



# Plandaí Biotechnologies South Africa (Pty) Limited

## **CULTIVATION OF CANNABIS AND MANUFACTURE OF CANNABIS-RELATED PHARMACEUTICAL PRODUCTS FOR MEDICINAL AND RESEARCH PURPOSES**

This document sets forth the security and standard operating procedures relating to the cultivation, manufacture and use of Cannabis and related pharmaceutical products for medicinal and research purposes in South Africa.

**Prepared: July 2017**

## 1 INTRODUCTION

Plandaí, through its wholly-owned subsidiary, Dunn Roman Holdings (Pty) Ltd., currently owns and operates a botanical extraction facility on the Senteeko Tea Estate in Mpumalanga South Africa. The unique extraction process used on Senteeko is proprietary to Plandaí and, unlike other extraction processes, relies on live plant material and through a process called “sonoluminescence” to extract the essential plant nutrients. The resultant product has been clinically tested in humans and animals and has been shown to possess unique physical attributes that render the product highly bioavailable and of pharmaceutical grade purity.

The proprietary extraction process employed by Plandaí is effective on all plant molecules that share a double hydrogen bond chemical structure, including Cannabis. Unlike conventional cannabis extraction systems that use “super-critical extraction” to isolate the cannabinoids, the Plandaí’s process does not rely on extreme heat, pressure or drying. As a result, the natural structures of the plant chemicals are not metabolized during extraction. For cannabis, this means that the acid form THC-A is not converted into the psychoactive metabolite THC.

From an application standpoint, Plandaí sciences are be able to produce a pharmaceutical-grade cannabis extract that contains the entire plant chemical profile while also not possessing any psychotropic properties. This product will offer all of the potential medicinal benefits of the full cannabinoid spectrum including terpenes and polyphenols without the unwanted side effects including euphoria and psychosis.

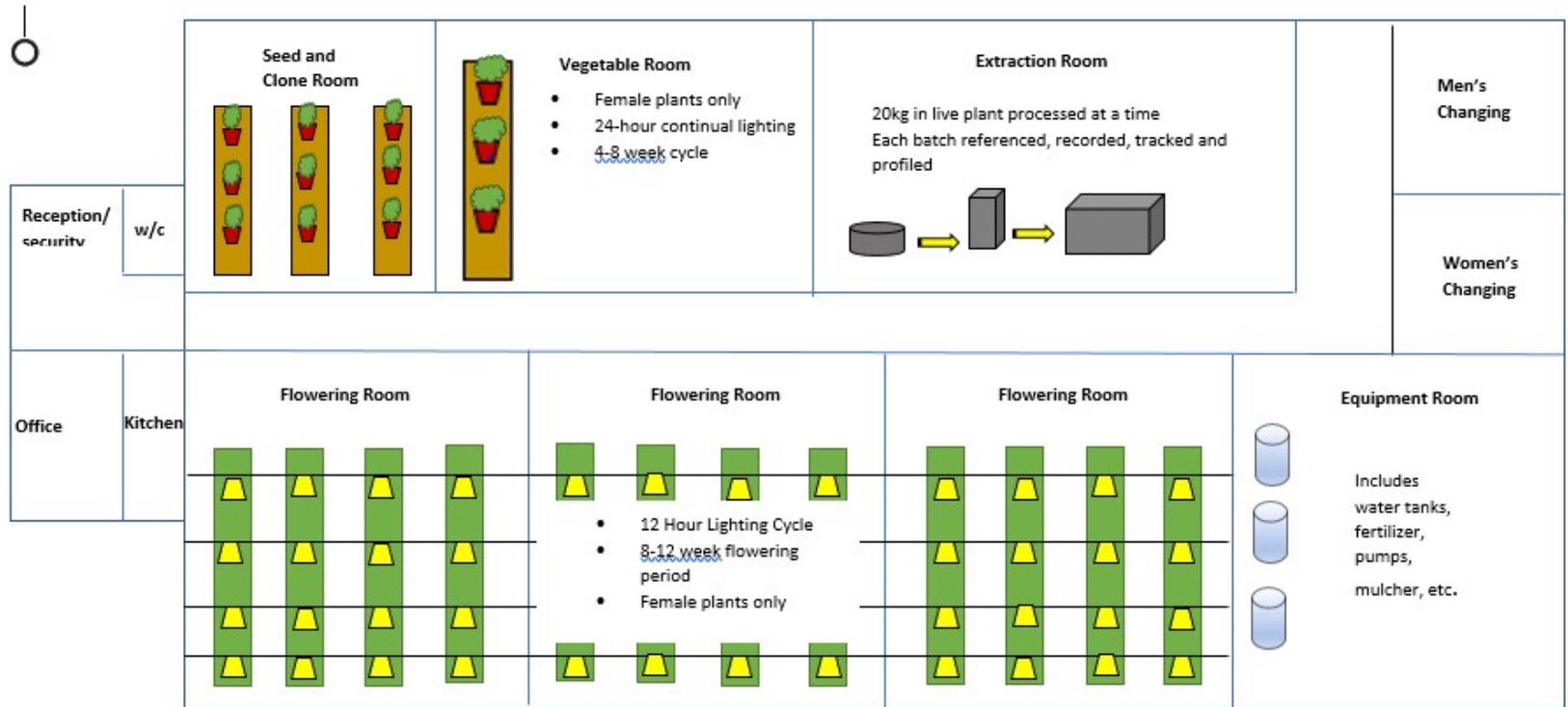
Plandaí proposes establishing a soil cultivation and extraction facility in South Africa where a small number of cannabis plants will be grown and the resultant extract produced for future clinical trials. Working with established laboratories and research institutes and universities both in South Africa and the United States, Plandaí will establish the chemical profile of its extract, test for bioavailability, and confirm that there are no psychotropic properties. Upon the successful outcome of these studies, Plandaí will undertake in-vitro and mouse-model studies to determine the efficacy of using Phytofare(R) cannabinoid complex with a variety of medicinal outcomes, including reducing inflammation to treat arthritis, Crohn’s disease, and others.

This guideline is prepared to outline the company’s overall strategy with respect to operations, management and quality control and should be read in conjunction with the Standard Operating Procedures Manual and Quality Control Manual.

## 2 FACILITY

Plandaí has secured facilities 35 Wilkens Road, Rockys Drift, White River 1240, Mpumalanga (GPS coordinates S25.22.56.2 E030.59.32.2) that will serve as the cultivation and extraction facility. The facility is a stand-alone building, completely enclosed, and adaptable to meet the necessary security and operational requirements. A copy of the facility blueprint is attached hereto. The below schematic details the proposed layout and work flow of the facility:

## Facility Layout



The following details the specific room requirements and work flow:

*Reception/Security* – This is the only authorized entrance to the facility. All other external doors are locked during business hours, alarmed, and used for emergency exit only. Access beyond this point requires approval from the Company Chief Executive Officer. Approved guests and workers will be required to wear identification badges. Guests will be accompanied by company employees at all times and will be required to sign in and present government-issued identification, which will be photocopied and retained for control purposes. The doors leading from reception to the production area and office are to be locked 24 hours a day using biometric scanning for access.

*Office* – This area is where all production and business records are to be stored, including operating manuals, batch records, shipping documents, plant use and disposal records, personnel files, etc. The door to this area will be locked and accessible only through biometric key pad. File cabinets will be locked and access restricted to authorized personnel.

*Men's and Women's Changing* – These separate rooms will be where the production workers don the required clothing to their specific job functions. Clothing worn will have no pockets or other areas for potential concealment, and free from pollen and other outside contaminants. The rooms will be equipped with individual lockers for security and subject to management inspection.

*Seed and Clone Room* – Pharmaceutical-grade extraction operations necessitate that all plants used share identical chemical properties and that such properties are maintained within set tolerances throughout production. This requirement is met by using a genetically pure seed stock and then cloning the desired plants for all future production. As a final stage, male plants are segregated from the female plants and destroyed (see Equipment Room). Access to this room is through biometric identification to ensure that only authorized personnel are admitted. There will be a plexiglass window in the corridor for monitoring work and observation to minimize access, helping to maintain security and the tight environmental controls. Temperature, light and humidity will be monitored and regulated automatically using the controls in the Equipment room. Plants are watered and fed automatically through installed micro-irrigation systems.

*Vegetable Room* – Only female plants are brought to this room. Plants are kept here from 4-8 weeks where they are exposed to 24-hour LED lighting. LED lights are the most energy efficient and generate no unwanted heat, which is necessary to maintain stable temperature levels. Temperature, light and humidity will be monitored and regulated automatically using the controls in the Equipment room. Plants are watered and fed automatically through installed micro-irrigation systems. Air flow to this room will be fed through a micro-particulate filter to remove any unwanted contaminants including airborne pollen, spores, dander, etc. Plants are introduced to this room via a pass-through from the Seed and Clone Room. Access to this room is through biometric identification to ensure that only authorized personnel are admitted.

*Flowering Rooms* – A total of three flowering rooms will be installed, but only two kept in operation, each with 50 plants. This will allow for staggering production so that 50 plants are harvestable, 50 plants maturing, and the empty room being

prepared for the next group of plants. This system is preferable to one large room as it prevents possible contaminants, including insect or bacteria, from destroying the entire operation. Plants are kept from 8-12 weeks with alternating 12-hour on, 12-hour off LED lighting. Temperature, light and humidity will be monitored and regulated automatically using the controls in the Equipment room. Plants are watered and fed automatically through installed micro-irrigation systems. Air flow to this room will be fed through a micro-particulate filter to remove any unwanted contaminants including airborne pollen, spores, dander, etc. Access to this room is through biometric identification to ensure that only authorized personnel are admitted.

*Extraction Room* – This room will house the necessary extraction equipment to product the finished extract. Equipment includes the cavitation chamber, filters to remove the residual solids, and the powder drying equipment. Finished extract will hermetically sealed in 500g poly bags, batch labeled, and stored in this room. Access to this room is through biometric identification to ensure that only authorized personnel are admitted. Lighting and humidity controls in this room are less stringent, but temperatures need to be maintained to preserve the integrity of the stored extract.

*Equipment Room* – This room will house the water and fertilization tanks, pumps, and automation equipment in order to minimize human contact. There will be a monitoring station so that humidity, temperature, air flow and lighting can be controlled. This room will also serve as a quality control station where any outside products (soil, fertilizer, supplies etc.) can be inspected and cleared before introduction. A mulcher will be installed to dispose of male plants and residual solids from the extraction process. In accordance with the laws governing plant disposal in South Africa, plant waste is mulched and reintroduced as fertilizer supplement so that no plant material leaves the facility.

With the exception of the changing rooms, the entire facility will have security cameras which are monitored 24 hours from the Reception/Security Room. Cameras will be installed in all rooms, the main corridor, and the building exterior. Video footage will be recorded and retained for two weeks.

### **3 PERSONNEL REQUIREMENTS**

#### **3.1 Suitable Fit and Proper Requirements: Applicant**

All employees will, prior to their hiring, be subject to a third-party investigation and background check to determine if there are any prior criminal convictions, imposition of civil penalties, revocation of medicine regulation licenses, and the financial situation of individuals, amongst others. These requirements are designed to enable the exclusion of criminal elements, including organized crime, who may otherwise be tempted to use their position for illicit activities.

In addition, employees will undergo an initial drug screening prior to hiring, followed by random drug testing throughout their employment, but no less than quarterly.

### **3.2 Personnel**

Employees candidates will be rejected, or terminated following hiring, for any of the following:

- is under the age of 18 years
- has been convicted of a serious offence
- has a drug addiction, or undertaking, or has undertaken, treatment for drug addiction
- has a history of illicit drug use or a conviction for an illicit drug-related offence
- fails a drug screen

Employee files will be maintained that document results of drug screens, training, disciplinary actions and the background check. Additional background checks will be performed on an annual basis.

### **3.3 Personnel Training**

Personnel involved in the agriculture side of the business must have a background in botanical/horticultural and undergo specific job function training before starting work. The company will establish a training manual upon the installation of all equipment and maintain training records on all staff.

The Company intends to hire and outside security firm to ensure that such personnel are property trained and bonded. Any security staff assigned to the company will need to undergo the same background checks and drug screening procedures as full-time employees.

## **3. Hygiene**

All personnel entrusted with handling herbal material must maintain proper personal hygiene to ensure that the quality of processing, manufacturing and production of Cannabis and Cannabis products are not compromised. Persons suffering from infectious diseases transmittable via food, including diarrhea or carriers of these diseases may not access areas where they could come into contact with herbal material. Persons with open wounds, inflammation and skin infections are not be allowed in areas where they could come into contact with herbal material, unless they wear protective clothing or gloves. All personnel that proceed pass the security check point must wear suitable, approved clothing that, at a minimum, incorporates the following:

- Shoes must be covered with disposable booties. Full-time staff may exchange street shoes for appropriate work shoes in the clothing rooms.
- Hair must be covered with approved netting.
- Staff may not wear pants or other clothing that has pockets while in contact with herbal material.
- All personnel admitted past security must don approved outerwear to prevent the introduction or transmission of contaminants.
- All personnel and guests that will have contact with herbal materials shall

wear protective gloves and particulate face masks in areas with plant material.

- The Equipment Room will be fitted with rubber gloves and protective eyewear to minimize the risk of exposure to chemicals, including fertilizer.

#### **4 SECURITY REQUIREMENTS**

**4.1** The Company will maintain 24-hour on-site security whenever there is plant material or extract on premises. Security will be provided by an outside firm specializing in business protection. All security personnel assigned to the company will be required to undergo the same background checks and drug screening process as employees. During non-business hours, security will be restricted to external patrols to minimize unsupervised human interaction inside of the facility.

**4.2** Video cameras will be stationed in all rooms of the facility in addition to the building exterior covering all points of ingress and egress. Video recordings will be captured and retained for a minimum of two weeks and stored off-site.

**4.3** There will be only one point of entrance to the facility which will be manned by security personnel. Access beyond the entry will be controlled by biometric locks, with each room having separate access permissions. Changes to access authorization can only be made by the company Chief Executive. All other external doors shall be constructed of metal, locked from the inside, fitted with alarms, and only accessible in the event of an emergency evacuation.

**4.4** All internal doors shall be of metal construction and shall be locked at all times.

**4.5** The Security Room will be fitted with an alert button that will trigger an alarm while also automatically notifying police and disabling all biometric internal entry locks. This will prevent access beyond the entry room to anyone and also prevent the coercion of personnel by outside forces.

**4.6** The company maintains a “zero tolerance” policy with respect to security. The following actions will result in immediate termination and/or notification of authorities:

- Unauthorized access to restricted areas
- Granting of access to unauthorized visitors
- Failing random drug screening
- Unauthorized removal of plant material or extract from the facility
- Failure to follow security protocols

Any breach of security, disciplinary action, and/or violation of protocols will be documented and retained in the company’s permanent files. Any such incidence that results in a criminal activity or missing plant material shall be noticed to the proper authorities (MCC and the South African Police Services)

The personal property (handbags, backpacks, briefcases, etc.) of all personnel and visitors shall be inspected by a security officer prior to leaving the facility

## **5 Plant Disposal**

- 5.1 Crop Integrity – All cultivated plants are intended to be clones to ensure genetic and chemical purity, thus the absence of variation in the finished product. Only female plants will be propagated, with excess male plants being destroyed. In addition, aberrant plants, mutations, infected, or other plants deemed unsuitable for production will be destroyed.
- 5.2 Disposal – The company will maintain a mulching and composting system for all undesirable plant material. This is the most secure practice as it ensures that no plant material leaves the restricted areas of the facility. Commercial mulching and composting equipment will be installed in the equipment room.
- 5.3 Records – A detailed record of all plants cultivated and destroyed will be maintained on site. Each individual seedling will be numbered and inventoried with an electronic record kept to detail all production, germination, culling, harvesting, extraction and destruction carried out by plant number. This will ensure that the company can quickly detect if any plants are misappropriated. All records will be maintained electronically and stored in the Office. A backup to all electronic records will be maintained offsite at the corporate headquarters located at 9 Palm Street, White River 1240. Files will all be password protected.

## **6 Transportation**

The initial company focus will strictly entail the production of cannabis extract for research purposes with no intent to sell, market or distribute product. Thus, the only projected transportation will be that of non-psychoactive extract that will have no recreational or street value.

Transportation of extract within South Africa will be handled in person by the company's Chief Executive Officer and be restricted to approved research and laboratory facilities. Product will be transported by personal vehicle from the point of origin to the destination and will be kept in a locked, biometric safe in the locked trunk of the vehicle. All such deliveries and transportation will be logged to identify the quantity and batch number of product being transported, the date and time of pick up, the intended recipient, the date and time of delivery, and the identity of the person signing for the shipment on the receiving end. In the event of a vehicle breakdown, the driver shall immediately notify company security who will be dispatched to help safeguard the product and/or return the product to the facility or final destination.

Shipments to locations outside of South Africa will be to qualified and approved research facilities only. Prior to shipment, the company will obtain all necessary export and import certification. Such shipments will be processed through

approved carriers. A similar log for all such international shipments will be maintained.

At such time when commercial shipments or deliveries are anticipated, the Company will revise its procedures accordingly and submit such to the MCC for approval prior to commencing such activities.

## **7 Production and Manufacturing**

**7.1** Standard operating procedures will be developed and implemented for all production and manufacturing activities in accordance to GMP practices prior to commencing operations. SOPs, and any changes thereto, will be submitted to the MCC for review. SOPs will be dependent on specific equipment installed and will include the following parameters, each of which will be standardized to ensure consistency of finished product:

- Order of daily tasks
- Plant tracking
- Equipment usage
- Watering schedule
- Water and fertilization system operation
- Waste water disposal
- Lighting schedule
- Cultivation procedures
- Harvesting procedures
- Extraction procedures
- Waste disposal procedures
- Packaging
- Pest control and mitigation
- Environmental controls and settings, including humidity, airflow and temperature

## **7.2 Processing**

Only live plant will be used in the extraction process, thus there will be no concern with drying, storing, or packing of plant material. Finished extract will be in a powder form and inert.

Packaging of finished extract will be no larger than 500g (1/2 kg) mylar bags. Each bag will have a desiccant sachet and will be immediately vacuum sealed to ensure that the chemical profile is not compromised. Bags will be labeled by batch to record date of manufacture.

Solids removed in the extraction process will be composted and re-introduced as fertilizer.

Wastewater from the extraction process will be filtered and recycled into the production process such that the entire system will be self-contained.

## **8 GOOD MANUFACTURING PRACTICES (GMP)**

### **8.1 Compliance with Good Manufacturing Practice (GMP), Good Laboratory Practice (GLP) and Good Agricultural and Collection Practices (GACP)**

*[Refer to separate Quality Control Manual]*

### **8.2 Quality and Safety**

The following analytical tests will be performed by Labserve Analytical Services, Nebo Park, Suikerriet Street, Nelspruit 1200 ([www.labserve.net](http://www.labserve.net)) on every batch of extract produced:

- Appearance
- Foreign Material
- Fineness
- Identification A: Microscopic Properties
- Identification B: TLC
- Microbiological Contamination
- Aflatoxins
- Pesticides
- Heavy Metals
- Assay and Related Substances
- Chemical profile

## **9 ACCESS TO UNREGISTERED CANNABIS FOR MEDICINAL USE FOR PATIENTS**

The Company's products shall, initially, be restricted to research purposes in a controlled, laboratory environment. There will be No sales to the public. Prior to commencing sales and marketing activities, the company will set in place controls and procedures to ensure compliance with all South African laws governing access to cannabis for medical patients, and will submit such procedures and controls to the MCC for review and approval.

## **10 Reporting**

The Company shall notify the MCC in writing for each of the following actual and suspected events:

- A security breach at, or unauthorized access to, the cultivation site
- A theft or loss of Cannabis
- A discrepancy in quantity of Cannabis
- A serious incident involving Cannabis.

Where an actual or suspected criminal act (theft or trespass, etc.) take place, law enforcement agencies will be notified immediately and a copy of the police incident report shall be provided to the MCC.