LEGAL NOTICE NO……..2019

THE OPIUM AND HABIT – FORMING DRUG ACT 1922

The Production of Cannabis for Medicinal and Scientific Use Regulations, 2019

(Under section 12)

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In exercise of the powers conferred by Section 12 of the Opium and Habit Forming Drugs Act 37 1912, the Minister for Health makes the following Regulations-

PART I
PRELIMINARY PROVISIONS

Citation and Commencement

1. These Regulations may be cited as the Production of Cannabis for Medicinal and Scientific Use Regulations, 2019.

2. This Notice shall come into for by date of publication in the Gazette.

Interpretation

2. In these Regulations —

"appropriate fee" means the fee prescribed in the First Schedule;

"form" means the appropriate form set out in the Second Schedule;

"licensed producer" means the holder of a licence issued under Part II;

"medical practitioner" means a person registered as such in terms of the Medical and Dental Practitioners Act 1970;

"Authority " means the Medicines Regulatory Authority established under the Medicines and Related Substances Control Act of 2016;

*"*production*"* means cultivation, drying, extraction, packaging, labelling, storage, and processing of cannabis;

"Registrar" means the Registrar of the Medicines Regulatory Authority ;

"Site" means —

(a) a building or a place in a building used by a licensed producer; or

(b) an area occupied exclusively by buildings used by a licensed producer.

Application

3. These Regulations shall apply to the production of cannabis intended for medicinal or scientific purposes.

PART II
LICENSING OF SITES AND PERSONS

Application for producer's licence

4 (1) An application for the issue of a licence in terms of section 4 of the Act shall be made to the Minister through the Authority, in duplicate and shall be accompanied by—

(a) the appropriate fee;

(b) three copies of a plan of the site proposed to be licensed which shall comply with the requirement specified in these Regulations;

(c) in the case of an individual, proof of citizenship or proof of being ordinarily resident in Eswatini .

(d) In the case of a company, proof of citizenship or proof of being ordinarily resident in Eswatini of the majority of directors or proof of an exemption by the Minister and proof of incorporation in Eswatini of the company; and a declaration, signed and dated by the proposed authorised person in charge, stating that the proposed authorised person in charge, the proposed responsible person in charge and, if applicable, the proposed alternate responsible person in charge are familiar with the provisions of the Act.

(2) The application shall contain a detailed description of the method that the applicant proposes to use for keeping records, which shall permit

(a) compliance with the requirement of Part VI

(b) the Authority to audit the activities of the licenced producer with respect to cannabis.

(c) the reconciliation of orders for cannabis and shipments and inventories of cannabis.

(3) The application shall contain -

(a) if applicable, the maximum quantity expressed as the net weight in grams of fresh cannabis. Cannabis oil the applicant under produced by the licence and the production period.

(b) if applicable, the maximum quantity expressed as the net weight in 6grams of fresh cannabis, dried cannabis, cannabis oil and cannabis seeds to be sold or provided by the applicant under the licence and the period in which that quantity is to be sold or provided; and

(c) if applicable, the maximum number of cannabis plants to be sold or provided by the applicant under the licence and the period in which that quantity is to be sold or provided.

(4) An application made in terms of sub-regulation (1) shall be accompanied by a security clearance referred to in the Third Schedule, for the following persons -

(a) the authorised person in charge;

(b) the responsible person in charge;

(c) if applicable, the alternate responsible person in charge;

(d) if a producer's licence is applied for by an individual, that individual; and

(e) if a producer's licence is applied for by a compan*y*,

each officer and director of the company.

(5) In the case of an application for a licence to sell or provide fresh cannabis or cannabis oil under, the applicant shall provide the Authority, before commencing to sell or provide the substance, with the dried cannabis equivalency factor determined under Regulation 73 and the method that they used to determine it.

(6) If the applicant intends to possess, produce, sell, provide, deliver, transport or destroy cannabis at more than one site, a separate application shall be submitted for each proposed site.

(7) An application made in terms of sub-regulation (1) shall -

(a) be signed and dated by the proposed authorized person in charge; and

(b) include a statement signed and dated by the person indicating that -

(i) all of the information and documents submitted in support of the application are correct and complete to the best of their knowledge, and

(ii) they have the authority to bind the applicant.

Authorised person in charge and responsible person in charge

5. (1) A licensed producer shall designate -

(a) one authorised person in charge to have overall responsibility for management of the activities conducted by the licensed producer under their licence at their site who may, if appropriate, be the licensed producer; and

(b) one responsible person in charge to work at the licensed producer' site and have responsibility for supervising the activities with respect to cannabis conducted by the licensed producer under their licence at that site and for ensuring that the activities comply with the Act and these regulations who may, if appropriate, be the authorised person in charge.

(2) A licensed producer may designate one or more alternate responsible persons in charge to work at the licensed producer's site and have authority to replace the responsible person in charge when that person is absent.

(3) The authorized person in charge, the responsible person in charge and, if applicable, the alternate responsible person in charge shall be up-to-date with the provisions of the Act and its regulations.

Issuance of licence

6. Subject to Regulation 7, the Authority shall, after examining the application under Regulation 4 issue to the applicant a producer's licence that indicates—

(a) the licence number;

(b) the name of the licence holder;

(c) the list of authorised activities;

(d) the address of the site and, if applicable, of each building within the site where the licensed producer may conduct the authorised activities;

(e) in respect of each building, the authorised activities that may be conducted at that building and, in respect of each activity, the substances in respect of which the activity may be conducted;

(f) the security level, determined in accordance with the security requirements, of each location within the site where cannabis is stored;

(g) the effective date of the licence;

(h) the expiry date of the licence,;

(i) Any conditions that the licence holder shall meet in order to -

(i) comply with any international obligations and any other obligations that may be imposed by the Authority from time to time;

(ii) provide the security level referred to in paragraph (f);

(iii) put in place the security measures referred to in Part III; or

(iv) reduce any potential public health, safety or security risk, including the risk of cannabis being diverted to an illicit market or use.

Grounds for refusal

7. The Authority shall refuse to issue, renew or amend a producer's licence in the following circumstances—

(a) the applicant is not eligible under Regulation 4;

(b) the requirements of Regulation 11 have not been met;

(c) an inspector, who has requested an inspection, has not been given the opportunity by the applicant to conduct an inspection;

(d) the Authority has reasonable grounds to believe that false or misleading information was submitted in, or false or falsified documents were submitted with, the application;

(e) information received from a peace officer, a competent authority or the United Nations raises reasonable grounds to believe that the applicant has

been involved in the diversion of a controlled substance or precursor to an illicit market or use;

(f) the applicant does not have in place the security measures set out in the Part III in respect of an activity for which the licence is sought;

(g) the applicant is in contravention of or has contravened in the past 10 years -

(i) a provision of the Act or these regulations, or

(ii) a term or condition of another licence or a permit issued to it under any other Act.

(h) the issuance, renewal or amendment of the licence is likely to create a risk to public health, safety or security, including the risk of cannabis being diverted to an illicit market or use.

(i) any of the following persons does not hold a security clearance -

(i) the authorised person in charge;

(ii) the responsible person in charge;

(iii) if applicable, the alternate responsible person in charge;

(iv) if the applicant is an individual, that individual;

and

(v) if the applicant is a compan***y***, any of its officers or directors;

(j) the proposed method of record keeping does not meet the requirements of Regulation 65; or

(k) if applicable, the information required under Regulation 16 has not been provided or is insufficient to process the application.

Duration of licence

8. A producer's licence issued by the Authority in terms of regulation 4 shall be valid for a period of five years and may be renewed thereafter before its expiry.

Display of licence

9. (1) Subject to sub-regulation (2), a holder of a producer's licence shall ensure that his or her licence is conspicuously displayed at all times on the licensed site to which they relate.

(2) Sub-regulation (1) shall not apply in respect of any period during which the licence is necessarily removed from the licensed site concerned for the purposes of doing anything in terms of the Act or for any other lawful purpose the proof whereof, in any

proceedings against any person for contravention of sub-regulation (1), shall lie upon that person.

Production and return of licence

10. (1) Whenever the Authority—

(a) cancels any licence; or

(b) varies or amends the conditions of any licence; or

(c) imposes new conditions on the renewal of any licence ,

the Authority shall request the holder of the licence to produce such licence within such period as Authority may specify and the holder thereof shall produce such licence within the specified period.

(2) Any person who fails to comply with a request in terms of sub-regulation (1) shall be guilty of an offence and liable to a fine not exceeding level six or to imprisonment for a period not exceeding one year or to both such fine and such imprisonment.

(3) Whenever the Authority varies amends or imposes any new conditions on any licence, the Authority shall return such licence duly endorsed to the holder thereof.

Application for variation or amendment of a licence

11. (1) A licensed producer proposing to amend the content of his or her licence shall provide the Authority with the following documents—

(a) an application in writing describing the proposed amendment, as well as any information or documents mentioned in regulation 4 that are relevant to the proposed amendment;

(b) if applicable, a declaration signed and dated by the authorized person in charge stating that the notices to local authorities have been provided and specifying the names, titles and addresses of the senior officials to whom they were addressed and the dates on which they were provided, together with a copy of each notice; and

(c) a copy of the original licence.

(2) The application shall -

(a) be signed and dated by the authorised person in charge; and

(b) include a statement signed and dated by that person indicating that all of the information and documents submitted in support of the application are correct and complete to the best of his or her knowledge.

(3) Subject to Regulation 7, the Authority shall, after examining the information and documents required under this Regulation and, if applicable, Regulation 16, amend the licence accordingly and may add any conditions that the licence holder shall meet in order to -

(a) comply with any international obligations;

(b) provide the security level referred to in regulation 6(f) or the new level applicable as a result of the amendment of the licence;

(c) put in place the security measures referred to in Part III; or

(c) reduce any potential public health, safety or security risk, including the risk of cannabis being diverted to an illicit market or use.

Notice to Authority on change of personnel

12. (1) A licensed producer shall—

(a) apply for and obtain the Authorities approval before making a change involving the replacement or the addition of—

(i) the authorised person in charge;

(ii) the responsible person in charge and, if applicable, the alternate responsible person in charge;

(iii) if applicable, an officer or director referred to in regulation 4(2)(d) or

(iv) an individual authorised to place an order for cannabis on behalf of the licensed producer;

(b) except in the case referred to in sub-regulation (3), notify the Minister, not later than five days after the event, when a person referred to in Regulation 5 ceases to carry out their duties; and

(c) notify the Authority, not later than five days after the event, when a person referred to in Regulation 4(1)(d) ceases to be an officer or director.

(2) The licensed producer shall, with the application for approval referred to in sub-regulation (1) (a), provide the Authority with the following information and documents with respect to the new person-

(a) in the case of the replacement of the senior person in charge or the responsible person in charge or the replacement or addition of an alternate responsible person in charge-

(i) the information stated in Form DDPC1 and Form DDPC2, and

(ii) The declaration specified in Regulation 4 (1)(e);

(b) in the case of the replacement or addition of an officer or director, the information specified in Form DDPC1 concerning that person.

(3) A licensed producer shall notify the Authority not later than the next business day if the responsible person in charge ceases to carry out their duties and there is no person designated as an alternate responsible person in charge.

Notice to Authority on various changes

13. A licensed producer shall, within five days after the change, notify the Authority of any change to—

(a) the method used for keeping records;

(b) the telephone number, mobile number and, if applicable, the email address ;

(c) their site; and

(d) if applicable, each building within the site where the activities are conducted under the licence; or

(e) the security of their site, other than a change that affects the security level of any location within the site where cannabis, other than cannabis plants, is stored.

Application for renewal of licence

14. (1) An application for the renewal of a producer's licence shall be made by a licensed producer and lodged with the Authority before the expiry of such licence and shall be accompanied by the following -

(a) the appropriate fee; and

(b) a copy of the original licence; and

(c) a declaration signed and dated by the authorised person in charge stating that as of the date of the application -

(i) to the best of that person's knowledge the information shown on the producer's licence as specified in Regulation 6 (a) to (i) is correct and complete, and if applicable, the requirements of Regulations 12 and 13 have been met.

(2) Subject to Regulation 7, the Authority shall, after examining the information and documents required under sub-regulation (1) and, if applicable, regulation 16, issue a renewed licence that contains the information set out in regulation 6 (a) to (j)

(3) If a licensed producer submits an application in terms of Regulation 11 or 12 together with an application in terms of sub-Regulation (1), the Authority may process them together.

(4) Where an application for the renewal of a licence has been lodged with the Authority, the validity of the licence shall, where the applicant has not been given notice of the renewal or refusal of the application by the date of expiry of such licence, continue after the date of expiry until the decision of the Authority on the application is notified to the applicant by the Authority.

Statement by signatory of notice

15. An application or notification made under Regulation 12 or 13, respectively, shall -

(a) be signed and dated by the authorised person in charge; and

(b) include a statement signed and dated by that person indicating that -

(i) all information and, if applicable, documents submitted in support of the application or notification are correct and complete to the best of their knowledge, and

(ii) they have the authority to bind the licensed producer.

Annual returns

16. (1) Every licensed producer shall submit to the Authority, at every anniversary of the licence and upon payment of annual return fees specified in the First Schedule, records of all transactions which are required to be kept in terms of this Act.

(2) The Authority may prescribe the manner in which records may be submitted to him or her.

(3) Every licensed producer who fails to submit to the Authority the records by the period specified in sub-regulation (1) shall be liable to the daily penalty of E**** which shall stop to accrue after a period of one month.

(4) The Authority may suspend the licence of a producer who has failed to submit the records within the one month referred to in Sub-Regulation (3):
Provided that—

(i) before suspending the licence, the Authority shall invite the producer to make representations;

(ii) the suspension of the licence shall not prevent the Authority from instituting a claim for the recovery of outstanding daily penalties which may have accrued in terms of sub-regulation (3).

(5) Upon considering the evidence which he or she may have received, the Authority may proceed to act in terms of Regulation 18 or Regulation 19.

(6) The Authority may require information from the licensed producer at any time and whereupon such producer shall, within seven days or any shorter or longer period as the Authority may fix, submit such information.

Temporary suspension of licence

17. (1) The Authority may in the public interest require the temporary suspension of a licence for such period as he or she may determine.

(2) Where the Authority suspends a licence in terms of sub-regulation (1), he or she shall forthwith notify the licensee of the reasons therefor and call upon the license to show cause why the licence should not be suspended.

Reinstatement of suspended licence

18**.** The Authority shall, by notice to the licensed producer, reinstate a licence, in respect of any or all activities or substances affected by the suspension, if the licensed producer demonstrates to the Authority that—

(a) the failure that gave rise to the suspension has been rectified; or

(b) the suspension was unfounded.

Cancellation of licence following suspension

19. (1) The Authority shall cancel a licence if the licensed producer fails to comply with the decision of the Authority to suspend the licence under Regulation 17 or if the failure that gave rise to the suspension is not rectified.

(2) The Authority shall give notice thereof in writing to the licensed producer of the intended cancellation.

(3) A notice given in terms of Sub-Regulation (2) shall—

(a) specify the grounds on which the opinion of the Authority is based; and

(b) indicate that the person to whom it is directed may within seven days after the receipt thereof submit to the Authority any comments he may wish to put forward in connection with the matter failure of which the Minister shall proceed with the cancellation.

Cancellation on other grounds

20**.** The Authority shall cancel a producer's licence in the following circumstances -

(a) the Authority has reasonable grounds to believe that the licence was issued on the basis of false or misleading information submitted in, or false or falsified documents submitted with, the application;

(b) the licensed producer has, since the issuance of the licence, contravened a provision of the Act or its regulations or a condition of their licence or of an import or export permit issued under this Part;

(c) the licensed producer is no longer eligible under Regulation 4;

(d) information received from an inspector**,** a competent authority or the United Nations raises reasonable grounds to believe that the licensed producer has been involved in the diversion of a controlled substance or precursor to an illicit market or use; or

(e) any of the persons referred to in Regulation 7(1)(i) does not hold a security clearance.

Notice of cessation of activities

21. (1) A licensed producer who intends to cease conducting activities at their site, whether before or on the expiry of their licence shall submit to the Authority a written notice to that effect at least thirty days before ceasing those activities.

(2) A notice referred to in sub-regulation (1) shall be signed and dated by the licensed producer in charge and shall contain the following information —

(a) the expected date of the cessation of activities at the site;

(b) a description of the manner in which any cannabis remaining on the site as of the date referred to in paragraph (a) will be dealt with by the licensed producer, including —

(i) if some or all of it will be sold or provided to another licensed producer who will be conducting activities at the same site, the name of that producer;

(ii) if some or all of it will be sold or provided to another licensed producer or a licensed dealer, the name of that producer and the address of their site or the name of that dealer and the address of their premises; and

(iii) if some or all of it will be destroyed, the date on which and the location at which the destruction is to take place;

(c) the address of the location at which the licensed producer's records, books, electronic data and other documents will be kept after activities have ceased; and

(d) the name, address, telephone number, mobile number and, if applicable, the email address of a person whom the Authority may contact for further information after activities have ceased.

(3) After having ceased the activities, the licensed producer shall submit to the Authority a detailed update of the information referred to in paragraphs (2) (a) to (d), if it differs from what was set out in the notice submitted under sub-regulation (1 and such update shall be signed and dated by the licensed producer in charge.

(4) If the activities cease before the expiry of the licence, the licensed producer shall return to the Authority the original of the licence and the Authority shall then revoke the licence.

PART III
SECURITY MEASURES
PART A –PERIMETER OF SITE

Compliance with security measures

22. A licensed producer shall ensure that the security measures set out in this Part are carried out.

Unauthorised access

23. A licensed producer's site shall be designed in a manner that prevents un authorized access.

Visual monitoring of the Perimeter of Site

24**.** (1) The perimeter of the licensed producer's site shall be visually monitored at all times by visual recording devices to detect any attempted or actual un authorised access.

(2) The devices referred to in Sub -Regulation (1) shall, in the conditions under which they are used, be capable of making a visible recording of any attempted or actual un authorised access.

Intrusion detection system of the perimeter of site

25. The perimeter of the licensed producer's site shall be secured by means of an intrusion detection system that operates at all times and that allows for the detection of any attempted or actual un authorised access to or movement in the site or tampering with the system.

Monitoring by personnel of the perimeter of site

26. (1) The intrusion detection system shall be monitored at all times by personnel who shall determine the appropriate steps to be taken in response to the detection of any occurrence referred to in Regulation 24 or 25.

(2) If any such occurrence is detected, the personnel shall make a record of—

(a) the date and time of the occurrence; and

(b) the measures taken in response to it and the date and time when they were taken.

PART B – AREAS WHERE CANNABIS IS HANDLED

Restricted access

27. (1) Access to areas within a site where cannabis is present shall be restricted to persons whose presence in those areas is required by their work responsibilities.

(2) The responsible person in charge or, if applicable, the alternate responsible person in charge shall be physically present while other persons are in those areas.

(3) A record shall be made of the identity of every person entering or exiting those areas.

Physical barriers

28 A holder of a producer's licence shall include physical barriers that prevent un authorised access within a site where cannabis is present.

Visual Monitoring

29. (1) A holder of a producer's licence shall ensure that areas where cannabis is present are visually monitored at all times by visual recording devices to detect illicit conduct.

(2) The devices referred to in sub-regulation (1) shall, in the conditions under which they are used, be capable of making a visible recording of illicit conduct.

Intrusion detection system

30. A licensed producer shall ensure that areas where cannabis is present are secured by means of an intrusion detection system that operates at all times and that allows for the detection of any attempted or actual unauthorized access to or movement in those areas or tampering with the system.

Filtration of air

31. A licensed producer shall ensure that areas where cannabis is present are equipped with a system that filters air to prevent the escape of odours and, if present, pollen.

Monitoring by personnel

(1) The intrusion detection system referred to in Regulation 30 shall be monitored at all times by personnel who shall determine the appropriate steps to be taken in response to the detection of any occurrence referred to in Regulation 29 or 30.

(2) If any such occurrence is detected, the personnel shall make a record of—

(a) the date and time of the occurrence; and

(b) the measures taken in response to it and the date and time when they we.

PART IV
GENERAL CONDITIONS OF PRODUCTION

Good Production Practices

33. (1) A licensed producer shall ensure that standard operating procedures are developed and implemented for all activities during production of cannabis.

(2) The procedures referred to in sub-regulation (1) shall be in accordance with the Good Agricultural Practices and Good Manufacturing Practices.

Cultivation of cannabis

34. Good Agricultural Practices shall be applied in the cultivation of cannabis, as determined by the Ministry responsible for agriculture.

Soil and Fertilisers

35. (1) Cannabis shall be grown on soil not contaminated with sludge, heavy metals, pesticide residues or other chemicals.

(2) The chemicals and quantities used for production shall be justified.

(3) Monitoring of soil contamination shall be performed and reported on.

(4) Manure applied shall be thoroughly composted and shall devoid of human faeces. Fertilisers shall be used in such a way that leaching is reduced to minimum level.

Irrigation

36. (1) Irrigation shall be controlled to ensure quality cultivation of the cannabis plant.

(2) The quality of the irrigation water shall be controlled to ensure minimum contaminants, including faeces, heavy metals, herbicide, pesticides and toxicologically hazardous substances.

(3) All tillage operations shall be adapted to plant growth and requirements.

Pest control products

37. (1) Fresh or dried cannabis or cannabis plants or seeds shall not be treated with a pest control product unless the product is authorised or registered for use under the Plant control Act of 1981 or is otherwise authorised for use under that Act.

(2) The use of herbicides and pesticides shall be avoided as far as possible.

Harvesting

38. Good harvesting practices with appropriate procedures, as determined by the Ministry responsible for agriculture shall be followed to ensure that the appropriate quality product is obtained for the intended use.

Drying

39. (1) A licensed producer shall ensure that there is a uniform drying speed of the crops and prevention of mould growth by applying appropriate measures.

(2) In cases where cannabis is dried in open air, the cannabis shall be spread in a thin layer, to ensure good air circulation of the drying rakes placed at sufficient distance from the drying surface.

(3) Where cannabis is not dried in open air optimal drying conditions, i.e. temperature and drying time shall be followed and recorded.

Microbial and chemical contaminants

40. The microbial and chemical contaminants of fresh or dried cannabis or cannabis oil shall be within generally accepted tolerance limits for herbal medicines for human consumption.

Disintegration of capsules

41. A capsule or similar dosage form of cannabis oil that is intended to be swallowed whole or used as a suppository shall meet the requirements of a disintegration test that is applicable to the formulation of the capsule or similar dosage form.

Maximum yield quantity— cannabis oil

42. (1) Cannabis oil shall not exceed a maximum yield quantity of 30 mg of delta;9;tetrahydrocannabinol per millilitre of the oil in the immediate container, taking into account the potential to convert delta;9;tetrahydrocannabinolic acid into delta;9;tetrahydrocannabinol.

(2) If cannabis oil is in a capsule or similar dosage form, each capsule or unit of the dosage form shall not exceed a maximum yield quantity of 10 mg of delta;9;tetrahydrocannabinol, taking into account the potential to convert delta;9;tetrahydrocannabinolic acid into delta;9;tetrahydrocannabinol.

Solvents

43. (1) Cannabis oil shall not contain residues of solvents other than Class 3 solvents listed in the Guidance Document — Impurities: Guideline for Residual Solvents, ICH Topic Q3C(R5), as amended from time to time.

(2) Those residues shall not exceed the limits established under that document.

Analytical testing

44. Analytical testing for the following shall be conducted using validated methods—

(a) the disintegration referred to in Regulation 41;

(b) the residues of solvents referred to in Regulation 43; and

(c) the content of delta;9;tetrahydroca delta;9;tetrahydrocannabinolic acid, cannabidiol and cannabidiolic acid.

Premises

45. **(1)** Fresh or dried cannabis, cannabis oil or cannabis plants or seeds shall be produced, packaged, labelled and stored in premises that are designed, constructed and maintained in a manner that permits those activities to be conducted under sanitary conditions, and in particular that—

(a) permits the premises to be kept clean and orderly;

(b) permits the effective cleaning of all surfaces in the premises;

(c) permits the substance to be stored or processed appropriately;

(d) prevents the contamination of the substance; and

(e) prevents the addition of an extraneous substance to the substance.

(2) The substances referred to in sub-regulation (1) shall be stored under conditions that will maintain their quality.

Equipment

46. Fresh or dried cannabis, cannabis oil or cannabis plants or seeds shall be produced, packaged, labelled and stored using equipment that is designed, constructed, maintained, operated and arranged in a manner that -

(a) permits the effective cleaning of its surfaces;

(b) permits it to function in accordance with its intended use;

(c) prevents the contamination of the substance; and

(d) prevents the addition of an extraneous substance to the substance.

Sanitation program

47. Fresh or dried cannabis, cannabis oil or cannabis plants or seeds shall be produced, packaged, labelled and stored in accordance with a sanitation program that sets out —

(a) procedures for effectively cleaning the premises in which those activities are conducted;

(b) procedures for effectively cleaning the equipment used in those activities;

(c) procedures for handling any substance used in those activities; and

(d) all requirements, in respect of the health, hygienic behavior and clothing of the personnel who are involved in those activities, that are necessary to ensure that those activities are conducted in sanitary conditions.

Standard operating procedures

48. Fresh or dried cannabis, cannabis oil or cannabis plants or seeds shall be produced, packaged, labeled and stored in accordance with standard operating procedures that are designed to ensure that those activities are conducted in accordance with the requirements of this Part.

Recall

49. (1) A licensed producer shall establish and maintain a system of control that permits the rapid and complete recall of every lot or batch of fresh or dried cannabis, cannabis oil or cannabis plants or seeds that has been made available for sell.

(2) The procedure for recall shall be in accordance with the provisions set out in the Fourth Schedule.

Recall reporting

50. Before commencing a recall of fresh or dried cannabis, cannabis oil or cannabis plants or seeds, a licensed producer shall provide the Authority with the following information in respect of the substance to be recalled –

(a) its brand name;

(b) the number of each lot or batch to be recalled;

(c) if known by the licensed producer, the name and address of each licensed producer who produced any of it;

(d) the reasons for commencing the recall;

(e) the quantity that was produced by the licensed producer;

(f) the quantity that was sold or provided in Eswatini by the licensed producer;

(g) the quantity remaining in the possession of the licensed producer;

(h) the number of persons to whom it was sold or provided by the licensed producer; and

(i) a description of any other action that the licensed producer is taking in respect of the recall.

Quality assurance

51. (1) A licensed producer shall employ a quality assurance person who

(a) is responsible for assuring the quality of the fresh or dried cannabis, cannabis oil or cannabis plants or seeds before they are made available for sale, and

(b) has the training, experience and technical knowledge relating to the conducted and the requirements of this Part; and activity

(c) investigates every complaint received in respect of the quality of those substances and, if necessary, takes corrective and preventative measures.

(2) The substances shall be produced, packaged, labeled and stored using methods and procedures that, prior to their implementation, have been approved by a quality assurance person.

(3) Every batch of the substances shall be approved by a quality assurance person before it is made available for sell.

(4) Any of fresh or dried cannabis, cannabis oil, or cannabis plant or seeds that are sold or provided and subsequently returned to the licensed producer shall not be resold or provided again.

Sample of lot or batch

52. (1) Subject to sub-regulation (3), if the Authority has reasonable grounds to believe that a lot or batch of fresh or dried cannabis, cannabis oil or cannabis plants or seeds made available for sale or provision by a licensed producer, may by reason of the manner in which the substance was produced, packaged, labeled or stored, pose a risk to the health of a person who obtains the substance for their own medical purposes, the Authority may require the licensed producer to provide the Authority with a sample of that lot or batch.

(2) A sample referred to in sub-regulation (1) shall be of sufficient quantity to enable a determination of whether the lot or batch meets the requirements of Regulations 40 and 41 and, if applicable, Regulations 42, 43 and 44.

(3) The Authroity shall not require a sample to be provided if more than one year has elapsed after the expiry date or provision of any portion of the batch.

PART V

PACKAGING, LABELLING AND SHIPPING

Packaging

53. (1) A licensed producer who sells or provides fresh or dried cannabis or cannabis oil shall ensure that-

(a) the substance is packaged in an immediate container—

(i) that is in direct contact with the substance or, in the case of a substance in a capsule or similar dosage form, that is in direct contact with the capsules or units of that dosage form;

(ii) that prevents the contamination of the substance and, in the case of dried cannabis, keeps it dry;

(iii) that has a security feature that provides reasonable assurance to consumers that the container has not been opened prior to receipt, and

(iv) that is a child resistant package; and

(b) not more than the equivalent of 30 g of dried cannabis is in the immediate container.

(2) A licensed producer who sells or provides cannabis seeds shall ensure that they are packaged in a container that —

(a) is in direct contact with the seeds;

(b) keeps them dry and prevents their contamination; and

(c) has a security feature that provides reasonable assurance to consumers that the container has not been opened prior to receipt.

(3) A licensed producer who sells or provides cannabis plants shall ensure that they are sold or provided in a package that has a security feature that provides reasonable assurance to consumers that the package has not been opened prior to receipt.

Accuracy of weight

54. (1) A licensed producer who sells or provides fresh or dried cannabis or cannabis oil shall ensure that the net weight of the substance in the immediate container is not less than 95% and not more than 105% of the net weight specified on the label in accordance with Regulation 56.

(2) A licensed producer who sells or provides cannabis oil shall ensure that the net volume of the oil in the immediate container is not less than 95% and not more than 105% of the net volume specified on the label in accordance with Regulation 56.

(3) A licensed producer who sells or provides cannabis oil in a capsule or similar dosage form shall ensure that number of capsules or units in the container is the same as the number specified on the label in accordance with Regulation 56.

(4) A licensed producer who sells or provides cannabis seeds shall ensure that the number of seeds in the immediate container is the same as the number specified on the label in accordance with Regulation 57

Accuracy on number of plants

55. A licensed producer who sells or provides cannabis plants shall ensure that the exact number of plants in the package referred to in Regulation 53(3) is indicated on the package.

Product label for cannabis or cannabis oil

56. (1) In this Regulation—

"w/w" means weight in weight

(2) A licensed producer who sells or provides fresh or dried cannabis or cannabis oil shall ensure that a label that contains the following information and the information set out in Sub-Regulation (3), (4) or (5), as applicable, is affixed to the immediate container -

(a) the name, telephone number, physical and email address of the licensed producer;

(b) the words "Fresh cannabis", "Dried cannabis" or "Cannabis oil" (or the equivalent term "Cannabis oil"), as applicable;

(c) in respect of the substance in the container -

(i) its brand name,

(ii) its batch number,

(iii) its recommended storage conditions,

(iv) its packaging date, and

(v) either -

A. its expiry date established in accordance with Regulation 60, or

B. a statement that no expiry date has been determined;

(d) the symbol "N" set out in the upper left quarter of the label in a colour contrasting with the rest of the label or in type not less than half the size of any other letters used on the label;

(e) the warning "KEEP OUT OF REACH OF CHILDREN."

(3) In the case of fresh or dried cannabis , the label shall also contain the following information in respect of the cannabis in the container—

(a) its net weight in grams;

(b) the percentage of delta;9;tetrahydrocannabinol w/w, followed by the word "delta;9;tetrahydrocannabinol";

(c) the percentage of delta;9;tetrahydrocannabinol w/w that the cannabis could yield, taking into account the potential to convert delta;9;tetrahydrocannabinolic acid into delta;9;tetrahydrocannabinol;

(d) the percentage of cannabidiol w/w, followed by the word “cannabidiol”;

(e) the percentage of cannabidiol w/w that the cannabis could yield, taking into account the potential to convert cannabidiolic acid into cannabidiol; and

(f) in the case of fresh cannabis, the dried cannabis equivalency factor determined under Regulation 73.

(4) In the case of cannabis oil that is not sold in a capsule or similar dosage form, the label shall also contain the following information in respect of the oil in the container –

(a) its net weight in grams;

(b) its net volume in millilitres;

(c) the quantity of delta;9;tetrahydrocannabinol, in milligrams per millilitre;

(d) the quantity of delta;9;tetrahydrocannabinol, in milligrams per millilitre, that the oil could yield, taking into account the potential to convert delta; 9; etrahydrocannabinolic acid into delta; 9; tetrahydrocammabonol;

(e) the quantity of cannabidiol, in milligrams per millilitre;

(f) the quantity of cannabidiol, in milligrams per millilitre, that the oil could yield, taking into account the potential to convert cannabidiolic acid into cannabidiol;

(g) the dried cannabis equivalency factor determined under Regulation 73;

(h) the carrier oil used; and

(i) in the case of cannabis oil that is intended for topical use only, the warning **“FOR TOPICAL USE ONLY. DO NOT INGEST.”.**

(5) In the case of cannabis oil that is sold in a capsule or similar dosage form, the label shall also contain the following information in respect of the oil in the container—

(a) the number of capsules or units of that dosage form;

(b) the net weight in grams as well as the net volume in millilitres of each capsule or unit;

(c) the quantity of delta;9;tetrahydrocannabinol, in milligrams, in each capsule or unit;

(d) the quantity of delta;9;tetrahydrocannabinol, in milligrams, that each capsule or unit could yield, taking into account the potential to convert delta;9;tetrahydrocannabinolic acid into delta;9;tetrahydrocannabinol;

(e) the quantity of cannabidiol, in milligrams, in each capsule or unit;

(f) the quantity of cannabidiol, in milligrams, that each capsule or unit could yield, taking into account the potential to convert cannabidiolic acid into cannabidiol;

(g) the dried cannabis equivalency factor determined under Regulation 73;

(h) the carrier oil used; and

(i) in the case of cannabis oil that is intended for topical use only, the warning "FOR TOPICAL USE ONLY. DO NOT INGEST."

Product label for cannabis seeds

57. A licensed producer who sells or provides cannabis seeds shall ensure that a label that contains the following information is affixed to the immediate container—

(a) the name, telephone number, mobile number, physical and email address of the licensed producer;

(b) the words "Cannabis seeds";

(c) in respect of the seeds in the container—

(i) the number of seeds,

(ii) their brand name,

(iii) their batch number,

(iv) their recommended storage conditions, and

(v) their packaging date; and

(d) the information required by Regulation 56 (2) (d) and (e)

Product label for cannabis plants

58. A licensed producer who sells or provides cannabis plants shall ensure that each plant bears a label that contains the following information -

(a) the name, telephone number, mobile number, physical and email address of the licensed producer;

(b) the words “Cannabis plant” ;

(c) in respect of the plant -

(i) its brand name,

(ii) its batch number,

(iii) its packaging date; and

(d) the information required by Regulation 56 (2)(d) and (e) .

Presentation of information on label

59. (1) All information that is required under Regulation 56 and as applicable, to appear on a label shall be —

(a) in English and any other language that may be approved by the Authority***;***

(b) clearly and prominently displayed on the label.

(2) All information in a document that is required under Regulation 56 shall be in English and in any other language that may be approved by the Authority and readily discernible under the customary conditions of use.

Expiry date

60. (1) A licensed producer shall not include an expiry date on a label referred to in Regulation 56 unless —

(a) the licensed producer has submitted data to the Auhority that establishes the stability period during which, after the fresh or dried cannabis or cannabis oil is packaged in accordance with Regulation 53 and when it is stored under its recommended storage conditions referred to in Regulation 57(c)(iv)

(b) the substance maintains not less than 80% and not more than 120% of its delta;9;tetrahydrocannabinol content and cannabidiol content; and

(c) the microbial and chemical contaminants of the substance remain within the limits referred to in Regulation 40;and

(d) in the Authority opinion the data submitted by the licensed producer meets the requirements of paragraph (a) and the Authority has notified the producer to that effect.

(2) For the purposes of sub regulation (1) and Regulation 57(c)(iv), *expiry date* means the date, expressed at minimum as a year and month, that is the end of the stability period.

Reference to Act or Regulations

61. It is prohibited to include a reference, direct or indirect, to the Act or any regulations made under the Act on a label of or in an advertisement for fresh or dried cannabis, cannabis oil or cannabis plants or seeds unless the reference is a specific requirement of either of the Act or those regulations.

Transportation.

62. (1) A licensed producer who transport fresh or dried cannabis or cannabis oil to any person shall-

(a) transport the substance in only one load per order;

(b) prepare the package in a manner that ensures the security of its contents, such that —

(i) it will not open or permit the escape of its contents during handling and transportation;

(ii) it is sealed so that it cannot be opened without the seal being broken;

(iii) it prevents the escape of cannabis odour; and

(iv) it prevents its contents from being identified without it being opened;

(c) use a transporting method that ensures the tracking and safekeeping of the package during transportation; and

(d) transport it only to the following address —

(i) in the case of an authorised recipient or an individual who is responsible for that, the delivery address specified and

(ii) in the case of any other person, the delivery address indicated in the order referred to in Regulation 71; and

(e) in the case of a client or an individual who is responsible for that client, ship the substance in a quantity that does not exceed the equivalent of 150 g of dried cannabis.

(2) A licensed producer who transports cannabis seeds to any person referred shall—

(a) comply with the requirements of sub-regulation (1)(a) to (c); and

(b) transport the package only to the following—

(i) the delivery address indicated in the order referred to in Regulation 71; and

(ii) the address of the site for the production of cannabis plants or the site for the storage of cannabis that is specified in the person's registration with the Authority made under Part II.

(3) A licensed producer who transports cannabis plants to any person shall —

(a) prepare the package in a manner that ensures the security of its contents, such that -

(i) it will not open or permit the escape of its contents during handling and transportation,

(ii) it is sealed so that it cannot be opened without the seal being broken, and

(iii) it prevents its contents from being identified without it being opened;

(b) use a transport method referred to in sub-regulation (1)(c); and

(c) transport it to the address referred to in sub-regulation (2)(b).

(4) A licensed producer who transports cannabis to any person shall—

(a) use a transportation method referred to in sub-regulation (1)(c); and

(b) transport it only to the delivery address indicated in the order referred to in Regulation 71.

Import and Export

63 The import or export of cannabis shall vest in the Authority in terms of section 4quart (5) of the Act.

63. **A licensed producer who wishes to import or export cannabis shall, upon payment of fees specified in the First Schedule, submit an application to the Authority in terms of Section 3 the Opium and Habit- Forming Drugs Act .37 1922.**

Persons authorised to handle cannabis

64. (1) Any of following persons, namely—

(a) a person licensed to do so under the Medicines and Related Substances Control Act of 2016 .

(b) any medical practitioner, dental practitioner or veterinary surgeon;

(c) any pharmaceutical chemist licensed in terms Medicines and Related Substances Control Act 2016 or pharmaceutical chemist or other person -

(i) employed in a hospital, clinic, dispensary or like institution administered by the State or by a local authority, or in any other hospital, clinic, dispensary or like institution approved by the Minister responsible for health.

or

(ii) employed in any medical store of the State;

(d) any person in charge of a laboratory used for the purposes of research or instruction and attached to—

(i) a university, a recognized university college or other educational institution; or

(ii) any hospital referred to in subparagraph (i) of paragraph (c);

(e) any analyst employed by the State; or

(f) any inspector appointed in terms of the Medicines and Related Substances Control Act 2016.

(g) any other person prescribed by the Minister responsible

for justice by the notice in a statutory instrument after consultation with the Minister ; may in that capacity and in so far as is necessary for the practice or exercise of that Person's profession, function or employment, lawfully acquire possess and supply cannabis

(2) A qualified nurse -

(a) in charge of a ward, theatre or out -patients' department in any hospital referred to in sub-regulation (1)(c)(i); or

(b) who -

(i) is employed in a supervisory capacity over two or more wards in any hospital referred to in sub-regulation (1) (c)(i); and

(ii) has been appointed by the medical practitioner in charge of the hospital to be responsible at any time for the distribution of Part I scheduled drugs within the hospital;

may, in that capacity and so far as is necessary for the practice of that nurse's profession, function or employment, lawfully acquire, administer, possess and supply a Part I scheduled drug.

PART VI
RECORD KEEPING

Record keeping by licensed producers

65. (1) Except in the case referred to in regulation 70, a licensed producer who receives cannabis shall record the following information—

(a) the name of the person from whom it was received;

(b) the address of the site at which it was received;

(c) the date on which it was received; and

(d) an indication of which substance was received, as well as the following information -

(i) in the case of fresh or dried cannabis or cannabis oil, the quantity and, if applicable, brand name, or

(ii) in the case of cannabis other than cannabis referred to in subparagraph (i), its quantity, description, intended use and, if applicable, brand name.

(2) A licensed producer who imports cannabis shall retain a copy of the export permit issued by a competent authority in the country of export.

(3) A licensed producer who exports cannabis shall retain a copy of the import permit issued by a competent authority in the country of final destination.

Record keeping by authorised persons

66. An authorized person shall keep records which shall include the following information —

(a) if applicable**,** the given name, surname and date of birth of the authorized recipient for whom the order is placed;

(b) the given name and surname of the individual placing the order;

(c) the quantity, brand name and lot number of the fresh or dried cannabis oil or cannabis plants or seeds sold or provided.

(d) the date on which the order was received;

(e) the date on which the substance was shipped; and

(f) the address to which the substance was shipped.

Manner of keeping records

67. (1) A licensed producer shall ensure that the records, documents and information referred to in this Part are kept in a manner that will enable an audit of them to be made in a timely manner and are available at their site.

(2) A licensed producer shall retain the records, documents and information for the following periods—

(a) in the case of a notice that the producer is required to provide or send under this Part, for a period of five years after the day on which the notice is provided or sent;

(b) in the case of information that the producer is required to record under Regulations 65, and Regulations 66, 69 and 70, for a period of five years after the day on which the information is recorded;

(c) in the case of the visual recordings or the records referred to in Part III, for a period of five years after the day on which they were made;

(d) in the case of the records demonstrating that each batch of fresh or dried cannabis, cannabis oil or cannabis plants or seeds, for a period of five years after the date of the last sale or provision of any portion of the batch of fresh or dried cannabis, cannabis oil or cannabis plants or seeds.

(e) in the case of a document for the period during which it is current and for an additional period of five years after the day on which it is replaced by a new version;

(f) in the case of a document detailing the description of the qualifications of the quality assurance person for the period during which the quality assurance person acts in that capacity and for an additional period of five years after the day on which the person ceases to do so;

(g) in the case of the records of complaint, for a period of five years after the day on which the complaint was recorded;

(h) in the case of the records of any testing conducted by or on behalf of the licensed producer for a period of five years after the date of the last sale or provision of any portion of the batch, other than a sale or provision for destruction;

(i) (i) in the case of the records of the information that the licensed producer is required by Regulation 50 to provide to the Authority in respect of recall of cannabis, for a period of five years after the day on which the substance was recalled;

(j) in the case of the information concerning the method referred to in Regulation 73, for a period of five years after the day on which the information is recorded;

(k) in the case of the records and documents referred to in Regulation 76, for a period of five years after the day on which the cannabis was destroyed;

(l) in the case of a document or record of a request received from a licensing authority, for a period of five years after the day on which the information was provided to the licensing authority;

(3) A licensed producer shall retain the serious adverse reaction case reports and the summary reports referred to in Regulation 50, respectively, for a period of twenty; five1 years after the day on which they were made.

Preservation of records

68. Every licensed producer shall keep or cause to be kept a record of such production for a period of five years and shall preserve such record on the premises in which the production takes place:

Provided that where the premises cease to be used or licensed such person shall make arrangements, acceptable to the Authority, for the preservation or destruction of such records.

Cannabis Inventory

69. (1) A licensed producer shall keep a record of the net weight of each of the following in an inventory at their site at the end of each quarter of the calendar year —

(a) cannabis seeds, other than cannabis seeds referred to in paragraph (h);

(b) harvested cannabis, other than cannabis referred to in paragraphs (e) and (f), that is not to be subjected to a drying process;

(c) harvested cannabis, other than cannabis referred to in paragraphs (e) and (g), in respect of which the drying process has not been completed;

(d) harvested cannabi**s**, other than cannabis referred to in paragraphs (e) and (g), in respect of which the drying process has been completed;

(e) cannabis that is destined for destruction;

(f) packaged fresh cannabis;

(g) packaged dried ***c***annabis;

(h) packaged cannabis seeds; and

(i) cannabis or cannabis oil, with an indication of the name and net weight of each of the substances in question.

(2) A licensed producer shall keep a record of the number of cannabis plants destined to be sold or provided that are in inventory at their site at the end of each quarter of the calendar year.

(3) A licensed producer shall keep a record of the net weight of each of the following that are in inventory at their site at the end of each quarter of the calendar year—

(a) cannabis oil that has not been packaged, other than cannabis oil referred to in paragraph (c);

(b) packaged cannabis oil, other than cannabis oil referred to in paragraph (c); and

(c) cannabis oil that is destined for destruction.

Returned substance

70. A licensed producer who receives fresh or dried cannabi***s***, cannabis oil or cannabis plants or seeds that are returned shall record the following information—

(a) the given name and surname of the person who returned the substance or on behalf of whom the substance was returned;

(b) the address of the site at which it was received;

(c) the name of the substance, its quantity and brand name;

(d) the date on which it was received; and

(e) reason of the return.

Order for export

71. (1) A licensed producer who fills an order for export shall record the following information -

(a) the name of the person to whom the substance was sold or provided;

(b) the shipping address;

(c) an indication of which substance was ordered, as well as the following information -

(i) in the case of fresh or dried cannabis or cannabis oil, its quantity and, if applicable, brand name, or

(ii) in the case of cannabis other than cannabis referred to in subparagraph (i), its quantity, description; if applicable, brand name; and

(d) the date on which the substance was shipped;

(e) the number and date of the import certificate; and

(f) the authority by whom such certificate is issued.

(2) A licensed producer who refuses to fill an order for export shall retain a copy of the written notice of refusal to fill the order.

Security Inventory

72. A licensed producer shall keep —

(a) the visual recordings referred to in Regulations 24 and 29;

(b) the records referred to in Regulations 26(2) and 32(2); and

(c) the record referred to in Regulation 27(3).

Dried cannabis equivalency factor

73. A licensed producer shall keep a record of the information concerning the method that they have used to determine the dried cannabis equivalency factor.

Batch reconciliation

74. (1) A licensed producer shall keep a record of the following information concerning each batch of cannabis that they propagate, sow, harvest, dry, package or destroy -

(a) the date on which cannabis plants are propagated by means other than sowing seeds and the number of new plants propagated in this manner;

(b) the date on which cannabis seeds are sown and their net weight on that date;

(c) the date on which cannabis is harvested and its net weight on that date;

(d) the date on which the drying process for cannabis is completed, if any, and its net weight on that date;

(e) the date on which cannabis is packaged and its net weight on that date; and

(f) the date on which cannabis is destroyed and its net weight on that date, before the destruction.

(2) A licensed producer shall keep a record of the following information concerning each lot or batch of cannabis oil that they produce, package or destroy

(a) the date on which the oil is produced and its net weight or volume on that date;

(b) if applicable, the date on which the oil is put into a capsule or other similar dosage form and the number of capsules or units of that dosage form;

(c) in respect of the cannabis that was used to produce the oil, its description, its net weight or volume, its lot or batch number and the date on which it was produced;

(d) the date on which the oil is packaged and its net weight or volume on that date; and

(e) the date on which the oil is destroyed and its net weight or volume on that date, before the destruction.

Research and development

75. Every licensed producer shall keep a record of the following information concerning cannabis that they use in a research and development activity-

(a) its description, the quantity used, its lot or batch number and, if applicable, its brand name;

(b) the date on which it was used in that activity;

(c) the purpose and a brief description of that activity;

(d) in respect of any product or compound containing that cannabis that they have made or assembled in the course of that activity –

(i) its description;

(ii) the date on which it was made or assembled and the quantity made or assembled;

(iii) if applicable, the date on which it was used for testing and the quantity used;

(iv) .if applicable, the date on which it was placed in inventory and the quantity placed in inventory;

(e) any other details permitting the reconciliation of the quantity of cannabis referred to in paragraph (a) and the quantities of products or compounds referred to in paragraph (d).

Destroyed cannabis

76. (1) A licensed producer shall keep, for each instance in which they destroy cannabis, a record of the following information—

(a) the date on which the cannabis was destroyed, the name of the substance destroyed and its net weight on that date, before the destruction;

(b) the location at which it was destroyed;

(c) a brief description of the method of destruction;

(d) the names of the witnesses to the destruction and the basis on which they are qualified to be witnesses; and

(e) if applicable, the name of the person who accompanied the cannabis to the location at which it is to be destroyed.

(2) A licensed producer shall keep, for each instance in which they destroy cannabis, a statement signed and dated by each of the witnesses referred to in sub -regulation (1) (d) stating that they have witnessed the destruction and that the cannabis was destroyed in accordance with a method that complies with environmental legislation applicable to the location at which it is to be destroyed.

Disposal of cannabis

77. (1) Where cannabis requires to be destroyed the licensed producer shall notify the Authority who shall give directions as to the disposal of the cannabis in terms of section 13 of the Act .

(2) For the purposes of sub-regulation (3) there is hereby established a panel comprising of a police officer of or above rank of a superintendent designated by the Commissioner of Police, a senior customs officer designated by the Eswatini Revenue Authority or an inspector designated by senior customs officer and a senior official of the Ministry responsible for Justice designated by the Attorney General or any person appointed by the Authority.

(3) On a date and time appointed by the Authority, the panel referred to in sub regulation (2) shall attend to the destruction by appropriate means of the cannabis concerned in the full view and presence of each other and shall immediately thereafter, subscribe to and sign a joint declaration attesting to the total destruction of such cannabis, which shall be forwarded forthwith to the Authority.

Adverse reactions

78. (1) In this regulation—

"adverse reaction" means a noxious and unintended response to fresh or dried cannabis or cannabis oil;

"case report" means a detailed record of all relevant data associated with the use of fresh or dried cannabis or cannabis oil by a person;

"serious adverse reaction" means a noxious and unintended response to fresh or dried cannabis or cannabis oil that requires inpatient hospitalisation or a prolongation of existing hospitalisation, that causes congenital malformation, that results in persistent or significant disability or incapacity, that is life threatening or that results in death.

(2) A licensed producer who sells or provides fresh or dried cannabis or cannabis oil or any person referred to in Regulation 64 shall provide the Authority with a case report for each serious adverse reaction to the substance, within fifteen days after the day on which the producer becomes aware of the reaction.

(3) A licensed producer who sells or provides fresh or dried cannabis or cannabis oil shall prepare annually and maintain a summary report that contains a concise and critical analysis of all adverse reactions to the substance that have occurred during the previous twelve months.

(4) If, after reviewing a case report provided under sub-regulation (1) or after reviewing any other safety data relating to the fresh or dried cannabis or cannabis oil, the Authority has reasonable grounds to believe that it may, by reason of the manner in which it was produced, packaged, labeled or stored, pose a risk to the health of a person who in accordance with these Regulations obtains it for their own medical purposes, the Authority may request that, within thirty days after the day on which the request is received, the licensed producer-

(a) provides the Authority with a copy of any summary report prepared under sub ;regulation (2); or

(b) prepares and provides the Authority with an interim summary report containing a concise and critical analysis of all adverse reactions to the substance that have occurred since the date of the most recent summary report prepared under sub-Regulation (2).

Destruction of cannabis after change in production area

79. If a registration is amended or at the time of the renewal to reflect a change in the production area, the person authorised to produce cannabis shall destroy –

(a) any cannabis plants under production that are in excess of the maximum number of plants that may be produced under the registration, as amended; and

(b) any cannabis that they are storing that is in excess of the equivalent of the maximum quantity of dried cannabis that may be stored under the registration, as amended.

Advertisement of Cannabis

80. A person shall not publish, distribute or in any other manner whatsoever bring to the notice of the public or cause or permit to be published or distributed or to be so brought to the notice of the public any advertisement concerning cannabis without the permission of the Authority.

PART VII

GENERAL

Fees

81**.** The fees payable in terms of these regulations shall be the appropriate fee opposite the appropriate item specified in the first column of the First Schedule.

Penalties

82. Any person who contravenes the provisions of these regulations shall be guilty of an offence and liable to a fine not exceeding level XXX or to imprisonment for a period not exceeding xxxxx or to both such fine and such imprisonment.

Appeals

83. (1) Any person who is aggrieved by any decision made in terms of these Regulations may, within thirty days, appeal to the Authority.

FIRST SCHEDULE

(Regulations 2, 4(`1)(a), 14(1)(a, 63 and 81)

Item	Fees
	xxxxx
.Application for renewal of licence to produce cannabis	xxxxx
.Application for renewal of a licence to conduct research on cannabis	xxxxxxx
.Application for variation or amendment of a licence	xxxxxxx
.Application for import/export licence	xxxxxx0
.Inspection	xxxxxx0
.Annual return fees	xxxxxx

SECOND SCHEDULE (Regulation 4(1))

FORM

OPIUM AND HABIT-FORMING DRUG ACT No; 37 of 1922

APPLICATION FOR ISSUE OF A LICENCE FOR PRODUCTION OF CANNABIS

This form is submitted in terms of Regulation 5 (1) of the Opium and Habit; Forming Drugs Act Production of Cannabis for Medicinal and Scientific Use Regulations, 2019.

(*To be submitted in* duplicate)

PART A (*To be completed by individuals and sole traders*)

1. Full name…….

2. Date and place of birth……

3. Gender……..

4. Address (Home)……..

5. Email address……

6. Mobile phone number……..

7. Present place of employment……..

8. Position of applicant at place of employment (e.g. owner, manager, etc.)

PART B ***(To be completed by companies)***

9. If a company: Name of company …….

(a) Physical address……..

(b) Registered Office…….

(c) Email Address……

(d) State shareholders or distribution of shares ……

10. PARTICULARS OF DIRECTORS:

(a)Full names……

(b) Address……

(c)Citizenship……..

(d)Date of Birth……

(e)Gender……

PART C (*To be completed by all applicants*)

11. Name under which business is conducted…….

12. Physical address of premises to be licensed……...

…….

13. Postal address of business…….

…….

14. Telephone/Mobile number of proposed site……

……..

14A. Email address……

15.PARTICULARS OF AUTHORISED PERSON

(a)Full name…….

(b) Date and place of birth……

(c)Gender……..

16. PARTICULARS OF RESPONSIBLE PERSON

(a)Full name…….

(b) Date and place of birth……

(c)Gender …….

17. State the proposed activities……

18. The substances in respect of which each activity is to be conducted……

19. State the building/s within the site where the proposed activities are to be conducted (*if applicable)*

……

……

20. Have you previously held a licence to produce cannabis? YES / NO*……

If YES, give details……

21.Has any application made by you for a licence been refused or cancelled?
YES/NO*……

If YES, give details……..

22. Name and address of nearest police station……

23. Name and approximate distance of nearest residence from premises to be licensed……

24. Particulars and date of any trading or other licence held by the applicant or business…….

25. If an individual:;

(*a*) are you a citizen of, or ordinarily resident in Eswatini?
YES/NO*; (b) if YES supply proof thereof;

(e)Have you within the preceding ten years of this application been convicted inside or outside Eswatini of an offence involving the wrongful dealing in or supply or possession of

cannabis, or of an offence involving dishonesty? YES/NO* (Attach affidavit)

(f) If YES state details…….

26. If a company:;

(*a*) Are the directors of the company or a majority thereof citizens or ordinarily resident in

Eswatini? YES/NO*.....

(b) If YES supply proof thereof;

(c)If NO supply proof of exemption by the Authority;

(d)Has the company or any of the directors of the company within the preceding ten years of this application been convicted inside or outside Eswatini of an offence involving the wrongful dealing in or supply or possession of cannabis, or of an offence involving dishonesty? YES/NO*****(Attach Affidavit)……

(e)If YES state details……

**Delete the inapplicable*

NOTE:

1. Plans of the premises, the appropriate fee, proof of citizenship, residency or an exemption by the Authority, etc, are required to be attached to the application.

2. Copies of original documents must be properly certified.

3. If any plan document or fee required to be attached is not attached, the application cannot be accepted.

4. If insufficient space is provided in the application, attach a sheet of paper with the additional information.

I enclose **the proof of payment of the** fee of

…….

I do hereby declare that the facts herein are fully within my knowledge and to the best of my knowledge are true and correct.

Signature of applicant …… Date……

…….
Name and position of person in the company

OPIUM AND HABIT-FORMING DRUG ACT 1922

LICENCE FOR SITE

PRODUCTION OF CANNABIS FOR MEDICINAL AND SCIENTIFIC USE

Receipt No: Licence No: File No:

1. Licensee:
2. In the case of a company

   Names of Directors *Citizenship*

3. Type of site licensed:
4. Description of licensed site:
5. Location of site:
6. Name of person carrying on business on licensed site:
7. Name of business:

8. Conditions of renewal imposed by the Authority:

9. The site shall, for the purposes of Regulation of the, be under the supervision of the following person (s)

Expiry date of licence:

Date:

Name:

Date of renewal of licence:

Licence Number:

Date:

Minister

THIRD SCHEDULE (Regulation 4(4))

Security Clearance Requirements

Upon an application made in terms of Regulation 4(4), an applicant is required to provide the security requirements for the authorised persons and shall include the information set out below.

1. Date and place of birth

2. Gender

3. Height

4 Certified copy of National Identity Document

5Address (Home)

6 The addresses of all locations at which each of the stated persons resided during the years preceding the application

7An identification of the stated person(s) activities during the five years preceding the application, including the names and addresses of the persons' employers and any post secondary educational institutions attended.

8 The stated persons' fingerprints taken by the Royal Eswatini Police.

9 The full names of the person~~s~~ or spouse~~s~~

FOURTH SCHEDULE (Regulation 49(2))

RECALL

A process for withdrawing or removing cannabis or cannabis product from the distribution chain because of defects in the product, complaints of serious adverse reactions to the product and/ or concerns that the product is or may be counterfeit. The recall might be initiated by the producer or the Authority.

Classification of Recalls

Recalls are classified according to the following system:

3.2.1 Class I recall

Occur when products are potentially life-threatening or could cause a serious risk to health. Examples of Class I Defects ; Wrong Product (label and contents are different products) ; Correct product but wrong strength, with serous medical consequences ; Microbial contamination of sterile injection or ophthalmic product ; Chemical contamination with serious medical consequences ; Mix up of some products with more than one container involved ; Wrong active ingredient in a multi-component product with serious medical consequences ; Lack of effectiveness for a life threating condition.

3.2.2 Class II recall

Occur when product defects could cause illness or mistreatment, but are not Class I. Examples of Class II Defects ; Mislabeling e.g. wrong or missing text or figures ; Missing or incorrect information; leaflets or inserts ; Microbial contamination of non-injectable, non-ophthalmic sterile product with medical consequences ; Chemical/ physical contamination (significant impurities, cross contamination, particulates);

Mix up of products in containers ; Non-compliance with specification (e.g. assay, stability, fill/ weight or dissolution) ; Insecure closure with serious medical consequences (e.g. cytotoxics, child resistant containers, potent products) ; Lack of efficacy/effectiveness for medical condition that is not life threatening.

3.2.3 Class III recall

Occur when product defects may not pose a significant hazard to health i.e. low risk to health but recall may be initiated for other reasons, due to quality, safety or efficacy concerns. Examples of Class III Defects, Faulty packaging e.g. wrong or missing batch number or expiry date.

Class I or Class II recalls are considered to be urgent safety related recalls. They must be reported to the MRA for further evaluation and investigation. Class III recalls are considered to be minimum risk to public health but should however still be reported to the MRA. Note: Each recall is a unique exercise and there may be occasions when the scope of a recall can be narrowed to particular customer groups. The classification is determined by the MRA. Expert advice might be sought where the nature of the hazard or its significant is not clear. Decision made by other stringent regulatory authorities internationally will also be considered.

The Guidelines do not apply to the recall of a medicine, vaccine or medical device related to regulatory issues such as cancellation of registration due to non-payment of retention fees, approved change of applicant, manufacturer, labeling, package insert or other registered particulars. Regulatory issues in which there is lack of compliance to GMP may lead to a recall and/or a cancellation of registration.

3.3 Levels of recall As with classification, the level (or depth) of a recall is to be assigned in agreement with the MRA. In determining the recall level, the principal factors to be considered are the significance of the hazard (if any), the channels by which

the medicine, vaccine or medical device pharmaceutical products have been distributed, and the level to which distribution has taken place. Again, expert opinion may be necessary to determine the significance of the hazard or risk.

There are three levels of recall: wholesale, retail and consumer.

3.3.1 Wholesale level

Includes all parties involved in wholesale distribution and may include wholesalers and retail pharmacies.

3.3.2 Retail level Includes: ; All public and private hospital pharmacies; ; Retail pharmacies; ; Clinical investigators and the institutions in which clinical investigations are performed; ; Medical, dental and other health care practitioners; ; Nursing homes and other related institutions; ; Other retail outlets e.g. medicine shops, supermarkets and health food stores;

NB: In the case where consumers that are known to be in possession of the affected products, a plan should be put in place where specific telephone calls are made to these consumers or recall letters sent to arrange for return of the recalled product.

3.3.3 Consumer level. Includes patients and other consumers.

The following stages shall be followed when initiating a recall:

Recall Stages Regulation

1. Notification to the Authority

Receipt of Cannabis or Cannabis Product Problem Report 1 Information on problem of cannabis or cannabis products

2. Initiation of a Recall 2

Information Required for Assessment of Recall

Information on product, problem and distribution is required

3. Assessment of Recall 3

The classification, level and strategy of recall are determined depending on the potential hazard of the defective product and the extent of product distribution.

4. Recall 4

Letters and press release (if required) are dispatched to relevant firms for notifying on the recall.

5. Progress of Recall and Report 5

Progress reports and final report are submitted to the Authority.

6. Evaluation of the Recall 6

The effectiveness of the recall is monitored by the

Authority 7. Reinstatement of Supply