BARBADOS MEDICINAL CANNABIS LICENSING AUTHORITY

GENERAL GUIDE

Let's Grow Together

The Barbados Medicinal Cannabis Industry Act, 2019 (the Act) establishes that an application for a license must be filed with the regulatory body, the Barbados Medicinal Cannabis Licensing Authority (BMCLA), in the form and manner specified by the Act and the Medicinal Cannabis Industry Regulations, 2020, (the Regulations) and must include all the information required.

This General Guide provides general terms and conditions which apply to the operation of all licenses within the medicinal cannabis industry.

This Guide should be read in conjunction with the Act, the Regulations and is intended to supplement the provisions of the Regulations.

It is the responsibility of the applicant to ensure that they are familiar with these guidelines and the Regulations. Your application may be denied, or your operations delayed if you fail to meet the requirements outlined.

The BMCLA is committed to protecting personal information as well as confidential business information that is under its possession. Ensuring the confidentiality, integrity, and availability of information is essential to the regulator's decision making and the delivery of services. The BMCLA recognizes that the protection of this information is an essential element in maintaining public trust.

Publication Date: January 2021
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Disclaimer:
This document is a living document, which may be updated and changed by the BMCLA as it sees fit. Users are advised to ensure they are using the most recent version. This document should be read in conjunction with relevant sections of the Act and the Regulations. In the case of any discrepancies between this document and the Act and the Regulations, please seek direction from the BMCLA.

CONTENTS

LET'S GROW TOGETHER

FOREWORD

The Medicinal Cannabis Industry Act, 2019 (the Act) was proclaimed on September 30, 2020. It establishes the conditions under which the Medicinal Cannabis Industry in Barbados will operate. Provisions for the licensing regime, patient access to medicinal cannabis and the establishment of the regulating Authority, the Barbados Medicinal Cannabis Licensing Authority (herein referred to as the BMCLA) and its Board are all found within the Act. Further, the Act is supported by the Barbados Medicinal Cannabis Industry Regulations, 2020 (the Regulations).

This guidance document is intended to provide further direction to the the applicant based on the provisions established in the Act and the Regulations.

Section 4 (1) of the Act provides for the BMCLA to develop policies, procedures and guidelines for the industry. Additionally, section 4 (2) of the Regulations also provides the BMCLA with the right to request any additional information that pertains to the licensee, its agents or directors and that is necessary to consider the application. It is the responsibility of all applicants to make sure that they are aware of all rules, regulations and policies which pertain to their application and operations.

The BMCLA is not responsible for any circumstance in which an applicant or licensee might find themselves non-compliant due to lack of awareness of the necessary requirements.

This document, while aimed at being comprehensive, may not contain every answer an individual may need. In those cases, it is suggested that the applicants contact the BMCLA at clo@bmcla.bb or visit the BMCLA's website at www.bmcla.bb.

The overall intent of the regulatory framework, including all guidelines governing the Barbados Medicinal Cannabis Industry, is to ensure patient safety and the administration of an orderly and efficient industry.

GLOSSARY

Disposal
Disposal is to render unrecognizable and unusable for the purposes of ingestion.

Good Agricultural and Collection Practices (GACP)
The World Health Organisation (WHO) developed the Guidelines on Good Agricultural and Collection Practices (GACP) for medicinal plants, providing general technical guidance on obtaining medicinal plant materials of good quality for the sustainable production of herbal products classified as medicines.

Good Manufacturing Practices (GMP)
Good Manufacturing Practice (GMP) is the minimum standard/requirements for ensuring that products are consistently produced and controlled according to quality standards. It is designed to minimize the risks involved in any pharmaceutical production that cannot be eliminated through testing the final product.

Person
A person for the purpose of this document can refer to both a person and an entity unless otherwise directed.

Standard Operating Procedures (SOPs)
These are Standard Operating Procedures which are collated into a document consisting of step by step instructions on how to complete a particular job or procedure within the licensed activities.

BACKGROUND

The Barbados Medicinal Cannabis Industry Act, 2019, (the Act) and Barbados Medicinal Cannabis Industry Regulations, 2020, (the Regulations) provide, among other things, the framework for legal access to medicinal cannabis, control and regulation of medicinal cannabis use and commercial engagement in Barbados. It in no way makes legal the use, in the production, manufacturing and handling of cultivation or production of cannabis for any purpose other than that as stated under the Act. The Act lays out the allowance under which persons can engage in medicinal cannabis within the jurisdiction of the Barbados Government.

The Act speaks to the establishment of the Authority, the allowance for the use of cannabis for medicinal purposes which must be prescribed by a doctor and dispensed by a licensed pharmacist (as defined under the Pharmacy Act, Cap. 372D). The Act also makes provision for the establishment, licensing, regulation, monitoring, control and enforcement of the medicinal cannabis industry by the Barbados Medicinal Cannabis Licensing Authority (BMCLA). It established eight (8) different types of licenses and tiers and gives the Authority the right and responsibility for the importation, cultivation, processing, exportation, transportation, analyzing as well as research and development of cannabis for medicinal purposes.

Under this framework, a person is required to obtain a license issued by the BMCLA in order to conduct various activities with cannabis for medicinal purposes. Applicants and license holders are responsible for compliance with the Act and the Regulations as well as compliance with other applicable laws as made by the Government of Barbados.

The Act establishes that an application for a license must be submitted to the Authority in the form and manner specified by the industry regulations and must include all requested information and supplemental documentation as requested. This guide sets out the application process including the form and manner for submitting an application and the information that is required.

The BMCLA will publish other guidance documents and information as needed on its website (www.bmcla.bb) that may be used in conjunction with this document to assist applicants in preparing their applications. In order to maintain consistency and transparency, this guide, as well as other guidance documents and information, will be updated, as required, to reflect changes to policies and/or operations.

GENERAL REQUIREMENTS

1. **Operational**

1.1. Personnel & Training
The employment of staff must be in accordance with all Barbadian labour laws and regulations. It is the responsibility of the licensee to ensure appropriate training for relevant personnel based on the scale of operations and the business model.

1.2. Ongoing Training
Management should provide at a minimum, ongoing training in accordance with a written programme for all personnel whose duties require access to or involve interaction with medicinal cannabis, areas which contain medicinal cannabis and/or its derivatives (including technical, maintenance and cleaning personnel).

2. Building and Facility

2.1. General
Each licensee will be required to have designated areas for the specific activities they intend to undertake. These areas must be shown on the relevant premise plans and must be clearly identified by signage. Below is a list of relevant areas which should be shown as applicable:

- office area
- pesticide storage
- fertilizer storage & soil storage
- drying areas
- curing areas
- processing areas
- packaging areas
- extraction areas
- treatment areas
- secured areas for the storage of medicinal cannabis meant for sale or transport
- secured areas for the storage of harvested medicinal cannabis
- chemicals storage and usage areas
- secured areas for the storage of medicinal cannabis materials and products in all forms
- secured areas for the storage of medicinal cannabis meant for disposal and disposal areas

2.2. Any licensee holding more than one license, who intends to execute those licenses at the same premises is required to designate separate areas for the execution of each license.

Further, this separation must be clear on any premises plan submitted, and must also include any shared areas which must be limited to entryways, lobbies, bathrooms, hallways, and breakrooms.

2.3. Per Regulation 16 (j) a licensee must not sublet or lease licensed premises to be used by any entity. However, a licensee may have several operators under one license once the licensee retains ownership of the property and there is no lease arrangement.

3. Storage Areas

3.1. Storage areas should be:

- designed to permit effective and orderly segregation of the various categories of materials stored, and to allow rotation of stock. Different cannabis materials should be separated within storage areas; and

- labeled in such a way as to ensure differentiation and adequate identification of materials and avoidance of any risk of cross-contamination.

3.2. Any accidental spillage in storage areas should be cleaned up immediately using methods that minimize the risk of cross-contamination of other materials and should be reported to the manager or supervisor in charge of health and safety

3.3. Cannabis raw material, should be stored off the floor and suitably spaced to permit cleaning of the area and inspection.

3.4. To protect the stored material, and reduce the risk of pest infestation, the duration of storage of any cannabis material in unpacked form should be limited to two (2) days.

3.5. Incoming fresh cannabis materials (seeds, plants, tissue culture, raw cannabis or cannabis products) should be recorded and entered into inventory unless specified otherwise, as soon as possible.

3.6. Where materials are stored in bulk, to reduce the risk of mould formation or fermentation, those materials should be stored in aerated rooms or containers using natural or mechanical aeration and ventilation. These areas should also be equipped in such a way as to protect against the entry of insects or animals, especially rodents.

3.7. The storage of plants, extracts, tinctures and other preparations may require special conditions of humidity and temperature or protection from light; appropriate steps should be taken to ensure that these conditions are provided, maintained, monitored and recorded.

4. Documentation & Record Keeping

4.1. All licensees are required to enter records for all activities into the authorities track and trace system and to make any internally kept records available to the authority and its agents at any time, per Regulation 32 (2).

4.2. In addition to the track-and-trace system, all licenses may keep internal records. These records may be kept electronically and may include photographic, video or written means.

Licensees should develop and follow procedures regarding the handling of electronic data recording and storage. These procedures should include:

- the limitation of access and ability to enter or modify the data on the system via passwords;
- there should be a method for recording changes and deletions;
- all entries should be double-checked and verified; and
- all records must be backed-up and stored securely.

5. Registers

5.1. There are two registers which licensees are required to record, store and make available to the BMCLA. These registers include the following:

- Visitor's Register
  This is a record of each person visiting the licensed facility and must include the full name of that person, their address, the reason for the visit and the contact phone numbers of the person.

- Waste Disposal Register
  This is a record of any cannabis waste disposed of and must include:
  - the type of cannabis, cannabis material or cannabis product or cannabis by-products being destroyed;
  - the amount by weight, lot, batch or tracking number of the cannabis, cannabis material or cannabis product or cannabis by-products being destroyed;
  - the date of the destruction
  - the reason for the destruction;
  - the employee/s who did the destruction; and
  - the BMCLA's officer, who supervised the destruction.

6. Annual Report

6.1. In accordance with Regulation, clause 36, licensees must provide the BMCLA with an annual report by the 31st of March each year.

This report must contain:
- Summary of all relevant records kept by the licensee (including those listed at 4 & 5 above)
- Summary of business operations
- Summary of financial operations
- Summary of all incident reports
- Summary of the ownership report
  (detailing who the shareholders are and their nationalities)

7. Transportation

7.1. All licensees must transport cannabis (in any form) or medicinal cannabis products only with a person granted a transport licence, per Regulation 16 (d).

7.2. All licensee must ensure that all cannabis materials being transported are clearly identified and tagged with the unique code as assigned by the Track-and-Trace system.

7.3. All licensees must prepare/receive a shipment manifest which lists:

- the strains of cannabis;
- the quantity of cannabis;
- the purpose of transport;
- the name and address of sender licensee
- the name and address of receiver licensee.

This must be done for every shipment and must be verified prior to transportation.

8. Standard Operating Procedures (SOPs) and Recording

8.1. All licenses must develop Standard Operating Procedures (SOPs) and ensure that records are kept for every critical task where appropriate. These procedures should comply with the relevant international standards for each licensee.

8.2. SOPs should be available for each action, instrument and piece of equipment (e.g. use, calibration, cleaning, maintenance) and easily available to employees.

8.3. Written SOPs for cleaning and sanitation should assign responsibility and describe in sufficient detail the cleaning schedules, methods, equipment and materials to be used and facilities and equipment to be cleaned.

9. Disposal

9.1. There are four acceptable methods of disposal for cannabis materials based on the Regulations of the industry, namely:

- Burial - Onsite
- Compost Pits - Onsite
- Burning - Onsite
- Incineration - Contracted

9.2. All applicants must submit a disposal plan which details the methods chosen by the licensee and the way they plan to abide by the Regulations concerning disposal and all the restrictions within this document.

9.3. For any utilization of cannabis waste (commercial or otherwise) other than disposal, a proposal must be made to the BMCLA and that proposal must be approved.

9.4. All licensees are advised that in the case of small quantities of cannabis waste for disposal, to store their waste for one (1) month or until it has reached a sufficient capacity for effective disposal.

9.5. No licensee shall dispose of cannabis materials without the presence of the BMCLA per Regulation 42 (3). Further to this, each planned disposal must be entered into the Track-and-Trace System.

Request for the presence of a BMCLA personnel for the purpose of disposal must be submitted in writing seven (7) days prior to the planned disposal. The request must include the date and time of planned disposal along with what is being disposed of, the quantity and the method of disposal.

9.6. Research and Development & Laboratory are exempt from the requirement at 9.5 above in respect to the presence of the BMCLA at every disposal. This is because the amount of waste is expected to be small quantities.

However, Laboratory and Research and Development licensees must maintain their waste disposal register, which must be available for inspection and submission to the BMCLA as required.

9.7. Licensees are advised to store their waste until they can arrange a disposal visit from the BMCLA.

9.8. All cannabis material meant for disposal must be rendered unrecognizable and unusable by grinding and incorporating the cannabis waste with the following non-consumable, solid waste such that the resulting mixture is at least 50% non-cannabis:

- Paper waste;
- Cardboard waste;
- Food waste;
- Grease or other compostable oil waste;
- Compost activators; and
- Other waste approved by the BMCLA

9.9. All licensees must keep accurate and comprehensive records regarding cannabis waste. These records must be such that they allow for the reconciliation and evidence of all activities.

9.10. All cannabis marked for disposal must be held in a locked storage room, must be clearly labelled and stored separately from cannabis for harvested, or cannabis for processing, sale or testing.

10. Alternative use of Cannabis Waste

10.1 Any applicant seeking to use cannabis refuse/waste for a productive commercial or non-commercial must submit a proposal in writing to the BMCLA for consideration and must wait for a response.

11. Quality Control

11.1. Each licensee must perform quality control activities.

11.2. Adequate resources should be available to ensure that all quality control is effectively and reliably carried out. The basic requirements for quality control are, as dictated by the relevant professional operating standard for each license.

12. Reporting of Theft

12.1. All licensees are required under Regulation 16 (i) to report any theft within 24 hours of discovery.

Further to this, the licensee must:

- report the theft to the police and to the BMCLA simultaneously;
- allow the BMCLA to visit and conduct its own investigations if deemed necessary; and
- furnish a copy of the official police report of the incident to the BMCLA.

13. Sign & Advertising

13.1. Signage and Advertising Guidelines are detailed in Section 43 & 44 of the Regulations.

For further clarity please note:

- Licensees are free to name their companies and create whatever logos they wish, however, the use of such is restricted only in relation to the logo and name being used on signage and on vehicles.

13.2. No licensee shall use false, misleading or deceptive information in their advertising and marketing. This means no licensee may use information which it knows to be false, misleading or deceptive and where those claims made, in respect of the product, cannot be scientifically substantiated and proven.

13.3. Licensees are free to market their products as long as that marketing does not violate the terms of 44 (1) a - e as set out in the Regulations.

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WE ARE HERE TO HELP!

For further information on the Barbados Medicinal Cannabis Licensing Authority (BMCLA) or the Barbados Medicinal Cannabis Industry, please contact us:

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