	Title: Guideline for the Cultivation and Processing of Medical Cannabis	
Rev No: 01	**Doc No: PBSL/GL/022**	Version 02
Issue date: 15 May 2024	**Effective date: 17 May 2024**	Approved by: Registrar

Adopted By PBSL	
Start of public Consultation	
End of public Consultation	
Agreed by QMS committee	
Approved by Board	

Pharmacy Board of Sierra Leone,

PMB 322

Central Medical Stores Compound

New England Ville

Freetown

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EXECUTIVE SUMMARY

1.0 INTRODUCTION

The Pharmacy and Drugs Act, 2001 mandates the Pharmacy Board to regulate the availability of quality medicines which are safe and efficacious for their intended use. This mandate requires the Pharmacy Board to apply standards for the manufacture, distribution, sale and marketing of medicines, medical devices and other regulated products, including the provision of information to applicants relating to the standards required for the production and processing of Cannabis as a herbal starting material and identifies the critical production steps that are needed to ensure a product of reliable and reproducible quality.

In recent years, a small but growing body of evidence has emerged claiming that Cannabis may have medicinal value for some patients in conditions where other treatments have failed.

Section 50 of the Pharmacy and Drugs Act, 2001 provides the legal basis for the cultivation of cannabis plants, and the production of cannabis and cannabis extracts for medical and scientific purposes.

In order to ensure availability of standardized quality-assured medicinal Cannabis grown locally for the manufacture of suitable pharmaceutical products, the Pharmacy Board through the Ministry of Health and Sanitation in collaboration with the Ministry of Agriculture, Forestry and Food Security may permit the cultivation of Cannabis solely for medicinal and research purposes. These guidelines developed

by the Pharmacy Board of Sierra Leone is intended to control the cultivation, production and manufacturing of Cannabis products for export and the implementation of control measures necessary to prevent diversion and misuse, as well as to ensure patient safety.

2.0 OBJECTIVE

The main objective of these guidelines is to ensure that the cannabis is produced:

a) the proper cultivation and processing of medical Cannabis
b) Hygienically to keep microbiological contamination to a minimum;
c) Such that the negative effects on the plants during cultivation, processing and storage are kept to a minimum;
d) Under conditions that ensure that the therapeutic properties of the end product are constant and reproducible.

3.0 SCOPE

These guidelines apply to regulation and control of the cultivation, harvesting and primary processing of cannabis plants intended for medicinal use or the preparation of medicinal drugs.

These guidelines are prepared in accordance with the Pharmacy Board Good Manufacturing Guidelines and other international guidelines such as European Good Manufacturing Practice (GMP) guidelines for active pharmaceutical products. They apply to all methods of production including organic cultivation. The guidelines also provide additional standards for the production and processing of herbal starting

materials in so far as they identify the critical production steps that are needed to ensure good, reproducible quality.

4.0 SPECIFIC REQUIREMENTS

4.1 SUBMISSION OF APPLICATION

Application for the cultivation, harvesting and primary processing of the raw material of *cannabis sativa* for medicinal use

a) An applicant shall apply for the cultivation, harvesting and primary processing of the raw material of *Cannabis Sativa* for medicinal use. The applicant shall be any one of the following:

i. Corporate body duly registered by the cooperate Service Commission of Sierra Leone and licensed by the Board.

ii. Registered manufacturer licensed by the Pharmacy Board.

iii. Governmental, Quasi-governmental agencies or Non-Governmental Organizations (NGOs) that run health programs and facilities approved by the Ministry of Health and Sanitation, Ministry of Agriculture, Forestry and Food Security and licensed by the Pharmacy Board of Sierra Leone

b) An application on an official letter head and filled Pharmacy Board application form shall be forwarded to the office of the Registrar of the Pharmacy Board of Sierra Leone using the under-mentioned address:

C/o Central Medical Stores compound

New England Ville

Freetown, Sierra Leone

West Africa

c) Applications shall be accompanied by:

i. A covering letter signed by the authorized person on behalf of (a) (i), (a) (ii) or (a) (iii)

ii. A completed official application form obtained from the Pharmacy Board of Sierra Leone

iii. All supporting documents (business registration, income tax clearance, etc) as specified in the Pharmacy Board of Sierra Leone application form.

iv. Non-refundable application fee as specified in the Board's fee schedule.

v.

4.2 REQUIREMENTS FOR THE CULTIVATION AND PROCESSING OF CANNABIS

4.2.1. Personnel Requirements

4.2.1.1 Suitable Fit and Proper Person: The Applicant

1. The integrity of a person (s) who is granted a license, or who has the ability to substantially influence the conduct of activities under a license, is fundamental to the medicinal Cannabis scheme. He/she must be of good character.

2. The applicant's interactions and associations must be suitable to consider him as a fit and proper person, taking into account convictions, imposition of civil penalties, revocation of medicine regulating licenses, and the financial situation of individuals, amongst others.
3. The applicant should not have a history of illicit drug use or a conviction for an illicit drug-related offence, and the Board must ensure that the applicant's relevant business associates are also fit and proper persons.

The Board will not be able to consider a license application if a person has engaged in conduct that would be considered to be a serious offence.

Applicants will be invited to make disclosures. Once licensed, it is a condition of the license that applicants inform the Board immediately upon becoming aware of any matter that would call into question the applicant's status, or that of the applicant's business associates' status as a fit and proper person.

4.2.1.2 Suitable Fit and Proper Person: The Personnel

Regardless of the quality of other security controls, all such arrangements are open to misuse or can be circumvented by insiders. This concept underpins the requirements for the license holder to employ or engage suitable staff. License holders must take all reasonable steps to ensure that staff members employed or engaged do not present a risk of diversion of Cannabis or compromise the manufacture and production of Cannabis and Cannabis products.

A person is **unsuitable** for employment in Cannabis - related operations if

such a person:

a) Is under the age of 18 years
b) Has been convicted of a serious offence
c) Has a drug addiction, or is undertaking, or has undertaken, treatment for drug addiction
d) Has a history of illicit drug use or a conviction for an illicit drug-related offence.

It is the responsibility of the license holder to ensure that employees do not fall into any of the descriptions above and, may include but are not limited to security checks, proof of identification, regular drug testing and statements on behalf of employees about specific matters. Where a license is granted, ongoing compliance with these measures must be maintained.

4.2.1.3 Personnel requirement Hygiene and Training

It is a requirement that applicants ensure that competent staff with appropriate skills are appointed to oversee the growing or manufacture of Cannabis for medicinal use. Training and hygiene policies must be developed and implemented and must include the following:

4.2.1.3.1 Requirements

An organogram of the organization with specific job description must be available with minimum management and technical staff that includes but not limited to general manager, a licensed pharmacist, production manager,

quality officer, stores manager, operations manager, internal audit, finance manager, etc.

4.2.1.3.2 Training

a. Personnel must have received adequate botanical/horticultural training before performing the tasks given to them.
b. Production personnel must be trained in the production techniques used.

4.2.1.3.3 Hygiene

All personnel entrusted with handling the herbal material must maintain proper personal hygiene.

a. Persons suffering from infectious diseases transmittable via food, including diarrhoea, or carriers of these diseases must be forbidden access to areas where they could come into contact with the herbal material.
b. Persons with open wounds, inflammations and skin-infections must be suspended from area where they could come into contact with herbal material, unless they wear protective clothing or gloves until they have recovered completely.
c. Personnel must be protected from contact with toxic or potentially allergenic herbal material by means of adequate protective clothing.

4.2.2 Buildings and Facilities

a. Buildings used in the processing of harvested crops must be clean, well ventilated and must never be used for other activities.

b. Buildings must be designed in a manner that protects the crops against pests and domestic animals.

The medicinal cannabis must be stored:

- ❖ In a suitable packaging;
- ❖ In rooms with concrete or similar floors which are easy to clean;
- ❖ On pallets;
- ❖ At a sufficient distance from walls;
- ❖ Well separated from other crops in order to prevent cross contamination.

i. Organic products must be stored separately from products not grown organically.

ii. Buildings where plant processing is carried out must have changing facilities, toilets and hand-washing facilities.

4.2.3 Equipment

Equipment used in plant cultivation and processing must be easy to clean in order to eliminate the risk of contamination.

a. Equipment and machinery should be mounted such that they are easily accessible.

b. Machines used in fertiliser and pesticide application must be calibrated regularly.

c. The equipment must be made from materials other than wood. If wooden materials such as pallets are used, they must not come into direct contact with chemicals and contaminated materials in order to

prevent contamination of the herbal materials. Equipment and machinery used for harvesting must be clean and in very good working condition. Machine parts that come into direct contact with the harvested crop must be cleaned regularly and must be free from oil and contamination, including residual plant matter.

4.2.4 Security Requirements:

Security arrangements deployed at the proposed site will form an integral part of the conditions to be considered prior to the Board's licence being issued.

The Board requires that applicants develop and implement appropriate security policies and procedures to comply with security requirements for the manufacturing and production of Cannabis and Cannabis products. Non-compliance in respect of security requirements will be grounds to revoke a licence issued to an applicant. The security policies and procedures to be implemented amongst others include the following:

a) Discouraging persons from attempting to breach security measures;
b) Preventing acts aimed at breaching security measures, including measures to delay security breaches to provide time for defence or leading to the intrusion being abandoned;
c) Preventative measures that allow access to authorised persons while declining access to others;
d) Detection measures to discover security breaches; and
e) Defined actions to be taken to respond to a security breach

These principles should be supported by effective recording and information management systems that allow the licence holder to both demonstrate how security arrangements are met, and provide tools to secure evidence where there are attempts to breach security arrangements

4.5.1 Seeds and propagating material

Applicants should note that the licence granted to growers

a. Will allow cultivation of only the recommended strains that have been shown to target specific medical conditions.

b. Labelling of seeds and other plant material must allow for botanical identification in respect of species, variety, chemo-type and origin

c. The materials used must be traceable.

d. Starting material must, as far as possible, be free from pests and disease in order to guarantee healthy plant growth.

e. Cuttings of female plants must be used as propagation material for the production of Cannabis.

f. During the entire production process (cultivation, harvest, drying, packaging), the presence of male plants and different species, varieties or different plant parts must be monitored and reported.

g. Any impurities found during the production process must be removed immediately.

4.2.5.1 CULTIVATION

4.2.5.1.1 Cultivation Site

a. The plantation site for the medical cannabis should be not less than 40km away from the nearest large settlement and should be at least 400m above sea level.

4.2.4.1.2 Soil and Fertilisation

a. Cannabis for medicinal purposes must not be grown on soil contaminated with sludge, heavy metals, pesticide residues or other chemicals. Any chemicals used must therefore be kept to the minimum effective dose.

b. Manure applied should be thoroughly composted and must be devoid of human faeces.

Irrigation should be controlled and according to the needs of the cannabis plant.

Fertilisers should be used in such a way that leaching is reduced to a minimum.

4.2.4.1.3 Irrigation

a. Irrigation must be controlled and only as required by the cannabis plant.

b. Irrigation water must contain as few contaminants like faeces, heavy metals, herbicides, pesticides and toxicologically hazardous.

c. All tillage must be adapted to plant growth and requirements. Using herbicides and pesticides must be avoided as much as possible. The use and storage of pesticides must be in accordance with the recommendations of the

manufacturer, Ministry of Agriculture, Standards Bureau and Environmental Protection Agency of Sierra Leone

d. Only qualified personnel are allowed to use such substances, but not in a period preceding the harvest as indicated by the buyer or producer.

4.2.4.2 HARVESTING

a. Harvesting must be done when the plants have reached the best quality for the intended use.
b. Male, damaged, and dead plants must be removed.
c. Harvesting must take place under the best possible conditions, avoiding wet soil or extremely high air humidity. If harvesting occurs in wet conditions, additional care needs to be taken to avoid the adverse effects of moisture.
d. During harvesting, care must be taken to avoid mix up with other species or variety of cannabis.
e. The harvested crop must not come into direct contact with the soil. Immediately after harvesting, the crop must be kept in clean, dry conditions (e.g., sacks, baskets, boxes) ready for transportation.
f. All containers must be clean and free from any residues from previous harvests; containers that are not in use must be kept in dry conditions, free of pests and inaccessible to domestic animals.
g. Mechanical damage and compacting of the herbal drug that could result in the undesirable quality changes must be avoided. In this respect, care

must be taken to avoid overfilling of sacks/containers as well as to avoid over stacking of sacks during transportation.

h. Freshly harvested herbal material must be delivered to the processing facility as quickly as possible in order to prevent thermal degradation.

i. The harvested crop must be protected from pests and domestic animals.

4.2.4.3 PRIMARY PROCESSING

a. Primary processing includes washing, cutting before drying, decontamination, freezing, distillation, drying, etc. The following may be applicable:

b. On arrival at the processing facility, the harvested crop must be directly unloaded and unpacked. Prior to processing, the material must not be exposed to direct sunlight (except in cases that specifically require this) and must be protected from rain.

c. Drying crops directly on the ground or under direct sunlight must be avoided.

d. Uniform drying speed and prevention of mould growth must be assured.

e. In the case that plant material is dried in the open air, it must be spread in a thin layer.

f. The drying racks must be placed at sufficient distance to the floor to ensure good air circulation.

g. In the case plant material is not dried in the open air, optimal drying conditions (such as recommended temperature and drying time) must be chosen.
h. A request should be made to the Pharmacy Board office for destruction of wastes. The destruction should be done by burning or incinerated in the presence of Pharmacy Board Staff.
i. Waste bins must be available and must be emptied and cleaned daily.
j. Waste must be stored in an appropriately designed storage facility.

4.2.4.4 DRYING

Drying conditions of crops must not adversely affect the quality such as drying on unsuitable surfaces, i.e. directly on the ground or under direct sunlight. A uniform drying speed of the crops and the prevention of mould growth by appropriate measures must be assured.

In cases where plant material is dried in the open air, the material must be spread in a thin layer, to ensure good air circulation of the drying racks placed at sufficient distance from the drying surface.

Where plant material is not dried in the open air optimal drying conditions, i.e. temperature and drying time must be followed, and recorded.

4.2.4.5 PACKAGING

a. Following repeated controls and removal of any sub-standard material or undesired objects, the product must be packaged in clean, dry and preferably new packaging.

b. The label must be clear, firmly fixed and made from non-toxic material.

c. Reusable packaging material must be well cleaned and dried prior to use.

d. Packaging material must be stored in a clean, dry place that is free of pests and not accessible to domestic animals. The packaging material must not contaminate the product.

4.2.4.6 STORAGE AND DISTRIBUTION

a. Dried, packaged products and extracts must be stored in a dry, well-ventilated building in which daily temperature fluctuations are limited and good ventilation is ensured.

b. Fresh products must be stored between 1°C and 5°C; frozen products must be kept at temperatures below 18°C (or below 20°C for long term storage).

c. In the event of bulk transport, it is important to ensure dry conditions. To prevent mould formation or fermentation, it is advisable to use ventilated containers, transport vehicles and other ventilated facilities.

d. Decontamination of the storage area to combat pests must be carried out only where necessary, and by authorised personnel only.

e. When frozen storage or saturated steam is used for pest control, the moisture content of product must be controlled after treatment.

4.3 SPECIAL PROVISIONS FOR THE PRODUCTION OF CANNABIS INTENDED FOR PROCESSING INTO A STANDARDISED HERBAL DRUG

i. If the cannabis is intended for processing into a standardised herbal medicine, the cannabis must be cultivated under such standardised conditions that the contents of the constituents are constant. Standard Operating Procedures or Protocols for the cultivation of cannabis must be kept available.

ii. The content of the main constituents, which includes Δ-9-tetrahydrocannabinol (Δ-9-THC) and cannabidiol (CBD) must be determined quantitatively. For a selection of the other constituents, fingerprinting with a suitable technique, such as GC-MS, GC, HPLC or TLC will suffice.

iii. Unless it is proven that omitting the standardisation of one of the following elements results in a constant and reproducible product, at least the following must be standardised during cultivation:

a. species of the cannabis plant;

b. cultivation substrate;

c. day length;

d. light intensity;

e. atmospheric humidity;

f. temperature;

g. ventilation;

h. plant age at the time of harvesting;

i. time of day of harvesting.

Unless it is proven that omitting the standardisation of one of the following elements results in a constant and reproducible product, at least the following must be standardised during drying:

a. atmospheric humidity;

b. temperature;

c. ventilation;

d. drying time.

4.3.1 Documentation

Quality

Applicants must develop and implement a document management system which will allow all processes and procedures which may affect the production and quality of the product to be recorded in the documentation for each batch. The following, in particular, must be documented:

a) The location of cultivation and the name of the cultivator in charge;

b) The size of the cultivation site in 'acres'

c) Details on crops previously grown at that location;

d) Nature, origin and quantity of the herbal starting materials;

e) Evidence of import permit from the Board for the starting materials or source of local origin

f) The chemicals and other substances used during cultivation such as fertilisers, pesticides and herbicides;

g) Standard cultivation conditions;

h) Particular circumstances which occurred during cultivation, harvesting and production which may affect the chemical composition, such as plant diseases or temporary departure from standard cultivation conditions, particularly during the harvesting period;

i) Nature and quantity of the yield;

j) Date or dates, and time or times of day when harvesting occurred;

k) Drying conditions;

l) Measures for pest control;

m) Reports of soil analysis must be documented and made available in the dossier.

4.3.2 Location

a. All batches originating from one location must be clearly labelled (e.g. with a batch number).

b. Batches originating from different geographic locations may only be combined if guaranteed to be the same, and that the mixture is homogenous. Mixing of batches must be documented.

c. It must be recorded in the documentation for each batch that the cultivation, harvest and primary processing procedures were in accordance with these requirements.

d. All parties involved in the production process must demand that their suppliers document all relevant stages and elements of the production process for each batch.

e. Audit results must be recorded in an audit report. The audit report and concomitant analysis reports and other documents must be kept for at least ten years.

4.3.3 Safeguarding the material

a. The buildings in which the cannabis is cultivated, processed, packaged and stored must be sufficiently secured. This means that there must be security in force and that only authorised personnel is allowed access to the buildings.

b. The personnel involved in the production process of cannabis must be authorised for that purpose by the employer. When concluding the supply contract, the supplier designates authorised persons and indicates how this will be verified.

c. The supplier should ensure that supply is strictly done in accordance with the quantity requested.

d. Waste must be stored in such a way that theft is impossible. If waste is collected in bags, it must be stored in a lockable container (for instance a pressing container) immediately

4.3.4 Destruction of Medical Cannabis Waste

If need arises that a manufacturer want to destroy cannabis, that

manufacturer shall follow the necessary guide stipulated by the Pharmacy Board.

a. The manufacturer shall quantify the cannabis to be destroyed by using appropriate weighing equipment.
b. The manufacturer shall notify the Board indicating appropriate quantity in kilograms to be destroyed.
c. The Board shall verify the quantity and an applicant should pay the appropriate destruction fee to be paid to Finance Department of the Board.
d. The cannabis plant waste, including stems and organic waste shall be rendered unusable by grinding and incorporating it with other ground materials.
e. The resulting mixture must be composed of at least 51% of non-cannabis waste by volume.
f. The cannabis plant can also be combined with other ground material, such as soil, plastics, food waste and cardboard to achieve the 51% of non-cannabis waste by volume.

4.4 COMPLIANCE WITH GOOD MANUFACTURING PRACTICE (GMP), GOOD LABORATORY PRACTICE (GLP) AND GOOD AGRICULTURAL AND COLLECTION PRACTICES (GACP)

All manufacturers of a product shall comply with all relevant aspects of GMP, GLP and GACP.

4.4.1 Quality and safety

This shall be done in accordance with pharmacopeia approved by the Board and all analytical tests must be validated. With regards to the in-house test methods, guidance on the principles and practices of validation of analytical procedures outlined by the Board for the analysis of medical cannabis.

4.4.2 Compliance and enforcement

As Cannabis and cannabinoids are controlled substances which are subject to abuse if not properly handled. Therefore, where a permit or licence has been granted, it must be subjected to strict monitoring to avoid any unintended usage. Monitoring of medicinal Cannabis has to cover the entire chain, i.e. cultivation, manufacture, import, export, distribution and access for medicinal or research purposes.

The Inspectorate and Enforcement departments of the Pharmacy Board will conduct compliance and monitoring activities of all regulated parties to ensure compliance with licence and permit requirements. These activities include compliance investigations and inspecting licensed sites, as well as sites applying to be licensed to conduct regulated activities. Licensed producers and manufactures are required to comply with all applicable legislation and regulations.

4.4.3 INTERNAL AUDIT

The manufacturer shall put in place an internal evaluation system to ensure that processes and procedures are followed in accordance with regulatory guidelines set by the Board and to make sure proper quality assurance system

is in place which ensures that:

a. Manufacturers of medical cannabis are in compliance with good manufacturing practices
b. Good documentation practices are done in accordance with regulatory requirement
c. Guidelines for personnel requirement are followed in accordance with set standards
d. Procurement procedures are properly followed

4.5 RESEARCH & DEVELOPMENT

Motivated by the need to provide patients with pharmaceutical grade products, a goal to develop the paradigm for medical cannabis will be set to ensure compliance with standards set by Pharmacy Board of Sierra Leone in accordance with international standards for pharmaceutical development and regulations in the field of research. Taking this road map, the Board shall approve pharmacopeia appropriate for this purpose and shall develop analytical method for the quantification of cannabinoids in cannabis plant material and products.

5.0 GLOSSARY

Applicants are encouraged to familiarize themselves with this document before submitting their applications.

INTERPRETATION

In these guidelines, unless the context otherwise states: -

a) "**Board"** means Pharmacy Board of Sierra Leone (PBSL)

b) "**Applicant"** means the product owner or licence holder. Representative of licence holder may not hold themselves as applicants unless they own the product.

c) **Herbal medicine** is any medicine that contains exclusively herbal drugs or herbal preparations as active ingredients.

d) **Herbal drugs** are plants or parts of plants in an unprocessed state which are used for medicinal or pharmaceutical purposes. A herbal drug or a preparation is regarded as one active substance in its entirety whether or not the constituents with therapeutic activity are known.

e) **Herbal drug preparations** are comminute or powdered herbal drugs, extracts, tinctures, fatty or essential oils, expressed juices, processed resins or gums, etc., prepared from herbal drugs, and preparations that are produced through fractionation, purification or concentration. In departure from the above, chemically defined isolated constituents or their mixtures are not considered herbal drug preparations.

Herbal drug preparations may contain other components such as solvents, diluents and preservatives.

f) **Cannabis** As defined by Pharmacy and Drugs Act 2001, refers to a dried flowering or fruiting top of the pistillate plant from which the resin has been extracted from the base and all extracts or tinctures obtained from the top.

g) **Primary processing** includes washing, cutting before drying, decontamination from pests, freezing, distillation, drying, etc.

h) **Manufacturer's License:** Authority given for the cultivation and processing of medical cannabis.

ABBREVIATIONS

GMP- Good manufacturing process

GLP- Good laboratory process

GACP- Good agricultural and collection practices

PBSL- Pharmacy Board of Sierra Leone

NGO- Non-Governmental Organization

GC-MS- Gas chromatography-Mass spectrometer

GC- gas chromatography

HPLC- High Performance liquid Chromatography

TLC- Thin Layer Chromatography

Δ-9-THC- 9 tetrahydrocannabinol

CBD- Cannabidiol

6.0 REFERENCES AND INFORMATION SOURCES

NONE

7.0 ANNEXES

Cultivation and processing request form

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