BARBADOS MEDICINAL CANNABIS LICENSING AUTHORITY

PROCESSOR LICENSE GUIDE

Let's Grow Together

The Barbados Medicinal Cannabis Industry Act, 2019 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 Barbados Medicinal Cannabis Industry Act, 2019, (the Act) and the Barbados Medicinal Cannabis Industry Regulations, 2020, (the Regulations) and must include all the information required.

This Processor License Guide provides general terms and conditions for the operation of a Cultivator License within the Barbados Medicinal Cannabis Industry.

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

It is the responsibility of the applicant to ensure that he/she is familiar with this Guide 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.

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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.

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LET'S GROW TOGETHER

FOREWORD

The Barbados 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 should be read with reference to both the Act and the Regulations. The intent is to provide further direction to the applicant based on the provisions established in the aforementioned documents. It also sets out the rules and regulations for a Processor License.

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

Standard Operating Procedures (SOPs)
Standard Operating Procedures is a set of step-by-step instructions compiled by an organization to help workers carry out routine operations.

Edible medicinal product
An edible medicinal product is a substance or combination of substances, plant-based or otherwise, used for food or drink, or which is ordinarily used in the composition or preparation of such food or drink which is infused, mixed, combined, blended or made with cannabis

Current Good Manufacturing Practice (cGMP)
The cGMP is the regulations enforced by the United States Food and Drug Administration (FDA), the country's federal agency of the Department of Health and Human Services.

BACKGROUND

The Barbados Medicinal Cannabis Industry Act, 2019, (the Act) and the 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, 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 the production manufacture and handling of medicinal cannabis within the jurisdiction of the Barbados Government.

The Act speaks to the establishment of the BMCLA, 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, regulating, monitoring, control and enforcement of the medicinal cannabis industry by the BMCLA.

It established eight (8) different types of licenses and tiers and gives the BMCLA 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. Applicants and license holders are responsible for compliance with the Act and its 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 BMCLA in the form and manner specified by the Regulations and must include all requested information and supplemental documents as requested. This guide sets out the 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. Licensed Activities

1.1. This license speaks to the processing of medicinal cannabis.

A holder of this license shall be issued for the processing and manufacturing of cannabis material and medicinal cannabis products. License holders can:

- purchase medicinal cannabis material from the holder of a cultivation license;
- process medicinal cannabis raw material through any processing technique, package and label according to the requirements of Barbados and those of any jurisdiction in which the items are intended for sale;
- offer for export medicinal cannabis products to someone with an export license; and
- distribute medicinal cannabis products for sale with all of the requisite permissions.

Wider manufacturing issues are regulated by the Ministry of Industry, International Business and Small Business Development and issues related to the environment are handled by the Ministry of Environment and Natural Beautification.

2. Products and Processing methods

2.1 The BMCLA reserves the right to prohibit the production of any product and the use of any processing method. Currently, the production and sale of edible medicinal cannabis products are prohibited.

3. Batch Method

3.1. All licensed activities by processors must be done using a batch method. This means that all processing material is separated into groupings called batches, and all activities must be done to the entire batch as a whole. This includes processing, testing and all other manufacturing activities.

3.2. All batch activities will be recorded and documented using the Track-and-Trace system. *(More information will be provided in the Track-and-Trace Guide)*

4. Approval of Medicinal Cannabis Product

4.1. The processing of medicinal products, to be used in the Barbadian market is governed by the Barbados Drug Service under the Ministry of Health and the Pharmacy Act Cap 372.

All processing licensees are advised that they must satisfy the requirements of the Barbados Drug Service under the Ministry of Health prior to producing any medicinal cannabis products.

5. Production Method

5.1. All licensees are required to follow current Good Manufacturing Practices (cGMP) as the basic minimum standard. However, they are advised to research the specific standards of their intended markets and where those standards exceed those provided for under cGMP, to follow those standards. However, no standards should fall below that required under cGMP.

5.2. All equipment and activities employed and conducted in the processing of medicinal cannabis in Barbados must comply with the Safety and Health at Work Act. 2005, Cap 356 of the laws of Barbados.

6. Production Areas

6.1. In order to minimize the risk of a serious medical hazard, dedicated and self-contained facilities should be used when producing pharmaceutical-grade products.

6.2. When agitation or thermal processing of the materials is utilized, a suitable ventilation system should be employed to prevent the accumulation of fumes and vapours.

6.3. To facilitate cleaning and to avoid cross-contamination, adequate precautions should be taken during the sampling, weighing, mixing and processing of medicinal cannabis products.

6.4. Production areas should be effectively ventilated and maintained at the appropriate temperature and humidity suitable for the operation, ingredients, and finished products.

7. Materials: Cannabis Raw Material

7.1. All incoming materials should be quarantined immediately after receipt until they are released for use or distribution.

7.2. No materials used for operations such as cleaning, lubrication of equipment, should come into direct contact with incoming materials.

Where possible, such materials should be of a suitable grade (such as food grade) to minimize health risks and should be stored separately from raw materials used in the processing of medicinal cannabis.

7.3. Cannabis raw materials should be purchased only from licensed local suppliers, including other processor and import licensees.

7.4. Cannabis materials in the storage area should be appropriately labelled.

Labels should bear at least the following information:

- the designated name of the product and the internal code reference where applicable;
- the batch number given by the supplier and, on receipt, the control or batch number given by the manufacturer, if any, documented so as to ensure traceability;
- where appropriate, an expiry date or a date beyond which retesting is necessary.

7.5. Only raw cannabis materials released by the quality control person and within its shelf-life should be used.

7.6. Raw cannabis materials should be dispensed only by designated persons, following a written SOP, to ensure that the correct materials are accurately weighed or measured in clean and properly labelled containers.

8. Packaging materials

8.1. Packaging materials should be issued for use only by designated personnel following an approved and documented SOP.

8.2. Particular attention should be paid to printed packaging materials. They should be stored in secure conditions so as to exclude the possibility of unauthorised access.

9. Finished products

9.1. Finished products should be stored separately as usable stock once approved by quality control procedures, under conditions established by the said manufacturer.

10. Quality Control: General

10.1. Processing license holders are required to retain the services of one individual as a Quality Assurance Person (QAP) who has the training, experience and technical knowledge related to the requirements of cGMP.

The QAP is responsible for assuring the quality of any medicinal cannabis raw material used and the cannabis product before it is made available for sale.

The QAP is also responsible for investigating every complaint received in respect of the quality of the cannabis, as well as taking any necessary corrective and preventative measures. Additionally, the QAP is responsible for the implementation and maintenance of the overall Quality Management System (QMS).

10.2. 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 follows:

- Training and documented SOPs should cover the sampling, inspecting, and testing of starting materials, packaging materials, and intermediate, bulk, and finished products, and where appropriate for monitoring environmental conditions for GMP purposes;

- The Quality Control person should inspect all incoming cannabis materials and Certificates of Analysis;

- Records should be maintained (manually and/or by recording instruments) demonstrating that all the required sampling, inspecting and testing cGMP for herbal medicines procedures have been carried out and that any deviations have been fully recorded and investigated;

- The finished products should contain ingredients complying with the qualitative and quantitative composition of the product as required by the product specifications;

- The ingredients should be of the required purity, in their proper container and correctly labelled;

- Records should be maintained of the results of inspecting the materials and intermediate, bulk and finished products against specifications;

- No batch of product is to be released for sale or supply prior to certification by the quality control person

10.3. Quality control should:

- establish, validate and implement all quality control procedures;

- evaluate, maintain, and store the reference standards for substances;

- ensure the correct labelling of containers of materials and products;

- ensure the stability of the active pharmaceutical ingredients; and

- monitor products, to participate in the investigation of complaints related to the quality of the product; and

- participate in environmental monitoring.

11. Standard Operating Procedures (SOPs)

All processor licensees must have documented SOPs for all activities. These SOPs are aimed at achieving efficiency, quality output and uniformity of performance, while reducing miscommunication and failure to comply with industry regulations.

Processors should also create SOPs for all functions engaged in the processing function including but not limited to:

- Processing/Manufacturing
- Inventory Processes
- Rejected, recovered, reprocessed and reworked materials
- Returned goods
- Sampling & Testing
- Record Review
- Quality Control
- Finished Products testing
- Test Records
- Record Review
- Validation
- Traceability
- Rejection

12. Inspections

12.1 License holders can expect inspectors from other agencies including the Barbados Drug Service and the Environmental Protection Division.

License holders are expected to comply with the requirements of all inspections.

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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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