BARBADOS MEDICINAL CANNABIS LICENSING AUTHORITY

RESEARCH & DEVELOPMENT 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 Research and Development License Guide provides general terms and conditions for the operation of a Research and Development 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 Research and Development 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.

Publication Date: January 2021

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 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 Research and Development License.

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

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

The Institutional Review Board (IRB)

The Institutional Review Board of the University of the West Indies/ Ministry of Health and Wellness (UWI/MOHW) is an administrative body established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of the University of the West Indies/Ministry of Health and Wellness (UWI/MOHW).

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. Entities with a Research and Development License can only conduct activities related to scientific research for the purpose of improving or further developing cannabis for medicinal, therapeutic, or scientific purposes (Barbados Medicinal Cannabis Industry Act, 2019).

1.2. Research activities can include but are not limited to, in vivo and in vitro studies, clinical trials, plant genetics, cannabis product development, and educational programmes.

1.3. A Research license holder is authorized to conduct experiments and testing on every form and derivative of cannabis, including live plants, fresh and dried plant material, seeds, oil, and manufactured items.

1.4. A Research and Development Licensee will automatically receive an Import and Export license as specified in section 31 (2) (a) of the Act.

However, the Import and Export licenses may only relate to the specified Research and Development activities. In other words, the import and export license granted with the Research and Development license cannot be used for purposes outside of those relating to imports and exports for the purposes of Research and Development.

1.5. A Research and Development Licensee may not sell medicinal cannabis seeds, plants or tissue culture to any other entity not licensed by the BMCLA.

1.6. A Research and Development Licensee may license the use of its Research and Development Intellectual Property (IP), commercial sales of plant stock, products, other research-based material can only be sold to cultivator, processor & retail distributor licensees.

1.7 The production and sale of such material by Research and Development Licensees must be entered into the BMCLA's Track-and-Trace system.

1.8 The BMCLA reserves the right to indicate limits on the quantities of materials (plant stock or semi-processed product) that can be produced for research purposes.

2. Propagation

2.1. Any cannabis propagation must be no more than a total of 100 plants (parent plants and progeny).

Permission for any increased propagation must be requested from the BMCLA and must be related to a specific Research and Development proposal.

2.2. A Research and Development Licensee must comply with all the reporting and documentation requirements with regard to the cultivation, harvest, and disposal of cannabis or medicinal cannabis products in the manner required by the BMCLA.

2.3 All activities of the Research and Development Licensee must be entered into the BMCLA's Track-and-Trace as required.

3. Human and Animal Testing

3.1. All Research and Development licensees are required to follow all applicable laws of the country which govern Human and Animal Testing.

Permission from the IRB for human testing must be submitted to the BMCLA, while permission for animal testing must be sought through the BMCLA in consultation with the Senior Veterinary Officer.

It is the responsibility of Licensees to be aware of the required IRB and/or ethic committee permissions required for their research.

3.2. All human testing proposals must outline that investigators are appropriately qualified (with evidence of qualifications) and have completed certification in Good Clinical Practice (equivalent or superior) to the course offered by the National Institute of Health in the USA.

3.3. All testing procedures must include vigorous reporting and recall mechanisms.

3.4. Licensees must follow the guidance of the Barbados Drug Service and IRB in relation to the testing, development and use of new drug formulations.

4. New Products

4.1. All medicinal products must be approved by the Barbados Drug Service.

5. Inventory

5.1. A Research and Development licensee must provide the BMCLA with the following list, which must be updated once a year:

- A chemical inventory must be maintained (including any waste on the site) and the location of each chemical; and

- An equipment list with respective location of each piece of equipment must be maintained.

6. Security

6.1. All Research and Development Licensees must comply with the security guidelines provided by the BMCLA.

6.2. If the quantity exceeds 11 kg of dried cannabis or equivalent, at any one site and there is no existing cultivation or processing licence at the site, any exemptions in the security guidelines will not apply.

BARBADOS MEDICINAL CANNABIS LICENSING AUTHORITY

Let's Grow Together

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:

clo@bmcla.bb

246-421-4141

Concierge Desk
Barbados Medicinal Cannabis Licensing Authority
Warrens House, Warrens, St Michael.

www.bmcla.bb