AusCann
AUSTRALASIAN MEDICINAL CANNABIS

Inquiry into the Regulator of Medical Cannabis Bill 2014

Contents

1. Definitions used

AusCann means AusCann Group Holdings Pty Ltd ACN 601 953 860 of 1 Alvan Street, Subiaco WA 6008

Bill means the Regulator of Medical Cannabis Bill 2014

CBD means cannabidiol

Convention means the Single Convention on Narcotic Drugs 1961

CSDA means Canada's Controlled Drugs and Substances Act

DPPL means a Designated Person Production Licence

GPP means the Good Production Practices provided in Division 4 of the MMPR, copy provided at Attachment A.

Master Specifications means the Canadian master specifications for cannabis product provided at Attachment B

MMAR means Canada's *Marihuana Medical Access Regulations*

MMPR means Canada's *Marihuana for Medical Purposes Regulations*

PUPL means Personal Use Production Licence

THC means tetrahydrocannabinol

2. Introduction

AusCann Group Holdings Pty Ltd (**AusCann**) was established in 2014 with the aim of cultivating and harvesting high quality, medicinal-grade cannabis strains in Australia for export to a range of importers who are licensed in accordance with the International Single Convention on Narcotic Drugs 1961 (**Convention**). AusCann is currently working with the Norfolk Island government to secure a licence to grow medical cannabis on Norfolk Island for export to licensed Canadian importers.

AusCann makes the following submission in respect to the Regulator of Medical Cannabis Bill 2014 (**Bill**) and in particular sections:

- 16 - 'Medical cannabis licensing scheme' –authorising persons to produce; transport; and store cannabis product, for medical or experimental use; and
- 23 - 'Determination of standards' – provision of standards for cannabis product.

In respect to these sections, AusCann submits:

1. **Any persons who are to be authorised to produce cannabis product, for medical or experimental use should evidence compliance with standards equivalent to the Good Production Practices (GPP) employed in the Canadian MMPR cannabis program**. The GPP provides standards in respect to the producer's premises, equipment, sanitation program, storage, standard operating procedures, analysis of the product, recall of product, and quality assurance personnel to ensure quality and efficacy of cannabis product.

2. **Persons authorised to produce cannabis product would be best placed to provide cannabis product directly to authorised patients or carers and/or other providers**. We would strongly recommend against patients or carers being authorised to produce their own cannabis product. The personal production approach has been tried in Canada with adverse consequences in respect to quality and efficacy of the product, public health, safety and security concerns. This led to Canada changing its laws to require medical cannabis be sourced from commercial licensed producers. It was recognised that it was critical that dried medical cannabis be treated as much as possible like a medication by creating a licensing scheme for the commercial production and distribution of dried cannabis for medical purposes.

3. Medical Cannabis

Cannabis is a flowering plant containing over 80 different types of cannabinoids along with many other molecules such as terpenes and flavonoids, many of which have documented medical value.

The most studied and abundant cannabinoids in the cannabis plant are tetrahydrocannabinol (**THC**) and cannabidiol (**CBD**).

Plant based cannabinoids, phytocannabinoids, are also found in other plants such as Echinacea and kava plants but are highest in concentration in cannabis plants. Cannabinoids are located in all parts of the cannabis plant but are highest in concentration in the female plant's flowers.

The human body naturally produces cannabinoids, endocannabinoids, which are critical to the body's regulation of many bodily functions, including brain development, immune function, inflammation, appetite, metabolism and energy regulation, cardiovascular function, digestion, bone development and density, reproduction, pain, and psychomotor behaviour. The endocannabinoids bind to cannabis receptor sites which are widely distributed in bodily tissues, both inside and outside of the central nervous system. Phytocannabinoids mimic the effect of endocannabinoids by binding to the body's cannabis receptor sites providing cannabinoids' therapeutic effects.

Different cannabinoids have different effects depending on which receptors they bind to. This concept is the cornerstone of cannabis as a medicine so much so that cannabinoids have been synthesized for legal prescription use including Marinol (appetite stimulant), Nabilone (pain) as well as naturally-derived Sativex (multiple sclerosis spasticity).

Whist some synthetic forms have positive effects, research shows that the wider variety of therapeutic compounds in herbal cannabis has a greater efficacy. The currently accepted belief is that the synergy between the various cannabinoids, terpenes and flavonoids produces a greater effect than any single compound on their own.

3.1.Variety of strains for different medical purposes

There are hundreds of strains of cannabis and each strain has a particular cannabinoid profile, ie ratio of THC to CBD etc; and specific balance and expression of terpenoids and flavonoids. It is thought that the ratio of main cannabinoids with minor cannabinoids, terpenes and flavonoids provides cannabis' therapeutic effect. Knowledge of these key factors is an important piece of the puzzle in ensuring consistent medicinal profiles in cannabis strains.

Since the endocannabinoid system plays an important regulatory function in many different parts of the body, it can also play a role in managing symptoms or modifying underlying disease states of the following symptoms and conditions:

3.1.1. Multiple sclerosis

3.1.2. Muscle spasms

3.1.3. Fibromyalgia

3.1.4. Arthritis

3.1.5. Anxiety states

3.1.6. Symptoms relating to HIV and AIDs

3.1.7. Chemotherapy-induced nausea, vomiting and anorexia

3.1.8. Chronic neuropathic pain

3.1.9. Gastrointestinal disorders including inflammatory bowel disease (Crohn's and ulcerative colitis) and irritable bowel syndrome

3.1.10. Epilepsy

3.1.11. Glaucoma

It is important that patients are using strains of medical cannabis that is appropriate for their condition and have appropriate ratios of CBD and THC for maximum efficacy.

The higher the THC percentage the more likely the patient will experience psychoactive effects. However, THC's extensive therapeutic action is a very important component of medical cannabis. CBD reduces THC's psychoactive effect and effective use requires finding a balance between THC's desired therapeutic effects and mitigating unwanted psychoactive effects.

Commercial licensed producers are best placed to provide these products as they have the expertise and means to breed and clonally produce appropriate strains.

3.2.Administration

Cannabis is unusual in many respects. As noted above, whilst synthetic versions of THC and CBD exist the biochemical effect does not seem to be as pronounced as the naturally occurring compounds. This is most likely due to interactions amongst the other cannabinoids present in the natural extract. Cannabinoids exist in their acidic form in the raw cannabis plant and are converted to THC and CBD through a process known as decarboxylation. This process involves heating the cannabis.

There are various portable vaporisers available on that market that can heat the dried flowers to sub combustible temperatures to release a vapour containing the cannabinoid molecules which can then be inhaled for rapid absorption and effective titration of dose.

Additionally tinctures containing extracts from the plant can be prepared and administered by:

- mouth in the form of a spray;
- transdermal patches, in particular for high CBD dosage for epilepsy; and
- dermal creams for certain cancers.

Patients should not be encouraged to smoke the dried product as inhaling combusted cannabis may increase the risk of chronic obstructive pulmonary disease and contribute to the development of lung cancer and other long term side effects.

4. The Canadian cannabis scheme and GPPs

In Canada cannabis for medical purposes is regulated under both the Controlled Drugs and Substances Act (**CDSA**) and the Food and Drugs Act. The CDSA and its regulations provide a legislative framework for the control of substances that can alter mental processes and that may produce harm to the health of an individual and to society when distributed or used without supervision. The legislative framework prohibits the possession, trafficking, production, importation and exportation of controlled substances except where authorised, such as under regulations.

Canadians have been able to access dried cannabis for medical purposes since 1999, when the Marihuana Medical Access Program was first established. At the time, individuals were authorised to possess dried cannabis and/or produce a limited number of cannabis plants for medical purposes via the issuance of an exemption under section 56 of the CDSA.

The Marihuana Medical Access Regulations (**MMAR**) were established in 2001 and set out a scheme by which Canadians cpuld, with the support of a medical practitioner, obtain an authorisation to possess dried cannabis for their own personal medical use. Under the MMAR, authorised persons had three options to obtain a supply of dried cannabis, they could:

- produce their own supply under a Personal Use Production Licence (**PUPL**);
- designate an individual to produce it on their behalf under a Designated Person Production Licence (**DPPL**); or
- purchase dried cannabis from Health Canada, which contracted a private company to produce and distribute cannabis under the MMAR program.

4.1.Issues with patients producing their own supply

It was found that growth in the MMAR program participation had unintended consequences for the administration of the MMAR, but more importantly, for public health, safety and security as a result of authorising individuals to produce cannabis under PUPLs and DPPLs in private dwellings.

Federal and provincial public safety officials, municipalities, law enforcement, and fire officials cited a number of serious public health and safety concerns with personal and designated production, including:

4.1.1. the potential for diversion of cannabis produced for medical purposes to the illicit market;

4.1.2. the risk of home invasion due to the presence of large quantities of dried cannabis or cannabis plants;

4.1.3. public safety risks, including electrical and fire hazards, stemming from the cultivation of cannabis in homes; and

4.1.4. public health risks due to the presence of excess mould and poor air quality associated with the cultivation of cannabis plants in homes.

In 2002, 477 individuals were authorised to possess cannabis for medical purposes. By August 13, 2012, this had grown to 21 986 individuals. At the time it was estimated that by 2014, over 50 000 individuals would be authorised to possess cannabis for medical purposes.

One result of increased participation in the MMAR program an increase in applications to Health Canada. This resulted in increased staffing costs, but more importantly, it resulted in a 10-week service standard for processing applications. Many Program participants expressed concerns regarding the length of time it took to obtain an authorisation to possess.

Of the 21,986 MMAR program participants in 2012, 13% accessed Health Canada's supply of dried cannabis, 64% produced under a PUPL, and 16% produced under a DPPL. The remaining 7% indicated in their application that they would buy from Health Canada, but ultimately did not. Health Canada does not have access to information regarding where these Program participants obtained their supply of cannabis for medical purposes.

Increases in the number of licences resulted in large quantities of cannabis being produced in homes and communities. In addition, the average daily amount continually increased since 2002 to almost 10 g per day which, if produced indoors, equates to approximately 49 plants. Under the MMAR, the number of plants that may have be produced under a licence was calculated based on the daily

amount agreed upon by the medical practitioner and the applicant. Program participants who either produced their own, or had designated producers, were the group where the daily amount increased the most. There were approximately 70% who produced 25 plants or more under the MMAR.

Municipalities and first responders, such as fire and police officials, raised serious public health and safety concerns regarding production of cannabis in private dwellings. Under the Program, applicants were not required to disclose their intent to produce to local authorities. Production sites, most often in private dwellings that were not constructed for large-scale horticultural production, were often in locations unknown by local authorities. Production activities were also linked to the presence of excess moisture in homes creating a risk of mould (particularly associated with drying of cannabis); electrical hazards creating a risk of fire; and exposure to toxic chemicals like pesticides and fertilizers creating a risk to residents. Such issues may not only have had impacts on individual producers, but also potentially on those living at the same address, adjacent residential units, and/or in the surrounding community, who may not even suspect the existence of these risks. There were also practical difficulties in imposing stringent quality and safety standards on production procedures where individuals lack the capacity to implement them and compliance could not be effectively monitored.

Police also raised concerns that residential production activities left the Program vulnerable to abuse, including criminal involvement and diversion to the illicit market, particularly given the attractive Canadian street value of cannabis at the time($10–$15/gram for dried cannabis). It was impossible to conduct effective inspection of the numerous production sites across the country, particularly given the legal requirement to either obtain permission, or a warrant, to enter a private dwelling. Finally, production in homes may have left residents and their neighbours vulnerable to violent home invasion by criminals who became aware that valuable cannabis plants were being produced and stored in the home.

Following are indicative numbers of potential patients in Australia who may seek access to medical cannabis:

Conditons known to benefit from Medical Cannabis	**Number of sufferers in Australia (indicative)**
Multiple Sclerosis	23,700
Cancer	775,000
Epilepsy	225,000

Dementia / Alzheimer's	322,000
Tourette Syndrome	113,400
Post Traumatic Stress Disorder	1,400,000
Schizophrenia	226,800
Motor Neuron Disease	1,900
HIV/AIDS	25,708
Glucoma	300,000
Aged Care	3,358,939
Diabetes	875,400
Chronic pain	4,536,000
Arthritis	2,400,000 (included in Chronic Pain)
Gastrointestinal Disorders (Crohns)	60,000
Insomnis (Chronic)	1,134,000

4.2.Implementation of supply from licensed commercial producers

Given the issues with the MMAR it was replaced with the current Marihuana for Medical Purposes Regulations (**MMPR**) which treats dried cannabis as much as possible like a medication by creating a licensing scheme for the commercial production and distribution of dried cannabis for medical purposes.

The MMPR provides patients with more choices of strains and suppliers, and provides access to quality-controlled cannabis. This, as well as ending Health Canada's role in the production and supply of cannabis, reduced the cost of running the MMAR program.

The MMPR authorises three key activities:

- possession of dried cannabis for medical purposes by individuals who have the support of an authorised health care practitioner;
- production of dried cannabis by licensed producers; and
- sale and distribution of dried cannabis by specific regulated parties to individuals who can possess it.

Licensed producers are subject to regulatory requirements related to security; Good Production Practices; packaging, labelling and shipping; record keeping and reporting; and distribution. They are also subject to regular Health Canada inspections.

The MMPR enables patients to obtain medical cannabis, of any strain commercially available, with information similar to a prescription from an authorised health care practitioner with quality and sanitation standards appropriate for a product for medical use.

4.3.Obtaining a supply of dried cannabis under the MMPR

To obtain dried cannabis for medical purposes, an individual sees an authorised health care practitioner and obtains a medical document, requirements for which are specified in the MMPR, signifying their support for their access to cannabis and indicating, among other things, the supported daily quantity in grams. They can then send the original medical document to a licensed producer of their choice. A medical document allows an individual to register with a licensed producer for the period of use indicated by the authorised health care practitioner, but for no more than one year. After registering as a client, individuals are able to order dried cannabis from the licensed producer. However, licensed producers are not allowed to sell or provide more than 30 times the daily amount in any 30-day period, taking into consideration the expected length of time for the shipment to reach the registered client, nor are they be able to ship more than 150 g at a time.

Health Canada publishes the name and contact information of each licensed producer on its web site to help individuals select a supplier. If an individual wishes to purchase a variety of strains that are not all available from one licensed producer, the MMPR permits the individual to do so by obtaining a new medical document. They would have to discuss this with their health care practitioner who can divide the daily quantity between multiple medical documents.

Registrations are not transferable from one licensed producer to another. If an individual wishes to change licensed producers, they are required to obtain a new original medical document which they would use to register with a new licensed producer. This is consistent with practices for prescription narcotics, as these are not transferable from pharmacy to pharmacy. The CDSA requires individuals seeking or obtaining an authorisation to obtain a controlled substance from a practitioner to disclose to the practitioner the particulars of any controlled substance they obtained or any authorisation to obtain any controlled substance that they received in the previous 30 days.

Health Canada does not regulate the price of cannabis under the MMPR. It is up to licensed producers to set the price.

Before selling dried cannabis to an individual, a licensed producer must register the individual as a client. In the process of registering a client, licensed producers must verify that the supporting authorised health care practitioner is entitled to practice their profession in the province in which they were consulted by the prospective client and that they have not been prohibited from prescribing narcotics. These tasks are similar to those conducted by a pharmacist when filling out a prescription. The licensed producer also has to confirm with the office of the authorised health care practitioner that the information in the medical document, including the daily quantity, is correct and complete.

4.4.Production of dried cannabis by licensed commercial producers

The MMPR sets out a licensing scheme that is intended to allow large-scale production, comparable to that for other narcotics used for medical purposes. This permits commercial production while regulating the quality and security of dried cannabis, thus reducing public health, safety and security risks.

A number of conditions need to be met before the issuance of a licence. The licensed producer must designate key personnel under their licence. The senior person in charge has overall responsibility for management of the activities carried out at the licensed site, while the responsible person in charge supervises all activities being carried out with cannabis. Key personnel, along with directors and officers in the case of a corporation, have to hold a valid security clearance, issued by the Canadian Minister of Health.

The applicant has to provide information that allows Health Canada to assess whether the applicant has certain key measures in place, such as:

4.4.1. a detailed description of the physical security measures that would be put in place at the site;

4.4.2. a detailed description of how the licensed producer would keep records of their activities with cannabis and cannabis other than cannabis;

4.4.3. a quality assurance report that shows that the buildings, equipment and proposed sanitation program to be used meet the Good Production Practices requirements (see section 4.4.7 below);

4.4.4. a copy of the notices provided to the local police force, local fire authority, and local government;

4.4.5. the maximum quantity of dried cannabis to be produced and sold or provided under licence (if applicable); and

4.4.6. floor plans of the site.

The MMPR also outlines a number of reasons for which the Canadian Minister of Health would be required to refuse to issue, renew or amend a licence.

Once issued, a licence is valid for up to three years, and can be renewed. The MMPR also set out a process for amendments to any information on the licence (e.g. the licensed producer wishes to increase its production yield or change sites).

4.4.7. Good Production Practices

Licensed producers are subject to Good Production Practices (**GPPs**). These requirements are outlined in Division 4 of the MMPR and are provided at Attachment A.

In order to achieve purity and quality of the cannabis product, Good Production Practices must be followed at all stages of production, packaging, labelling and storage of the cannabis.

The licensed producer is also required to employ a quality assurance person with appropriate training, experience, and technical knowledge to approve the quality of dried cannabis prior to making it available for sale.

The quality assurance person is also responsible for investigating quality-related complaints and taking corrective and preventive actions, if necessary.

Licensed producers have to test the cannabis product for, amongst other things:

- microbial and chemical contaminants and ensure they are below generally accepted tolerance limits for human consumption; and
- relevant amounts of THC and CBA to ensure efficacy of the product and for labelling purposes.

A full list of the requirements that must be met prior to distribution of the cannabis product is set out in the Master Specifications, a copy of which is provided at Attachment B.

4.4.8. Packaging and labelling

Dried products must be packaged in a tamper-evident and child-resistant container. Each package contains standard information about the product, including the weight in grams, the percentage by weight THC and of CBA, the packaging date, the expiry date if one has been established by stability testing, and any relevant warning statements such as “KEEP OUT OF REACH OF CHILDREN.”

The licensed producer, or authorised health care practitioner also must affix a client-specific label, similar to a patient-specific prescription drug label, to the package of dried cannabis. This label contains the names of the client and the authorised health care practitioner who provided the medical document, the daily quantity of dried cannabis as indicated on the medical document, and the end of the validity period as indicated on the medical document. The label also includes the shipping date and the anticipated date of delivery to the registered client. The licensed producer has to produce a separate duplicate document of this label to send to clients.

4.4.9. Shipping

Dried cannabis must be shipped directly to a registered client using a shipping service that includes a means of tracking the package during transit. Finally, dried cannabis must be securely packed and shipped in a container that would not allow the contents to be identified visually or by odour.

4.4.10. Security

The security measures required are designed not only to ensure that licensed producers take steps to ensure the physical security of their site, but also to prevent infiltration by criminal groups who may wish to exploit the lawful production of cannabis for medical purposes for illicit purposes.

Health Canada's Directive on Physical Security Requirements for Controlled Substances establishes security requirements for the storage of all controlled substances. These requirements are scaled to the illicit market value of the controlled substance and to the crime rates in various areas. This directive applies to the storage of dried cannabis by licensed producers.

The MMPR also sets out physical security requirements for the entire site, as well as for restricted-access areas. Restricted-access areas include all areas where a licensed activity is conducted with cannabis (i.e. a lab, the production room, the area where dried cannabis is packaged and labelled). Access to these areas is restricted only to individuals whose presence is required because of their work responsibilities. Licensed producers must put systems in place to ensure that access is controlled at all times, as well as 24-7 visual monitoring systems to detect unlawful conduct. The restricted areas have to be secured by an intrusion detection system that would detect attempted or actual unauthorised access to the area. The same principles of visual monitoring and intrusion detection apply to the perimeter of the entire site. Licensed producers also have to ensure the site and its restricted areas are designed in a manner that prevents unauthorised entry.

The MMPR also includes requirements that the holder of the production licence, directors and officers (in the case of a corporation) and all key personnel must hold enhanced security clearances prior to the issuance of a producer's licence.

To obtain an enhanced security clearance, these individuals are required to submit an application with personal information and documents to Health Canada, so that checks and verifications of relevant files of law enforcement agencies can be conducted.

4.4.11. Record keeping

Under the MMPR, licensed producers have to keep records of their activities with cannabis, including all transactions (sale, exportation, importation), all dried cannabis returned from clients, and an inventory of cannabis (e.g. seeds, fresh harvested cannabis, dried cannabis and packaged cannabis). All records have to be kept for a period of at least two years, in a format that would be easily auditable, and are to be made available to Health Canada upon request.

4.5. Analysis of benefits of supply from licensed commercial producers

Canada undertook an analysis that quantified and monetised the beneficial impacts of the MMPR prior to its introduction in terms of the reduction in risks associated with residential cannabis cultivation such as electrical fire hazards, potential home intrusions by criminals and the risks of sustaining serious injury or death in either case. Benefits were also estimated in terms of the economic efficiency impacts.

4.5.1. Reduction in residential fire risks

The focus on safety impacts was on the risk and consequence of residential fires resulting from faulty electrical wiring, overloading of electrical circuits, tampering with electrical usage monitoring and other electrical system malfunction arising from indoor cannabis cultivation. The analysis assumed that under the MMPR, the risks of property damage, personal injury or death resulting from cannabis production-related fires would be significantly reduced but not completely eliminated. The social cost of adverse safety events related to the production of cannabis for medical purposes was estimated to be reduced, over the period from 2014 to 2024, by about 40% under the MMPR, at a present value of $64.32 million. This represents annualised savings (avoided costs of property damage, injury and death from residential fires) of approximately $9.58 million per year for 10 years.

4.5.2. Reduction in risk of break-ins / home invasions

The focus of the security impacts was on the risk and consequences of home invasion, violence targeting residential production involved in misuse, and criminal activity related to cannabis distribution on the illegal market. Information from Canadian law enforcement authorities on misuse of production licences, home invasions and shootings was used as the basis to estimate the risk of violence. Overall, the analysis valued the projected reduction in the risks of break-ins / home invasions due to the MMPR at $0.38 million in 2014, rising to $26.48 million in 2024. The present

value of security cost-savings under the MMPR was estimated at approximately $89.03 million over the policy impact period, with an average annualized value of $13.27 million. The MMPR would have lower security costs (over 40% lower than under the status quo) due to the reduction in misuse activity that results from the expectation that eliminating personal and designated production in favour of a commercial licensing scheme would deter individuals interested in exploiting the Program.

4.5.3. Program administration cost savings

The Canadian government administration costs of the Program increased significantly as the number of Program participants grew. In the absence of the MMPR, the analysis assumed a continuation of the growth in Program applications and corresponding substantial increases in the cost to Health Canada to authorise legal possession and license production of cannabis for medical purposes. It was estimated that the administration cost of the Program would have increased from $20.63 million in 2014 to over $120 million in 2024, in the absence implementing the MMPR. These costs include salary, employee benefits and accommodation costs associated with dedicated staff, operations and maintenance costs, training, supplies and other corporate overhead costs.

Under the MMPR, Health Canada eliminated the role it played in determining the eligibility of persons to access a legal supply of cannabis for medical purposes and return to its traditional role as a regulator of industry. This resulted in significant administrative cost savings over the policy impact period. Under the scenario assumed for the new regulated market, the regulatory proposal was estimated to lead to more than a 90% reduction in Health Canada's administrative expenditures. The present value of administration costs savings over 10 years was estimated at $478 million. On average, the MMPR would generate administrative cost savings of approximately $71.24 million per year over this period.

4.5.4. Producer surplus gains

The MMPR established a regulated commercial market for the production and sale of cannabis for medical purposes. Private industry participation in the regime was expected to yield benefits to society. Under the previous MMAR, Cannabis was either produced through private arrangements or at a cost to the taxpayer. There were no benefits to society at large beyond the benefits to the individuals involved. Under the MMPR, there are beneficial impacts for the industry, over and above the benefits to the individuals involved in the market. The analysis measured this change in welfare by estimating a change in producer surplus gains under the policy. It was found that the new regulated market generated an overall producer surplus of $2.64 million in the first year of implementation (2014–15), rising to about $110 million in 2024 as the market expands. The present

value of producer surplus gains over the policy horizon (2014–24) was estimated at $339.85 million or about $50.65 million (annualized average) per year for 10 years.

Governments can also impose excises and taxes in respect to the licensed producers which can then flow back into the community as a whole.

5. In conclusion

Enabling individuals to produce their own medical cannabis is likely to have adverse consequences in respect to quality and efficacy of the product, public health, safety and security as shown in the Canadian model.

Administering such a personal growing licensing scheme could also be very costly and inefficient given the potential number of Australians who may seek access to medical cannabis.

It is critical that dried medical cannabis be treated as much as possible like a medication by creating a licensing scheme for the commercial production and distribution of dried cannabis for medical purposes.

It is essential that a system of supply and distribution by licensed producers be established and any producers should be highly regulated to ensure the necessary security requirements and Good Production Practices are complied with.

6. Contact details

Please do not hesitate to contact us with any queries that you may have in respect to this submission:

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Dr Mal Washer, Chairman AusCann Group Holdings Pty Ltd

Attachment A -Division 4 of the MMPR - Good Production Practices

Prohibition — sale or provision

47. (1) A licensed producer must not sell or provide to a person referred to in subsection 11(4) dried marihuana in respect of which the requirements of this Division have not been met.

Prohibition — export

(2) A licensed producer must not export dried marihuana in respect of which the requirements of this Division have not been met.

Microbial and chemical content

48. (1) The microbial and chemical content of dried marihuana must be within generally accepted tolerance limits for herbal medicines for human consumption, as established in any publication referred to in Schedule B to the *Food and Drugs Act*.

Pest control product residue

(2) Dried marihuana must not contain any residue of a pest control product in excess of any maximum residue limit specified for the product under section 9 or 10 of the *Pest Control Products Act*.

Analytical testing

(3) Analytical testing for microbial and chemical contaminants and for levels of delta-9-tetrahydrocannabinol and cannabidiol must be conducted using validated methods.

Premises

49. (1) Dried marihuana must be produced, packaged, labelled and stored in premises that are designed, constructed and maintained in a manner that permits those activities to be conducted under sanitary conditions, and in particular that

a) permits the premises to be kept clean and orderly;

b) permits the effective cleaning of all surfaces in the premises;

c) permits the dried marihuana to be stored or processed appropriately;

d) prevents the contamination of the dried marihuana; and

e) prevents the addition of an extraneous substance to the dried marihuana.

Storage

(2) Dried marihuana must be stored under conditions that will maintain its quality.

Equipment

50. Dried marihuana must be produced, packaged, labelled and stored using equipment that is designed, constructed, maintained, operated and arranged in a manner that

a) permits the effective cleaning of its surfaces;

b) permits it to function in accordance with its intended use;

c) prevents it from contaminating the dried marihuana; and

d) prevents it from adding an extraneous substance to the dried marihuana.

Sanitation program

51. Dried marihuana must be produced, packaged, labelled and stored in accordance with a sanitation program that sets out

a) procedures for effectively cleaning the premises in which those activities are conducted;

b) procedures for effectively cleaning the equipment used in those activities;

c) procedures for handling any substance used in those activities; and

d) all requirements, in respect of the health, the hygienic behaviour and the clothing of the personnel who are involved in those activities, that are necessary to ensure that those activities are conducted in sanitary conditions.

Standard operating procedures

52. Dried marihuana must be produced, packaged, labelled and stored in accordance with standard operating procedures that are designed to ensure that those activities are conducted in accordance with the requirements of this Division.

Recall

53. A licensed producer must establish and maintain a system of control that permits the rapid and complete recall of every lot or batch of dried marihuana that has been made available for sale.

Quality assurance

54. (1) A licensed producer must

a) have a quality assurance person who

i. is responsible for assuring the quality of the dried marihuana before it is made available for sale, and

ii. has the training, experience and technical knowledge relating to the activity conducted and the requirements of this Division; and

b) investigate every complaint received in respect of the quality of the dried marihuana and, if necessary, take corrective and preventative measures.

Materials and procedures

(2) Dried marihuana must be produced, packaged, labelled and stored using methods and procedures that, prior to their implementation, have been approved by a quality assurance person.

Approval prior to sale

(3) Every lot or batch of dried marihuana must be approved by a quality assurance person before it is made available for sale.

Returns

(4) Dried marihuana that is sold to a person referred to in subsection 11(4) and subsequently returned to the licensed producer must not be resold.

Lot or batch samples

55. (1) Subject to subsection (3), if the Minister has reasonable grounds to believe that a lot or batch of dried marihuana made available for sale may — by reason of the manner in which it was produced, packaged, labelled or stored — pose a risk to the health of an individual who in accordance with these Regulations obtains the dried marihuana for their own medical purposes, the Minister may require the licensed producer who sold or provided the dried marihuana to provide the Minister with a sample of that lot or batch.

Quantity

(2) The sample must be of sufficient quantity to enable a determination of whether the lot or batch of dried marihuana meets the requirements of section 48.

Period

(3) The Minister must not require a sample to be provided if more than one year has elapsed after the date of the last sale or provision of any portion of the lot or batch of dried marihuana.

Recall reporting

56. A licensed producer who commences a recall of dried marihuana must provide the Minister with the following information in respect of the recalled dried marihuana within three days after the day on which the recall is commenced:

a) its brand name;
b) the number of each lot or batch recalled;
c) if known by the licensed producer, the name and address of each licensed producer who imported or produced any of it;
d) the reasons for commencing the recall;
e) the quantity produced or imported into Canada by the licensed producer;

f) the quantity that was sold or provided in Canada by the licensed producer;

g) the quantity remaining in the possession of the licensed producer;

h) the number of persons referred to in subsections 11(2) and (4) to whom it was sold or provided by the licensed producer; and

i) a description of any other action that the licensed producer is taking in respect of the recall.

Adverse reactions

57. (1) A licensed producer who sells or provides dried marihuana must provide the Minister with a case report for each serious adverse reaction to the dried marihuana, within 15 days after the day on which the producer becomes aware of the reaction.

Summary report

(2) A licensed producer who sells or provides dried marihuana must annually prepare and maintain a summary report that contains a concise and critical analysis of all adverse reactions to the dried marihuana that have occurred during the previous 12 months.

Provide Minister with report on request

(3) If, after reviewing a case report provided under subsection (1) or after reviewing any other safety data relating to the dried marihuana, the Minister has reasonable grounds to believe that the dried marihuana may — by reason of the manner in which it was produced, packaged, labelled or stored pose a risk to the health of an individual who in accordance with these Regulations obtains the dried marihuana for their own medical purposes, the Minister may request that, within 30 days after the day on which the request is received, the licensed producer

a) provide the Minister with a copy of any summary report prepared under subsection (2); or

b) prepare and provide the Minister with an interim summary report containing a concise and critical analysis of all adverse reactions to the dried marihuana that have occurred since the date of the most recent summary report prepared under subsection (2).

Attachment B – Master Specifications

SCHEDULE "D" PART 2
MASTER SPECIFICATION FOR MEDICINAL MARIHUANA

Product: TBD **Product Code: TBD**

Parameter	Method	Specification
Appearance	Visual	Dried and milled *Cannabis sativa spp.* dark green to light green and tan coloured Flowering Heads plant particulates with characteristic aroma having citrus and pine overtones
Foreign Material	Microscopic	Stalks, insects and other vermin are absent
Percentage/Potency Delta-9-tetrahydrocannabinol (THC)	Third Party Lab in-house validated method	80-120% of the label claim
Percentage/Potency Cannabidiol (CBD)	Third Party Lab in-house validated method	80-120% of the label claim
Aflatoxins (B1+B2+G1+G2)	AOAC 991.31	<20 µg/kg (ppb) of substance
Microbiological purity Total Aerobic Plate Count Total Yeast and Molds	Current EP <2.6.12>	< 100 CFU/gram < 100 CFU/gram
E. coli Bile Tolerant Gram Negative bacteria Salmonella spp	Current EP <2.6.31>	Absent Absent Absent Absent
Pesticides Residues	Current USP <561>	Absent
Elemental Analysis for: Lead Total Mercury Cadmium Total Arsenic	Third Party Lab in-house validated method	<0.29 µg/kg b.w./day* <0.29 µg/kg b.w./day* <0.09 µg/kg b.w./day* <0.14 µg/kg b.w./day* * Based on average body weight of 70 kg

Product: TBD **Product Code: TBD**

Parameter	Method	Specification
Loss on Drying	Current USP <731> Milled material (0.500 gram) is stored for 24h at 40°C in vacuum in the presence of phosphorus pentoxide as a desiccant.	≤ 10.0 %

Approved By: _____ Date: _____
Quality Assurance

Approved By: _____ Date: _____
Senior Person in Charge (SPIC)