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LEGAL NOTICE NO. 40 OF 2018

Drugs of Abuse (Cannabis) Regulations, 2018

In exercise of the power conferred on me in terms of section 108 of the Drugs of Abuse Act, 2008: I

NKAKU KABI

Minister responsible for health, make the following Regulations:

Part title and commencement

1. These Regulations may be cited as the Drugs of Abuse (Cannabis) Regulations, 2018 and shall come into operation on the date of publication in the Gazette.

Interpretation

2. In these Regulations, unless the context otherwise requires -

"cannabis waste" - means -

(a) is plant waste, roots, stalks, leaves and stems which are not processed;

solid cannabis sample plant in the possession of an independent laboratory; and

any other waste as may be determined by the Minister.

"certificate of analysis" means a certificate issued by an independent laboratory in accordance with the provisions of regulation 20.

"batch" means a specifically identified quantity of a cannabis dried flower or trim, leaves and any other cannabis plant matter which is uniform in strain and harvested at the same time;

"fence" means a wall or barrier connected by boards, masonry, rails, panels or any other material for the purpose of enclosing a space or sep-

arating a piece of land;

'independent laboratory' means a company registered in accordance with the Companies Act, 2011² and which is licensed by the Minister in terms of regulation 20, to collect and test a sample of cannabis and cannabis resin for analysis purposes;

"manufactured cannabis batch" means an amount of cannabis concentrate or extract which is produced under one production cycle using the same extraction method and standard operating procedure from the same harvest batch.

Purpose

3. The purpose of these Regulations is to control, manage and regulate the cannabis industry by -
- (a) setting out a criteria for an application process to license a person who wishes to engage in the cultivation manufacturing and testing of a cannabis plant for medical or scientific purposes;
 - (b) identifying and providing for qualifications of an operator and condition which are suitable for premises used for an operation of a cannabis business in order to enable an operator to operate the cannabis business in a prudent, safe and secure manner;
 - (c) putting in place effective methods and procedures which will eliminate the diversion from lawful usage of the manufacturing of a cannabis plant for other unlawful usage or non-approved purposes; and
 - (d) setting out standards for testing the quality of cannabis plant intended to be cultivated or manufactured in order to ensure the safety, quality and purity of the product for medicinal human consumption.
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Application

4. . These Regulations apply to a person who wishes to be registered, or licensed to hold an operator cannabis license in terms of the Act.

Licensing

(1) For purposes of sections 1 and 13 of the Act, an operator may be granted one or more of the following three types of licenses:

- (a) an operator's license for entities which are engaged in the activity of cultivation, manufacturing, supply or distribution, storage, export, import or transit within Lesotho, of a cannabis plant for medical purposes or scientific use or for any other lawful use under the Act;
- (b) an independent laboratory license, for operating an independent testing laboratory; and
- (c) a transport license, for purposes of transporting cannabis plant or cannabis resin.

Application for a license

6. (1) An applicant shall, before making an application in terms of Section 11 of the Act, request an initial meeting with the Lesotho Narcotics Bureau here he

- (a) declare his intention to establish a medical cannabis business;
- (b) explain the objective of his company and make a disclosure in relation to his integrity and that of a person who can legally direct the management or policy of the applicant's company without being a shareholder or director and who has the potential and ability to substantially influence the conduct of an activity which an application for a license is made for;

- (c) provide the following documents to prove his capital adequacy in order to satisfy the Minister that he will be able to meet all the requirements of the business:
 - (i) a recent audited financial statements of the applicant and an auditor's report;
 - (ii) a bank statement from a bank approved by the Minister; and
 - (iii) any other relevant and related additional information which the Minister may require.

(2) The Bureau shall, within seven days of receipt of the applicant's request made under subregulation (1), inform the applicant of the date of the initial meeting, which date shall be not more than 45 days from the date of the request.

(3) The Bureau shall, during the initial meeting provide an applicant with an overview of the laws and regulations governing the control of drugs of abuse, environmental issues and the role of the International Narcotics Control Board and the Lesotho Narcotics Bureau.

(4) The Bureau shall explain the criteria for evaluating an application to an applicant during the initial meeting.

(5) The Bureau shall, if satisfied that an applicant has complied with the provisions of subregulation (1), provide the applicant with an application form provided for in Schedule 2.

(6) An applicant shall after he is provided with an application form in terms of subregulation (5), submit the application form to the Minister in accordance with section 11 of the Act and in a manner provided for in Form A of Schedule 1.

(7) An applicant shall for purposes of satisfying the requirements of section 12(a) and (e) to prove that the applicant's management satisfies the criteria of a fit and proper person, comply with the conditions provided for in Form D of Schedule 1.

(8) The Minister shall, within ten working days after receipt of the application form from the applicant, send to the applicant, a -

- (a) letter of acknowledgement, which notifies the applicant that the documents submitted with the application form are complete and the processing and evaluation of the application may commence; or
- (b) letter of deficiency which notifies the applicant that there are some deficiencies identified in the documents submitted with the application and provide a deadline for the rectification of the deficiencies and inform the applicant that application cannot be processed or evaluated until the deficiencies are rectified within ten days.

(9) For purposes of section 12 of the Act, the Minister shall process the application to grant or refuse to grant a license in a form A provided for under Schedule 1 of these Regulations, within forty-five days after receipt of an application from an applicant.

Refusal to grant a license

7. The Minister may, if satisfied that an application submitted in terms of Section 11 of the Act does not meet and fully satisfy the criteria set down in the Act and these Regulations, refuse to grant a license to conduct cannabis business in the Country.

Notification of commencement of operations

8. An operator who has been granted a license to operate a cannabis business in terms of section 12 and regulation 6, shall, thirty days prior to the commencement of operations notify the Minister of the commencement of the cannabis business operations.

Renewal of a license

9. (1) An operator shall, thirty working days prior to the expiration date of a subsisting license, submit an application for renewal of a license to the Minister, in form A provided for in schedule 1.

() The Minister shall, within twenty days of receipt of the renewal license application, approve or refuse renewal of the license.

(3) The Minister shall refuse to renew a license on the following conditions, where -

- (a) a material change in the business of the operator will compromise the quality of the product and increase the risk of unlawful diversion; and
- (b) an application for renewal is made ninety days or more after the expiration of a subsisting license.

(4) Where an operator has failed to submit an application of a license renewal ninety days or more after the expiration of a subsisting license, he shall pay a penalty fee of Five Thousand Maloti.

(5) Where an operator has failed to submit an application of a license renewal within ninety days after expiration of a subsisting license he shall forfeit his eligibility to apply for a license renewal but shall qualify to submit an application for a new license application.

(6) An operator who is applying for a license renewal shall submit any changes to information in their original license on Form C under schedule 2.

(7) An operator who is applying for a renewal license shall submit the following; documents to accompany the application:

- (a) a tax clearance certificate;
- (b) an original copy of the previous license;
- (c) Form C, if applicable and;
- (d) a renewable fee provided for under Schedule 2.

Notice of suspension or revocation of a license

10. . Where the Minister, suspends or revokes a license of an operator in terms of Section 23 of the Act , he shall give the operator -

- (a) a notice which clearly sets out the reasons for the suspension or revocation; and
- (b) an opportunity to be heard in respect of the decision to suspend or revoke the license to operate a cannabis business.

Notice of material change

11. (1) For purposes of section 22 of the Act , an operator shall, after every appointment or removal of a person in the management of the operator's business and within fifteen days of such appointment or removal, notify the Minister of the appointment or removal in a manner provided for in Form C of Schedule 1.

(2) The notice submitted to the Minister in terms of subregulation (1) shall be accompanied by a -

- (a) valid police clearance; and
- (b) personal declaration in a manner provided for in Form E of Schedule 1.

Qualifications for officers engaged in the Cannabis business

12. (1) For purposes of section 12(e) of the Act , an operator shall employ a person in his cannabis business only if the person -

- (a) is above the age of eighteen years;
 - (b) has not been convicted of a serious offence;
 - (c) is not a drug addict, is not undertaking and has not undertaken treatment for drug addiction; and
-

- (d) does not have a history of illicit drug use or a conviction for a drug related offence.

(2) An operator shall ensure that an employee who is employed by him where an activity is carried out of operating a cannabis business and for purposes of preventing abuse of cannabis and diversion from the lawful trade -

- (a) goes through security checks when entering the premises;
- (b) undergoes regular drug testing;
- (c) provides proof of identification when entering the premises; and
- (d) complies with the above at all times;

(3) A person who supervises an activity of -

- (a) **manufg** a drug of abuse qualifies to be a supervisor of **emarr** **:-i:be** -
 - (i) as a degree in Pharmacology;
 - (ii) is registered by the Medical, Dental and Pharmacy Council of Lesotho or an equivalent of that body in other jurisdictions recognised by the Council; and
 - (iii) has at least eight years' experience in the related field;
- (b) independent laboratory testing of a drug of abuse, qualifies to supervise the testing, if he has a -
 - (i) bachelor degree in physical sciences and at least ten years relevant experience; or
 - (ii) master's degree in physical sciences and at least five years relevant experience; or

- (c) cultivation of a drug of abuse, qualifies to supervise the cultivation if he is certified as a Master Grower and has at least ten years relevant experience.

Procedure for inspection of premises

13. (1) Where an inspector takes samples for the purpose of testing or analysis from a manufacturing premise in terms of section 66U, he shall intimate the purpose in writing and the sample shall be divided in three portions and treated as folio

- (a) one portion shall be retained by the operator who the sample is taken from;
- (b) a second portion shall be sent to the government or an independent laboratory for analysis; and
- (c) a third portion shall be kept in the custody of the inspector.

(2) An inspector shall ensure that a sample taken in terms of sub-regulation (1) is packed, fastened sealed and transported in accordance with the instructions on the label of a cannabis product.

(3) A sample taken for purposes of testing or analysis shall be considered as fastened sealed if it is packed in a container or package which protects the contamination and is marked with the name and address of the person from whom the sample is taken in such a manner which prevents the name and address and the opening of the container, without breaking the seal or package.

(4) If the sample fails the test, the batch shall be treated in the similar manner as a failed batch in terms of Regulation 20.

Security arrangements and requirements for premises

14. (1) For the requirement provided for under sections 9(c) and (d) 11(d), (e), (f) (g) and 12(2)(a) of the Act, applicant for a license to operate a cannabis business, shall develop and implement a security plan.

(2) A security plan provided for under subregulation (1) shall include a description of the security measures to be taken to -

- (a) prevent access to the manufacturing premises by an unauthorized person and protect the physical safety of employees through -
 - (i) establishing physical barriers which will secure perimeter access and all points of entry into a cultivation and manufacturing premise in order to lock primary entrances with commercial grade, non-residential door locks or providing fencing around the ground which has to be at least two metres in height and secured by a gate to prevent an authorized entry, to a driveway and any secondary entrances, including windows, ropes or ventilation system;
 - (ii) installation of a security alarm system which will notify; and record any incident where physical barriers are breached;
 - (iii) establishing an identification and sign in or sign out procedure for an authorized person, a supplier or visitor;
 - (iv) maintaining the premises to enable the visibility and security of monitoring the premises; and
 - (v) establishing procedures for the investigation of suspicious activities.
- (b) prevent the theft or loss of cannabis and cannabis products by -
 - (i) establishing an inventory system to track a cannabis product and a person responsible for processing it throughout the manufacturing process;

- (ii) limiting access of any person within the premises to an area which is considered necessary to complete the designated job duties and to time schedules specifically stipulated for completion on the job duties;
 - (iii) supervising tasks or processes with high potential for diversion, including the loading and unloading of cannabis transportation vehicles;
 - (iv) providing any designated area in which a personnel may store and access personal items; and
 - (v) having armed security guards at the entrance of the premises;
- (c) secure and back up electronic and hard copy records in a manner which prevents unauthorised access and ensures that the integrity of the records is maintained.
- (d) install a video surveillance -
- (i) at a licensed premises with a minimum camera resolution of 1280x1024 pixels which is capable of recording all pre-determined surveillance - an_ lighting conditions;
 - (ii) which is capable of supporting remote access by an operator;
 - (iii) in a manner which prevents intentional obstruction tampering or disabling; and
 - (iv) to the following areas which are to be recorded on the video surveillance system, an area:
 - (aa) where a medical cannabis or a medical cannabis product is weighed, packed, stored, quarantined, loaded or unloaded for transportation, prepared or moved

within the premises;

- (bb) where a medical cannabis is destroyed;
 - (cc) which has limited access;
 - (dd) which has security rooms;
 - (ee) which contains as surveillance system storage device where at least one camera shall record an access point to the area; and
 - (ff) which includes the interior and exterior of all entrances and exits to the premises.
- (e) to record continuously 24 hours per day at a minimum of twenty frames per second.
 - (f) detect recording and monitoring equipment shall be located in a secure room or area of the premises an access-controlled environment.
 - (g) determine which recording shall be kept on the operations recording device for a minimum of thirty days;
 - (h) determine which recordings shall be subject to inspection by an inspector which shall be copied and sent to the Minister upon request;
 - (i) ensure that those video recordings display the current date and time of the recorded events and which displayed date and time shall not significantly obstruct the view of the recorded images.

Manufacturing premises

For purposes of section 12(c) of the Act an operator shall, ensure a place
CEK where or in which the activity to be undertaken is in a fit and appropriate
 condition - b_ -

- (a) providing an adequate space for placing of equipment and storage of materials which are necessary for maintenance, sanitary operations and the production of safe cannabis products;
- (b) taking adequate precautions to protect product ingredients in installed outdoor bulk vessels by any effective means which -
 - (i) use protective coverings;
 - (ii) control areas over and around the vessels in order to eliminate harborage for pests; and
 - (iii) check the vessels on a regular basis for pests and pest infestation;
- (c) constructing floors, walls and ceilings which are adequately cleaned, and are in good repair;
- (d) constructing a drip or condensate from fixtures, ducts and pipes which will prevent contamination of the cannabis products, cannabis product contact surfaces or cannabis product packaging material;
- (e) constructing a wide and unobstructed aisle or working space between equipment and a wall which permits employees to perform their duties and protect against the contamination of cannabis product contact surfaces or cannabis product packaging materials through clotting or personal contact;
- (f) providing adequate lightening in hand-wash areas, dressing and locker rooms and toilet facilities, in all areas where a component or cannabis product is examined manufactured processed, packed or held and in all areas where an equipment or utensils are cleaned;
- (g) providing a shatter-resistant light bulb, fixtures, skylights or other shatter, resistant glass fixture in all areas where glass breakage may result in the contamination of exposed cannabis components or products at any step of preparation;

- (h) providing adequate ventilation or control equipment to minimize dust, odours and vapours, including steam and noxious fumes in areas where they may cause allergen cross-contact or contamination of cannabis products, locate and operate fans and the air-blow equipment, in a manner that minimises the potential for an allergen cross contact and the contamination of cannabis product, cannabis product-packaging materials and cannabis product control surfaces;
- (i) providing where necessary, an adequate screening or other protection against pests;
- (j) having a quality control ^{1. a) or a} if qualified staff and appropriate equipment to of materials and the finished products and quali _ - shall not be under the production uni- and
- (k) having adequate separate storage areas ~~or~~ rejected or recalled intermediate or finished product.

Cultivation

16. (1) An operator shall be granted a license under section 12 of the Act in accordance with the following terms and conditions he shall ensure that -

- (a) an area for cultivation of a cannabis plant is secure in order to prevent unauthorized entry by providing a secure locking mechanism which shall remain locked at all times;
- (b) the process and procedure of cultivating a cannabis plant is not and has no prospects of affecting the health, safety or general welfare of a person residing at, near or around the cultivation area or site caused by creation of dust, glare, heat, noise, noxious gases, odour, smoke, traffic or vibrations through use or storage of hazardous materials, processes, products, waste or in any other harmful manner;

-
- (c) a structure used for cultivation of a cannabis plant contains adequate ventilation air filtration and odour control filters to prevent odour mold and mildew in or around an area -
 - (i) used for cultivating cannabis plant;
 - (ii) designed or intended for human occupancy; or
 - (iii) adjacent to the area cultivating a cannabis plant.

(2) When an operator cultivate a cannabis plant, he shall ensure that during the cultivation process -

- (a) the soil used for cultivating the cannabis plant is not contaminated with sludge, heavy metals, pesticides residues or any other chemical;
- (b) the manure applied is thoroughly composted and is devoid of carnivore faeces;
- (c) irrigation is effectively supervised, controlled, and carried out in accordance to the specific needs of the cannabis plant;
- (d) the water used for irrigation does not contain any contaminants such as faeces, heavy metals, pesticides and toxicology hazardous substances.

(3) An operator shall, observe and comply to the following conditions; during the harvesting of a cannabis plant, that the -

- (a) harvesting is done during the period or stage when the cannabis plant has reached the best quality for the intended use;
 - (b) harvest takes place under the best possible condition which avoids wet or extremely high air humidity;
 - (c) other species or cannabis variety is not mixed with the
-

harvested cannabis;

- (d) harvested cannabis does not come into direct contact with the soil; and
- (e) harvested cannabis is immediately after the harvest is delivered to the processing facility in order to prevent the mal degradation.

Manufacturing

17. An operator shall develop a manufacturing operation procedure when manufacturing a cannabis product, which will ensure that compliance and implementation of -

- (a) a manufactured cannabis product, is conducted under conditions and controls which minimize the potential growth of micro-organisms allergen cross-contact, contamination of a cannabis product and a deterioration of the cannabis product -
- (b) a cannabis product capable of supporting the rapid growth of undesirable micro-organisms, is held at a temperature which prevents the cannabis product from being adulterated during the manufacturing, processing, packing and holding ;
- (c) sterilizing irradiating, pasteurizing, cooking, freezing, refrigerating, controlling or controlling water activity measures which is undertaken to destroy or prevent growth of undesirable micro-organisms, is adequate under the conditions of manufacturing, handling and transferring, to enable the prevention of the cannabis product from being adulterated;
- (d) work in process is handled in a manner which protects against an allergen cross-contact, contamination and growth micro-organism;
- (e) effective measures taken are made in order to protect a

finished cannabis product from allergen cross-contact and contamination by raw materials, any other ingredients, rejected components or refuse;

- (f) unprotected raw materials, any other ingredients, objected components or refuse, is not handled simultaneously within a receiving loading or shipping area if the handling will result in allergen cross-contact or a contaminated cannabis product;
- (g) a cannabis product transported by a conveyer is protected against allergen cross-contact and contamination;
- (h) an equipment, a container and utensil used to convey, hold or store a raw material and any other ingredient, work in process or other cannabis product, is constructed, handled and maintained during manufacturing, processing, packing and holding in a manner which protects against contamination of other: cannabis product;
- (i) adequate measures are taken in order to protect against the inclusion of metal or another extraneous material in a cannabis product;
- (j) an adulterated cannabis product, raw material and other ingredients - disposed of in a manner which protects against the contamination of another cannabis product;
- (k) washing, peeling; trimming, cutting, sorting, furling and inspecting, mashing, dewatering, cooling, shredding, extruding, drying, whipping, defatting and forming steps, is performed in a manner which protects a cannabis product against allergen cross-contact, and contamination;
- (l) a cannabis product is protected from a contaminant which may drip, drain or be drawn into the cannabis product;

- (m) heat blanching, when required in the preparation of a cannabis product, which is capable of supporting a microbial growth, is effected by -
 - (i) heating the cannabis product to the required temperature;
 - (ii) holding th temperature for the required amount of time; and
 - (iii) rapidly cooling the cannabis product or passing it to subsequent manufacturing without any delay;
- (n) growth and contamination by thermophilic micro-organisms in blanchers, is minimized by the use of adequate operating temperatures and periodic cleanly and sanitation;
- (o) batters, breading, sauces, gravies dressing, dipping solutions and any other similar preparations, which are held and used repeatedly over a period of time are treated or maintained in a manner which -
 - (i) protects them against allergen cross-contact and contamination; and
 - (ii) minimizes the potential growth of undesirable orgaisms;
- (p) the performance of filling, assembling, packaging and related operations, is conducted in a manner which protects the cannabis product against allergen cross-contact, contamination on growth of undesirable micro-organisms;
- (q) a cannabis product which relies mainly on the control of water activity in order to prevent the growth of an undesirable micro-organism, is processed and maintained at a safe moisture level;

- (r) a safe moisture level for an edible cannabis product is related to its water activity (aw);
- (s) a water activity, (aw) is safe for a manufactured cannabis product if its data is available to demonstrate that at or below the given water activity, the manufactured cannabis product is not supporting the growth of an undesirable micro-organism; and
- (t) when using ice on a cannabis product, the ice is freezeed using safe running water which has the suitable temperature and adequate sanitary quality.

Record keeping

18. (1) An operator who is engaged in a manufacturing, transportation and testing of cannabis business shall keep written records in a manner provided for in form F.

(2) An operator of a cannabis product shall establish and maintain for purposes of preventing unlawful diversion of lawfully manufactured cannabis an inventory and a record of the following -

- (a) an identity of the received cannabis product and a number or product number of the received cannabis product if they are used by the supplier;
- (b) a name of the supplier or vendor from which a shipment was received;
- (c) an original batch, lot or control number of a cultivation, processing manufacturing operation;
- (d) an original cultivation, processing or manufacturing operation where applicable;
- (e) a date and receipt of the received cannabis product; and
- (f) a method of a shipment delivery and a name of a commercial or private carrier.

(3) An operator who operates a manufacturing operation shall keep a record of the following information relating to the manufacturing of a cannabis plant -

- (a) a batch, lot or other control number which is assigned by a manufacturing operator of the shipment;
- (b) an inspection undertaken, a sample used for testing and an examination performed on a batch or lot and the findings and conclusions found from the inspection, sample, testing and examination;
- (c) any treatment, reprocessing or other deviation performed during by the operation on the batch or lot prior to use;
- (d) any disposition made by any control employee, of the batch or lot which includes the date, signature of the person responsible for accepting, rejecting the batch or lot and any processing or any other deviation performed on the batch or lot;
- (e) the use of a batch or lot which is produced and shall include -
 - (i) the quantity used and the unit of measuring the quantity;
 - (ii) the control number of the name, batch, lot or any other control number of a product batch within which the batch or lot is used;
 - (iii) the initials of a person who is responsible for removing the necessary quantity for use in the designated batch from the storage where the batch is kept.

(4) Any portion of the batch or lot which is returned from production to the storage which shall include -

- (a) the quantity returned and the unit of measure;

- (b) a name, batch, lot or any other control number of the batch or lot from which the portion is returned; and
- (c) the initials of a person responsible for verifying the quantity returned.

(5) An portion of the batch or lot which is disposed of from storage shall include the -

- (a) quality;
- (b) unity of measure;
- (c) reason; and
- (d) a person who is responsible for measuring the quantity.

(6) An inventory or record kept by an operator shall, when required, be made available to and inspector or an authorised law enforcement official for inspection or photocopying for a period of five year following the disposition of the cannabis product.

(7) Where a record or inventory is kept in terms of subregulation (6) at -

- (a) an inspection. ite or at a place where it can be retrieved b - a computer or other electronic means, it shall be read- il- aYailable for an authorised inspector; and
- (b) at a central location it shall be available for an authorised inspection within two working days of the request made by an authorised inspector or any authorised law eri- forcement official.

(8) An operator shall keep and make the following documents avail- able upon request made to an inspector or any law enforcement officer -

- (a) a valid licence to operate a cannabis industry issued by the Minister;

- (b) a valid permit or other approval issued by the Minister;
- (c) a premises diagram;
- (d) a shipping manifest ; and
- (e) a record of information for each employee employed by the operator which shall include the employee's qualifications, training, procedures and logs.

(9) The records kept in terms of subregulation (e) shall be maintained in a manner which is accessible upon request to an inspector or any authorised law enforcement official for a period of two years except that outdated standard operating procedures shall not be accessible for on-site employees.

(10) After the expiration of two years, records may be maintained by an operator in an alternate manner, provided the records may be made available to the Minister or an enforcement agent no later than forty-eight hours following a request and the records shall be retained for a total period of seven years.

(11) A record kept in accordance with this regulation shall be written in English or Sesotho.

Seed-to-Sale tracking.

19. (1) An operator is required to have in his premises where a cannabis plant is cultivated or manufactured, a seed-to-sale tracking system which will capture data throughout the cannabis supply chain from an individual plant through to harvesting; processing and distribution to prevent diversion of the product into the illegal market.

(2) An operator shall record and ensure that the cannabis waste material is identified, weighed and tracked while it is on the licensed premises and disposed of or deposited in accordance to the Act.

(3) The seed-to-sale tracking provided for under subregulation (1) shall be capable of reconciling inventories for all on premises and in-transit cannabis or non-manufactured cannabis products every month.

(6) An independent laboratory shall, in addition to tests made under subregulation (1), test samples for purposes of laboratory analysis for measurements of the following contaminants -

- (a) heavy metals which include -
 - (i) mercury;
 - (ii) lead;
 - (iii) cadmium; and
 - (iv) arsenic;
- (b) foreign material or related adulterant;
- (c) microbiological impurity, which includes -
 - (i) total aerobic microbial count (TAMC);
 - (ii) total coliform count (fCC);
 - (iii) total yeast mold count (YMC);
 - (iv) aflatoxin B₁, B₂, G₁ and G₂; and
 - (v) ochratoxin A;
 - (vi) pesticide residues;
 - (vii) residual solvent for extra and concentrates; and
 - (viii) any other contaminant which an operator may request to be tested.

(7) An independent laboratory shall within two working days the completion of the analysis issue a certificate of analysis to an operator for each sample of batch that it tests.

(8) A certificate of analysis issued under subregulation (4) shall contain the following information -

- (a) an operator's details, which include the name, mailing address, physical address and cannabis cultivation or manufacturer's license number;
- (b) a licensed independent laboratory's name, mailing and physical address;

- (c) a sample, identifying information which includes a matrix type and unique sample identifiers;
- (d) a sample history which includes the date -
 - (i) when the sample was collected;
 - (ii) when the samples were prepared and analysed;
- (e) test methods which are used to analyse -
 - (i) cannabinoids;
 - (ii) residual solvents;
 - (iii) pesticides;
 - (iv) microbiological contaminants;
 - (v) mycotoxins ;
 - (vi) heavy metals and;
 - (vii) where applicable, terpenes and
- (f) the signature of an authorised person who made the analysis .

(9) An independent laboratory shall notify the Minister within twenty-four hours of completion of testing , if the sample of a batch or the sample of a manufactured cannabis batch is found to have contaminants in levels exceeding those established as permissible under Schedule 3.

(10) If the batch or the manufactured cannabis batch is found to have contaminants in levels exceeding those established as permissible under the schedule 3 of these Regulations , then it shall be considered a failed contaminant testing.

(11) A batch that fails shall be destroyed by the operator in the presence of an inspector unless it can be remediated.

(12) A failed manufactured cannabis batch shall be destroyed in the presence of an inspector.

Labeling and packaging

21. (1) An operator shall ensure that a cannabis product is protected

against allergen cross-contact, contamination and growth of undesirable micro-organisms by adhering to the following package requirements -

- (a) the package shall not expose the product to any toxic or harmful substance;
- (b) the container within which a cannabis product shall be sealed in a manner where it cannot be opened without obvious destruction of the seal; and
- (c) the container within which a cannabis product is contained in, shall be labeled in a manner that provided for under subregulation (2).

(2) A label used on a package which contains a cannabis product shall have the following information -

- (a) the name of the operator and his cannabis plant license number;
- (b) the product identity matrix;
- (c) the product sample identity;
- (d) the date on which the product was made;
- (e) the net weight or volume of the product;
- (f) the concentration or amount by weight or volume of THC and CBD; and
- (g) the name of the independent laboratory - which performed a test, an associated batch number and a test analysis date.

Cannabis waste management

22. . An operator shall store, manage and dispose of any solid or liquid cannabis waste in accordance with the following requirements -

-
- (a) a cannabis waste shall be disposed of in a secured waste receptacle or in a secured area on a licensed premise, designated by the Minister as a cannabis waste disposal area;
 - (b) the cannabis waste which is processed with a solvent or solvent waste, shall be disposed of as a hazardous waste in accordance with the applicable law;
 - (c) the cannabis waste shall be in a non-usable and non-recognizable condition before it is delivered to a secure waste receptacle or secured area on the licensed premises designated as a cannabis waste disposal area by the Minister;
 - (d) for purposes of sub-paragraph (c), a method used to render the cannabis waste to be in non-usable and non-recognizable condition is -
 - (i) through a grinding and incorporation of the cannabis waste with compost or non-compost waste so that the result mixture is a least fifty percent non-cannabis waste by volume; or
 - (ii) any other method which may be approved by the Minister before it is used by an operator.
 - (e) a cannabis waste shall be weighed, recorded and entered into an inventory system by an operator before it is classified as non-usable;
 - (f) the process of disposal of a cannabis waste shall be performed by an inspector under video surveillance; and
 - (g) an electronic documentation of the disposal and destruction of a cannabis waste shall be kept for a period of not less than five years.

Transportation

23. (1) An operator shall deliver a cannabis product only through a cannabis transport operator who is licensed to carry on the transportation of a cannabis product between operators.

(2) A cannabis transport operator shall ensure that the following requirements are fulfilled during transportation of the cannabis product -

- (a) the cannabis product shall be contained within an intruder-resistant physical barrier;
- (b) the cannabis product shall be contained in a tamper-evident container or packaging;
- (c) the cannabis product shall have a physical intruder detection system which monitors and records its activity;
- (d) the consignment of a cannabis product shall be marked in a manner which does not identify its contents;
- (e) an operator shall put in place measures which can easily trace and readily identify a person who has custody of the cannabis product at every stage during transportation;
- (f) a cannabis transport operator shall keep a transportation log documenting the chain of custody for each delivery made which shall include driver's names and vehicles involved in each delivery; and
- (g) an employee of the cannabis transport operator shall be the only passenger accompanying the driver in a vehicle transporting a cannabis product.

(3) A vehicle used for transporting a cannabis product shall be considered as a licensed premise for cannabis industry and is subject to inspection in accordance to the provision of the Act and these Regulations .

(4) A cannabis transport operator shall have insurance to cover the cannabis products in transit in a case where an accident, theft or any form of destruction of the cannabis product may occur.

Import and export of a Cannabis product

24. (1) An operator who wishes to import a cannabis seed or export a cannabis product, shall make an application for an importation, exportation or transportation permit issued in accordance with the provisions of sections 14 and 15 of the Act, in a manner provided for in Form B of Schedule 1 and shall be accompanied by an application fee prescribed under Schedule 2.

(2) The Minister shall issue Import, Export and Transport Permit in the manner provided for in Form B 1, Form B2 and Form B3 of Schedule 1.

(3) An import or export permit issued under the Act is valid for facilitation, only one consignment.

(4) Notwithstanding subregulation (2) an import or export permit is valid for two months from the date of issue.

(5) An import or export permit is valid only at a port which is specified on the permit.

(6) An imported seed shall be accompanied by a phytosanitary certificate and an international orange certificate of the International Seed Testing Association and shall meet Lesotho quarantine requirements provided for in applicable law.

DATED:

ncAKIJ K.ABI
MINISTER OF HEALTH

NOTE

1. Act No. 5 of 2008
2. Act No. 18 of 2011

SCHEDULE 1

FORM A (REGULATIONS 6(5), (6), (8), (9) AND 9(1))

APPLICATION FOR CANNABIS LICENSE UNDER DRUGS OF
ABUSE ACT 2008

PART 1

1. License type:

License/ Permit	Commercial Use	Research	Individual use	Code
			1-5 6-14 15-20	

A: Licence for Cultivation

B1. Pharmaceutical
ProductsB: Licence for Manufacturing B. Infused nutritional
ProductB3. Extraction & Processing
of APIs

C: Licence for Testing (Independent Laboratory)

D: Operator Licence (Cultivation, Manufacturing, supply
or distribution of cannabis, cannabis resin, extracts and man-
ufactured products transportation of cannabis)E: License for research D1: Clinical trials
D2: Seed Bank
D3: Other

F: License for transportation of cannabis

G: License for storage

H: License for supply

Application N: New R: Renewal
 Ownership C: Company CC: Corporation P: Partnership SP: Sole
 Proprietor

PART 2

2. Applicant Details:

Name And Surname
 Position held
 Date Of Birth
 Phone Number
 Email Address
 Postal Address

3. Business information:

Name of business
 Business number
 Physical Address
 Phone number

4. Manufacturing activities:

Extraction of cannabis oil and / or resin	Packaging product into final product
ing purification of ab.	Export of manufactured product
Supply of manufactured cannabis to others	Laboratory analysis of extracts & products
Research	Labelling of products
Cultivation of cannabis	Other activities

Site Information

Site physical address

Land identification

Site area (hectares)

Is land owned by applicant? YES NO

Is land leased by the applicant? YES NO

6. Attachments

- (a) Certified Copy Of Passport
- (b) Certified Copy Of ID
- (c) Business extract, certificate of incorporation
- (d) Sub-lease agreement
- (e) Map of the proposed site
- (f) Proof of capital adequacy
- (g) Off take agreement or letter of intent where applicable
- (h) Site plan showing how the land will be used for the proposed licensed activities
- (i) Floor plan of the premises and facilities where the proposed licensed activities will be undertaken
- (j) Prescribed application fee
- (k) Record keeping plan
- (l) Security arrangements plan that will be implemented at the premises
- (m) Security plan for transportation
- (n) Form E

7. Personnel Requirements

NAME AND SURNAME
DATE OF BIRTH
COMPANY NAME

IDENTIFICATION

BIRTH CERTIFICATE
WORK PERMIT

PASSPORT/ID
DRIVE's LICENSE

PREVIOUS NAME (if applicable)
POSITION HELD IN COMPANY

CONTACT DETAILS

Email Phone Number

Residential address

POLICE CLEARANCE
Convictions

Attach copy / certified copy

Penalties
Revocations , suspensions relating
to prohibition / regulation of drugs

Qualifications

Resume

Bank statement

Signature

PART 3

2.1 **Security arrangement details**

Description	Yes	No
Measures that will be in place to prevent unauthorized persons entering the site where licensed activities are proposed to occur by fencing		
Gates to block access		
Visitors policy		
Sign in/out registers		

Monitoring of security officers

IT administrators, including audits of access.

Is there shrubbery immediately against fences?

Are there no large objects stored near access points?

Outdoor cultivation should have 2 layers of fencing

Indoor cultivation should have a separate room that is secure and locked

Bins should be kept in a locked room or within multiple layers of fencing

A safe, vault or strong room depending on the volume of Cannabis to be stored, and additional access controls into such space. - be considered

The site should be void of signs that identify the commercial business.

Cannabis should not be visible from the perimeter.

A physical separation of office space from cannabis cultivation and production sites

CCTV

Motion sensors.

Alarm system.

Schedule of Regular testing of security systems and drills

No external signage or symbols on vehicles or other items that would indicate that cannabis is being transported.

Access logs

IT systems to back up CCTV recordings.

Staff rotation or scheduling policy and Training for staff involved in the process.

Daily procedures for checking inventory and cross checking by a second person

Policies and procedures for staff management and referral to law enforcement.

Registers with signatures and names to record people who handle cannabis

A back up location for storage of cannabis that complies with site security expectations and Security bags or pouches.

PROCEDURES

SOP

Procedures for transfer and receipt of the cannabis.

Procedures to validate tamper evident packaging along chain of custody.

Plant stock takes and mortality registers.

Procedures that control and document the transfer testing, or cloning of plants

Standard operation procedures around destruction including storage and transport of material to destruction

Procedures for cleaning equipment between tasks or moving to another site

Designated waste bins for cannabis with procedures for emptying . .

Procedures for reporting when cannabis is exchanged and responsibility is securely transferred.

Procedures that outline the point in time where someone accepts responsibility for the cannabis.

Procedures to reconcile inventory when cannabis is handed from one to another.

Reporting procedures for incidents and Procedures for updating the recipient of deliveries to the deliveries arrival.

Procedures to verify tamper proof packaging/seals on containers.

Procedures to respond to alarms, regular and random checks of access logs, and review of CCTV footage

TRANSPORTATION

In transit, cannabis is packed in a secure locked receptacle within a secure locked room.

SCHEDULE I

FORM BI (REGULATION 24 (2))

MINISTRY OF HEALTH
PERMIT TO IMPORT CANNABIS SEEDS,

Issued under the provisions of Drugs of Abuse (Cannabis Cultivation) Regulations 2018

LICENCE NO. _____ PERMIT NO. _____

DATE OF ISSUE: — — VALIDITY PERIOD: _____

NAME: _____

PHYSICAL ADDRESS: _____

TO IMPORT INTO LESOTHO _____ KILOGRAMS OF CANNABIS SEEDS IN TERMS OF SECTION 15 OF DRUGS OF ABUSE ACT 0. OF W08 AND SUBJECT TO CONDITIONS STATED HERE UNDER.

NAME, ADDRESS AND LICENCE NUMBER OF SUPPLIER

CONDITIONS:

That the Cannabis seeds imported shall not be used otherwise than for medicinal and scientific purposes.

That the Cannabis Seeds should not be sold or supplied to some other person other than the applicant

The seeds are accompanied by a phytosanitary certificate

Upon entry into Lesotho, a representative of Lesotho will inspect the seeds

The permit is valid for one consignment

SIGNATURE

Official stamp

Designation:

SCHEDULE !

FORM B2 (REGULATION 24)

MINISTRY OF HEALTH
PERMIT TO EXPORT CANNABIS PRODUCTS (SECTION 16)

Issued under the provisions of Drugs of Abuse (Cannabis Cultivation) Regulations 2018

LICENCE NO. _____ PERMIT NO. _____

DATE OF ISSUE: _____ VALIDITY PERIOD: _____

PERMISSION IS HEREBY GRANTED TO:

NAME OF EXPORTER _____ of

(Physical address) _____ to export
_____ kilograms of Cannabis Products in terms of Section 15 of the Drugs of Abuse Act
No. 5 of 2008 and Subject to Conditions stated hereunder.

DETAILS OF IMPORTER

Name:

Licence Number:

Intended point of entry in a foreign state of import:

CONDITIONS:

That the Cannabis Product imported shall not be used otherwise than for medicinal and scientific purposes.

The permit is valid for one consignment

SIGNATURE:

Official stamp

Designation:

SCHEDULE 1

Form B3 (REGULATION 23)

MINISTRY OF HEALTH
PERMIT TO TRANSPORT,

Issued under the provisions of Drugs of Abuse (Cannabis) Regulations 2018

LICENCE NO. _____ PERMIT NO. _____

DATE OF ISSUE: _____ VALIDITY PERIOD: _____

NAME:

PHYSICAL ADDRESS:

TO TRANSPORT WITHIN LESOTHO THE FOLLOWING SUBSTANCE:

4. Substance details

Substance name: _____ International non-propriety name: _____

Pack type and size: _____

Volume: _____ The quantity : _____

NAME, ADDRESS AND LICENCE NUMBER OF WHERE THE PRODUCT IS DESTINED

CONDITIONS:

The permit is valid for one consignment

SIGNATURE

Official stamp

Designation:

SCHEDULE I**FORM C (REGULATION 9(6)(c) and 11(1))****NOTICE OF MATERIAL CHANGE (SECTION 22)****NAME OF OPERATOR****LICENCE NUMBER****PARTICULARS OF
MATERIAL CHANGE****Record of Actual Changes**

- (a) Name or address of the Operator or its Management both Executive and Non-Executive
- (b) Address of the Place or Premises where:
 - (i) The licensed or permitted activity is carried out
 - (ii) Any drug of Abuse, controlled chemical equipment or material is stored
- (c) Raw materials, or manufacturing or denaturing processes used in the licenced manufacture of any drug of abuse
- (d) Security arrangements implemented in any relevant address
- (e) Identity of person under whose supervision the licenced activity is carried out
- (f) Planned transport route, including the planned point of entry or exit from Lesotho of any export or imports

Signature**Date:**

*The form must be submitted within 14 days of the material change occurring

*Attach documents relating to the details of the material change

*The information contained herein may lead to revocation or suspension of the Licence in terms of section 23 of the Act.

*Any false entry in this form may lead to conviction of not less than 2 years or a fine not less than M 2,000 or both in terms of section 39(2) of the Act.

SCHEDULE 1

FORM D (REGULATIONS 6 AND 7)

Fit and Proper Requirement (SECTION 12 (a)(ii))

The following criteria shall be used to enable the Minister to assess fitness and propriety of a person:

- (a) If the person has previously been convicted of an offence which resulted in or if it occurred in Lesotho would have resulted in a maximum penalty of death, or imprisonment or other deprivation of liberty for a period of not less than 24 months especially relating to drugs.
- (b) If a professional has been subject to disciplinary or other action that is being, or has been, taken by a body empowered to take such disciplinary action
- (c) If the person is connected or associated with people that may affect applicant's reputation, character, honesty or professional or personal integrity
- (d) Previous business experience of Applicant and its directors
- (e) The financial circumstances of the applicant which must enable applicant to comply with obligations under the law
- (f) Past revocation or suspension of license held by applicant
- (g) The educational or technical qualification, knowledge, skills, and experience to satisfactorily discharge the responsibilities of the position
- (h) Failure to discharge responsibilities as a shareholder, director with competence, diligence, sound judgement, honesty or integrity.
- (i) Been obstructive, misleading or untruthful in dealing with a court, tribunal, official inquiry, complaint handling body, dispute resolution body, or regulatory agency
- (j) Perpetrated or participated in negligent, deceitful or otherwise discreditable business or professional practices

ment

b) Police clearance

Declaration and consent

I declare that to the best of my knowledge all the information provided in this schedule is true, correct and complete. I consent to the disclosure of and associated exchanges of this information for purposes confirming the information.

Signature

Date:

SCHEDULE 2

Form F

Register kept in terms of section 37 of the Drugs of Abuse Act No. 5 of 2008

To be updated within 24 hours of activity and signed by person making the entry

SEEDS SECTION

Quantity of	strain	Germinated	Transplanted	Date	Signature
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EXPORTS AND IMPORTS SECTION

Activity	Product	Quantity	Quantity already available	Total quantity	Form	Strength	Details	Signature	Date
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Import

Name of Exporter:

Export

Address of Exporter:

Name of Importer:

Address of Importer:

Manufacture

Name of
Manufacturer:

Address of acti-
vity of manufa-
cturing:

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TRANSPORTED SECTION

Transportation	Product	Quantity (available and transported)	Form	Strength	Name of person who received the Drug and physical address of where the drug was delivered	Date	Signature
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DISPOSAL SECTION

Quantity	Product	Form	Method of disposal	Name and Designation of person responsible for	Name and designation of witnesses	Date	Signatures
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Schedule 2

Fees

1.	Non-Refundable application fee for all licences	M 15 000
2.	Licence fee (sec 11(2) (b))	
	(a) Licence for cultivation	M150 000
	(b) Licence for Manufacturing	M150 000
	(c) Licence for testing	M 100 000
	(d) Operator Licence	M 500 000
	(e) Licence for research	M50 000
	(f) Licence for transportation	M50 000
	(g) Licence for storage	M10 000
	(h) Licence for supply	M50 000
3.	Renewal of Licence fee (sec 21)	
	(a) Licence for cultivation	M100 000
	(b) Licence for Manufacturing	M100 000
	(c) Licence for testing	M 75 000
	(d) Operator Licence	M 350 000
	(e) Licence for research	M 50 000
	(f) Licence for transportation	M 25 000
	(g) Licence for storage	M7 500
	(h) Licence for supply	M25 000
4.	. Permit in relation to Medical and Scientific Programmes and Seed bank	M 5 000
5.	Annual inspection fee	M 25 000
6.	Change of location fee M 10 000 Plus inspection fee	M 35 000
7.	Change of information (Amendment) fee	M 5 000
8.	Import, Export, transit and supply (sec 14)1.5% of the consignment value	

SCHEDULE 3

LEVELS OF CONTAMINANTS (SECTION 108 (1) (e))
REGULATION 20(6))

a) Cannabinoids	No Limits: THC, THCA, CBD, CBDA, CBG, CBGA, CBC, CBN, THCv, CBDV
b) Moisture Analysis/ Water Activity	Acceptable: ≤; 13% by weight Acceptable: ≤; 0.65 Aw
c) Heavy Metals	Acceptable Limits Per Gram
i) Mercury	Max Limit: <0.2 PP:NI
ii) Lead	Max Limit: <1.0 PP:NI
iii) Cadmium	Max Limit: <0.4 PPM
iv) Arsenic	Max Limit: <0.4 PPM
d) Foreign Material	
i) Mold or foreign material	Average of 5% or more, by weight
ii) Mammalian excreta	Average of 1 mg or more per pound
e) Microbial Impurities	Acceptable Limits Per Gram
i) Salmonella species Bacteria	<1 Colony Forming Unit (CFU)
ii) Pathogenic E. coli	<1 Colony Forming Unit (CFU)
iii) Total Yeast and Mold	<10 ⁴ Colony Forming Unit (CFU)
iv) Total Aerobic Bacteria	<10 ⁵ Colony Forming Unit (CFU)

f) Pesticide residues**20 ppb****g) Residual Solvents****Acceptable Limits**

i) Butanes	<500 Parts Per Million (PPM)
ii) Heptanes	<5,000 Parts Per Million
iii) Benzene	<2 Parts Per Million
iv) Toluene	<890 Parts Per Million
v) Hexane	<290 Parts Per Million
vi) Total Xylenes (m,p, o-xylenes)	<500 Parts Per Million