condition;

"speciality" means a speciality in medicine or surgery, including but not limited to: cardiology,

neurophysiology, immunology, neurology, oncology, ophthalmology, palliative medicine, radiology or rheumatology;

"specified substance" means a substance that —

(a) naturally occurs in cannabis; and

(b) is —

(i) a tetrahydrocannabinol; or

(ii) an isomer, ester, or ether of a tetrahydrocannabinol; or

(iii) an ester or ether of an isomer of a tetrahydrocannabinol; or

(iv) a salt of any substance described in subparagraphs (i) to (iii); or

(v) a substance that has a structure substantially similar to that of any substance described in subparagraphs (i) to (iv); and

(c) for substances listed in paragraphs (b)(ii) to (v), is capable of inducing more than a minor psychoactive effect, by any means, in a person;

"therapeutic" means intended to prevent, diagnose, monitor, alleviate, treat, cure, or provide palliative care for a disease, ailment, defect or injury in a person;

"visiting qualifying patient" means a person who is not a resident of Seychelles who is in possession of

a document issued in accordance with the laws of another country or a state or province of another country, which certifies that the person is suffering froma qualifying medical condition and which is equivalent to a permit issued pursuant to regulation 11.

Object of regulations

3. The object of these regulations is to provide for the lawful access to medicinal cannabis as an alternative treatment for persons who are suffering from a qualifying medical condition and to promote the right of every citizen to the protection of health under Article 29 of the Constitution subject to such supervision and conditions as are necessary in a democratic society.

PART II
IMPORTATION OF MEDICINAL CANNABIS

Importation of medicinal cannabis

4.(1) The Agency may import or export medicinal cannabis to supply a pharmacy of the Agency or an authorized pharmacy.

(2) A person, other than the Agency, shall not import or export medicinal cannabis without obtaining a licence.

(3) The Commissioner, where the Commissioner considers it necessary or expedient after consultation with the Authority, may grant a licence to a person to import or export medicinal cannabis on such terms and conditions the Commissioner may specify in the licence.

(4) A person who contravenes subregulation (2) commits an offence under the Act and that person is subject to the evidential burden of proving that the Commissioner granted that person a licence to import or export medicinal cannabis.

Records on imported medicinal cannabis

5. The Agency or any person who imports medicinal cannabis, in respect of each consignment of medicinal cannabis

so imported, shall provide the Commissioner with a copy of a register which shall specify —

(a) the date of the arrival of the consignment in Seychelles;

(b) the form and quantity of the medicinal cannabis, and the trade name or brand under which the medicinal cannabis is imported;

(c) the country from which the medicinal cannabis was imported;

(d) the name of the exporter in the foreign country;

(e) where an export certificate is required under any for the export of medicinal cannabis in a foreign country, the particulars of that certificate;

(f) any such other information that the Commissioner may require.

Prohibition on entering or leaving Seychelles with medicinal cannabis

6. A patient or visiting qualifying patient shall not enter or leave Seychelles with medicinal cannabis unless the Authority gives that patient or visiting qualifying patient prior written authorization to do so.

PART III
APPROVAL TO PRESCRIBE MEDICINAL CANNABIS

Submission of medical certification by Specialist

7.(1) Subject to subregulation (2), a Specialist may submit to the Authority, in respect of a patient, a medical certification for the approval to prescribe medicinal cannabis to treat a patient, where the patient has been diagnosed by the Specialist or medical practitioner with a qualifying medical condition after the Specialist has conducted an assessment of the medical history of the patient and is of the opinion that —

(a) all the medical treatments that have been prescribed to treat the patient for the qualifying medical condition have proven to be ineffective and provided little or no relief;

(b) the patient may receive therapeutic care from the use of medicinal cannabis; and

(c) the potential benefits of the use of medicinal cannabis would likely outweigh the health risks to the patient.

(2) Pursuant to subregulation (1), a Specialist shall not submit a medical certification to the Authority, in respect of a patient, unless —

(a) the patient has been under the continuing care of the Specialist for the treatment of the qualifying medical condition;

(b) the Specialist, in completing an assessment of the patient, has conducted all the appropriate diagnostic or personal physical examinations;

(c) the patient is suffering from a qualifying medical condition; and

(d) the Specialist has explained the potential risks and benefits of the use of medicinal cannabis to the patient or the patient's caregiver.

(3) A Specialist may submit a medical certification to the Authority, in respect of a patient, where the patient was referred to the Specialist by a medical practitioner and that medical practitioner had continuing care of the patient for the treatment of the qualifying medical condition and the Specialist complies with subparagraphs (b), (c) and (d) of subregulation (2).

Information to be included in medical certification

8.(1) The Authority shall provide a medical certification form which may contain the following particulars —

(a) the name, address, nationality and date of birth of the patient;

(b) the qualifying medical condition of the patient;

(c) sufficient information, in accordance with regulation 7(2), to confirm that the patient has been in the continuing care of either the Specialist or the medical practitioner who referred the patient to the Specialist;

(d) a medical plan prepared by the Specialist which outlines the on-going assessment and follow up care of the patient;

(e) whether the patient has a history of substance abuse;

(f) whether the patient is terminally ill;

(g) any requirement or limitation concerning the appropriate form of medicinal cannabis to be prescribed, and limitation on the duration of use, if applicable;

(h) proof of identity of the patient;

(i) the name, address and telephone number of the Specialist;

(j) the date of issuance of the medical certification; and

(k) where applicable, any information about the designated caregiver in accordance with regulation 15.

(2) A medical certification submitted to the Authority shall be signed by the Specialist and the patient or where applicable, the caregiver.

(3) The signing of the medical certification by the patient shall be proof of consent of the patient to have the medical records or information in relation to the patient's qualifying medical condition submitted to the Authority and for the Authority to discuss the patient's medical records or information with the Council.

(4) A Specialist shall —

(a) submit the original medical certification to the Authority;

(b) give a copy of the medical certification to the patient; and

(c) keep a copy of the medical certification of the patient.

(5) A medical practitioner who makes a false statement on a medical certification commits an offence and is liable on conviction to a fine not less than SCR 20, 000 or to imprisonment for a term not exceeding 2 year, or both a fine and imprisonment.

Review of medical certification by Authority

9.(1) On receipt of a medical certification submitted to the Authority in accordance with regulations 7 and 8, the Authority shall, in consultation with the Council, —

(a) review the contents of the medical certification;

(b) determine whether the Specialist, by training or experience, is qualified to treat the patient for the qualifying medical condition; and

(c) notify the Specialist, in writing, of the approval or refusal of the medical certification.

(2) If the Authority does not approve the medical certification, the Authority shall inform the Specialist.

(3) If the Authority approves the medical certification, the Authority shall register the patient by entering the particulars relating to the patient in the confidential register maintained under regulation 10.

(4) Where the Authorityapproves the medical certification, the Authority shall issue to the patient a medicinal cannabis permit in accordance with regulation 11.

(5) Where a patient has a caregiver, subregulations(3) and (4) shall apply mutatis mutandis in relation to the caregiver.

(6) In conducting a review of a medical certification under subregulation (1), the Authority, in consultation with the Council, may carry out an investigation to determine —

(a) the extent to which the patient is suffering from a qualifying medical condition;

(b) whether medical testimonial or scientific evidence exists in relation to the treatment of the qualifying medical condition with medicinal cannabis;

(c) the manner in which medicinal cannabis may be prescribed to treat the qualifying medical condition and the time frame regarding its use;

(d) the benefits to be derived by the patient from the use of medicinal cannabis to treat the qualifying medical condition.

Maintenance of xonfidenrtial register

10.(1) The Authority shall maintain a confidential register of all patients whose medical certification have been approved, and issued a medicinal cannabis permit, by the Authority.

(2) A patient's name and other identifying information contained in the confidential register shall be kept in the strictest of confidence and shall not be subject to disclosure, except in accordance with subregulation (3).

(3) Where the Authority needs toconfirm or attestthat a medicinal cannabis permit is valid, the Authority shall do so without disclosing, to any law enforcement agency, more information than is reasonably necessary in the circumstances.

Grant of medicinal cannabis permit by the Authority

11.(1) Pursuant to regulation 9(4), a medicinal cannabis permit shall be issued to a patient and where applicable, a caregiver, in a form determined by the Authority which may contain any of the following information —

(a) the name of the holder of the permit;

(b) the designation as to whether the holder of the permit is a patient or caregiver;

(c) a random alphanumeric identification number that is unique to the holder of the permit;

(d) the date of issuance and expiration date of the permit;

(e) if the holder of the permit is a caregiver, the random alphanumeric identification number of the patient whom the caregiver is authorized to assist shall also be included on the permit; and

(f) any other information that the Authority may require.

(2) A permit issued under these regulations to —

(a) a patient, shall authorize the patient to —

(i) obtain medicinal cannabis as is specified in a prescription issued by a Specialist or medical practitioner; and

(ii) possess, store and use medicinal cannabis;

(b) a caregiver, shall authorize the caregiver to —

(i) obtain medicinal cannabis on behalf of the patient whom the caregiver is designated to assist; and

(ii) possess and store medicinal cannabis on behalf of, and administer medicinal cannabis to, the patient whom the caregiver is registered to assist.

(3) A permit shall be valid for a period not exceeding 1 year or for such other period as determined by the Authority.

(4) A permit shall be renewed in the same manner in which it was issued.

(5) A person shall keep in that person's possession the permit issued by the Authority at all times whilst the person is engaging in any activity involving medicinal cannabis.

(6) The holder of a permit shall notify the Authority if the permit is lost, defaced or destroyed, and the Authority may grant the holder a substitute permit at a cost of SCR 200.

Issuance of prescription by Specialist or medical practitioner

12.(1) A Specialist shall issue to a patient or caregiver a prescription for medicinal cannabis if the Specialist has received approval, in writing, of a medical certification submitted in respect of the patient and on proof of issuance of a

permit by the Authority to the patient, and where applicable the caregiver.

(2) A prescription issued under subregulation (1) shall not exceed a 30 day supply of individual dose, after which the patient shall be examined by the Specialist or the medical practitioner who referred the patient to the Specialist pursuant to regulation 7(3).

(3) After examining a patient, the Specialist or medical practitioner referred to in subregulation (2) may issue further prescriptions for medicinal cannabis to the patient or caregiver in accordance with regulation 17.

PART IV
ACCESS TO MEDICINAL CANNABIS

Use of medicinal cannabis

13.(1) A person who uses medicinal cannabis without being authorized to use medicinal cannabis by the Authority commits an offence and is liable on conviction to a fine not exceeding SCR 10, 000 or to imprisonment for a term not exceeding 6 months, or both a fine and imprisonment.

(2) A parent or custodian of a minor shall obtain a document in writing from the Authority certifying that the use of medicinal cannabis is necessary in the case of that minor, and the parent or custodian shall consent in writing to the use of medicinal cannabis by the minor.

(3) A parent or custodian of a minor who fails to comply with subregulation (2) and permits or causes the minor to use medicinal cannabis commits an offence and is liable on conviction to a fine of SCR 10, 000 or to imprisonment for a term not exceeding 3 months, or both a fine and imprisonment.

Dose limitation

14. In circumstances where a prescription or recommendation by a medical practitioner requires repeated usage of medicinal cannabis which may span several months, a

pharmacy of the Agency or an authorized pharmacy shall not dispense to the patient more than a 30 day supply of individual doses at a time.

Caregiver

15.(1) Subject to these regulations, a patient may designate a person as a caregiver and that person has the responsibility for —

(a) the immediate care and safety of the patient;

(b) assisting the patient with obtaining and administering medicinal cannabis; or

(c) acting in the best interest of the patient.

(2) A person who has full authority over the care of a patient under the Mental Health Act, Cap. 127, shall be deemed to be the caregiver of that person.

(3) A person appointed a guardian or sub-guardian by the Supreme Court to a person who is interdicted under the Civil Code of Seychelles Act, Cap. 33, shall be deemed to be the caregiver of that person.

(4) A parent or custodian of a patient who is a minor shall be deemed to be the caregiver of that minor unless another person is designated as the caregiver of the minor by the court.

(5) A minor shall not be designated as a caregiver.

(6) A person who has been convicted of an offence under the Act or who is identified by the court as a drug user or drug dependent in accordance with the Act is ineligible to be designated a caregiver.

(7) A patient who changes the designated caregiver shall notify the Authority of the change and give the Authority

such information as the Authority may require in respect of the new caregiver.

(8) A person designated by a patient as a caregiver shall provide the Authority the following particulars —

(a) the name, address and date of birth of the caregiver;

(b) proof of identity of the caregiver; and

(c) any such other information.

(9) A caregiver who —

(a) gives medicinal cannabis to a person other than the patient;

(b) acts in contravention of regulation 11(2)(b); or

(c) sells the medicinal cannabis dispensed under regulation 16

commits an offence and is liable on conviction to a fine not less than SCR 20, 000 or to imprisonment for a term not exceeding 2 years, or to both a fine and imprisonment.

Dispensing of medicinal cannabis to a patient

16.(1) A pharmacy of the Agency or an authorized pharmacy may dispense medicinal cannabis to a patient and where applicable, to a caregiver for a patient.

(2) Apharmacy of the Agency or an authorized pharmacy shall only dispense or supply medicinal cannabis on the submission by a patient, or where applicable a caregiver, of a valid medicinal cannabis permit and prescription from a Specialist or medical practitioner in accordance with these regulations.

(3) On dispensing medicinal cannabis to a patient, or where applicable a caregiver, a pharmacy of the Agency or an

authorized pharmacy shall ensure that the label given in respect of the prescription has the information required by law.

(4) A pharmacy of the Agency or an authorized pharmacy shall enter the information referred to in subregulation (3) in a register kept by a pharmacy of the Agency or an authorized pharmacy and established for that purpose, in such manner as may be determined by the Authority.

(5) A pharmacy of the Agency or an authorized pharmacy shall not dispense to a patient, or where applicable a caregiver, a quantity of medicinal cannabis greater than that which the patient or caregiver is permitted to obtain under a prescription.

(6) A pharmacy of the Agency or an authorized pharmacy shall conform to any requirement or limitation set by a Specialistor medical practitioner with regards to the form or type of medicinal cannabis that is required in relation to the patient and shall provide to a patient, and where applicable a caregiver, the following information —

(a) the lawful methods for administering medicinal cannabis in individual doses;

(b) any potential danger stemming from the use of medicinal cannabis;

(c) how to prevent or deter the misuse of medicinal cannabis by a minor; and

(d) any other information that the Authority may consider to be relevant.

PART V
MISCELLANEOUS

General duties of medical practitioners

17.(1) A Specialist or medical practitioner who is authorized to prescribe medicinal cannabis to a patient in

accordance with these regulations, shall immediately notify the Authority, in writing, where —

(a) the patient no longer suffers from the qualifying medicinal condition for which a medical certification was approved by the Authority;

(b) medicinal cannabis is no longer proving to be therapeutic in the treatment of the patient for any qualifying medicinal condition;

(c) the patient is no longer under the care of the Specialist or medical practitioner; or

(d) the patient has died.

(2) A Specialist or medical practitioner who fails to comply with subregulation (1) commits an offence and is liable on conviction to a fine not less than SCR 20, 000 or to imprisonment for a term not exceeding 6 months, or both a fine and imprisonment.

Prohibition on advertisement

18.(1) A Specialist, medical practitioner or any person shall not in any way make use of any form of advertisement calculated to attract persons to a Specialist or medical practitioner, or any business or organization with which a Specialist or medical practitioner is associated with, for the purposes of a Specialist submitting to the Authority, in respect of a patient, a medical certification for the approval to prescribe medicinal cannabis to treat a patient.

(2) A Specialist, medical practitioner or any person who contravenes subregulation (1) commits an offence and is liable on conviction to a fine not less than SCR 20, 000 or to imprisonment for a term not exceeding 1 year, or both a fine and imprisonment.

Prohibition on smoking and cultivating cannabis

19.(1) For the avoidance of any doubt, a person shall not cultivate or smoke cannabis of any form or type.

(2) A person who contravenes subregulation (1) commits an offence under the Act.

(3) A police officer may arrest without warrant any person who is suspected of acting in contravention of subregulation (1).

General duties of caregivers and family members

20. On the death of patient, any medicinal cannabis issued to the patient shall be returned to a pharmacy of the Agency by the caregiver, executor, or family member of the patient.

SCHEDULE 1

(1) The Commissioner, acting on the advice of the Authority and Council, may by notice published in the Gazette, declare an illness or a medical condition to be a qualifying medical condition.

(2) A Specialist may submit to the Authority, in respect of a patient, a medical certification, in accordance with regulations 7 and 8, for approval to prescribe medicinal cannabis to treat a patient, where the patient has been diagnosed with an illness or a medical condition that is not declared a qualifying medical condition by the Commissioner.

(3) The Authority shall apply the procedures set out in regulation 9 to evaluate a medical certification submitted under paragraph (2) of this Schedule.

(4) Where the Authority does not approve a medical certification under paragraph (2), the Authority is deemed to be acting in the best interest of the patient.

MADE this 28th day of February, 2020.

MACSUZY MONDON
MINISTER RESPONSIBLE FOR HOME AFFAIRS