DEPARTMENT FOR ENTERPRISE

Consultation on A Regulatory Framework for Cannabis-derived Products for Export

October 2020

Isle of Man Government

Reiltys Ellan Vannin

1. Aim

The Department for Health and Social Care (DHSC) held a public consultation in 2019 which indicated strong support for the creation of a regulatory framework for facilitating an export-based cannabis sector.

In line with the Programme for Government's strategic objective, 'An Island of Enterprise and Opportunity', the Department for Enterprise is now consulting on the establishment of a Regulatory Framework ('Framework') for Cannabis-derived Products for Export.

The intent of such a Framework is to facilitate potential opportunities for new economic activity within the Isle of Man and the Department for Enterprise (the Department) is leading on the facilitation of these opportunities, which includes the development of a licensing framework prescribed by new Regulations and supporting guidance.

This consultation seeks feedback from interested parties on the details of the proposed Framework. The Council of Ministers has approved a consultation period of four weeks given the technical nature of the consultation and its limited scope on the Framework.

This consultation addresses only issues related to an export industry and doesn't consider any changes to the domestic legality of prescription medicinal cannabis or the legality of non-medical use of cannabis in the Isle of Man. Any comments made in this respect will not be addressed.

2. How to respond

The deadline for responses is **5pm on the 19th November 2020**.

Responses must be made in writing and sent by email or post to:

Business Isle of Man
Department for Enterprise
St George's Court
Upper Church Street, Douglas,
Isle of Man, IM1 1EX

Email: dfeconsultation@gov.im

When responding, please state whether you are responding as an individual or representing the views of an organisation. If responding on behalf of a larger organisation, please make it clear who the organisation represents and, where applicable, how the views of members were assembled.

If you cannot contact us in writing for any reason, please telephone us on +44 (0)1624 685670.

3. Freedom of Information

Information provided in response to this consultation, including personal information, may be subject to publication or disclosure in accordance with the Freedom of Information Act 2015 (FOIA).

If you want information that you provide to be treated as confidential, please be aware that, under the FOIA, there is a statutory Code of Practice with which public authorities must comply and which deals, amongst other things, with obligations of confidence.

In view of this it would be helpful if you could explain to us why you regard the information you have provided as confidential. If we receive a request for disclosure of the information, we will take full

account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances.

An automatic confidentiality disclaimer generated by your IT system will not, of itself, be regarded as binding on the Department. The Department will process your personal data in accordance with the Data Protection Act 2018 and in the majority of circumstances this will mean that your personal data will not be disclosed to third parties. A copy of the Act is available here:

https://legislation.gov.im/cms/images/LEGISLATION/PRINCIPAL/2018/2018-0010/DataProtectionAct2018_1.pdf

4. Data Protection

The Department for Enterprise (the "Department") is carrying out this consultation to seek feedback from industry, potential investors and other interested stakeholders on the proposals, with a particular focus on:

- the proposed regulations for domestic cultivation of industrial hemp, cannabis (including importation of biomass) and the manufacture of related cannabis-derived products for export, including prescribed fees; and
- a proposed licensing framework, minimum standards for applicants, and guidelines.

This feedback will help shape the regulatory proposals needed to support the Framework.

This consultation and the processing of personal data that it entails is necessary for the exercise of our functions as a government department. If your answers contain any information that allows you to be identified, the Department will, under data protection law, be the controller for this information.

As part of this consultation we're asking for your name and contact details. This is in case we need to ask you follow-up questions about any of your responses and to determine the relevance of your response to the proposed Framework.

You do not have to give us this personal information. If you do provide it, we will use it only for the purpose of asking follow-up questions and determining the establishment of the proposed Framework.

The Department's privacy policy has more information about your rights in relation to your personal data, how to complain and how to contact the Data Protection Officer, you can access this here:

https://www.iomdfenterprise.im/policy/privacy-policy

Your information will be kept securely and destroyed within 1 month after the consultation has been completed.

5. Consultation

This consultation paper sets out the details of the proposed Framework. Through consultation, the Department wishes to seek feedback from industry, inward investors and other interested stakeholders on the proposals, with a particular focus on:

(a) the proposed regulations for domestic cultivation of industrial hemp, cannabis (including importation of biomass) and the manufacture of related cannabis-derived products for export including prescribed fees; and

(b) the proposed licensing framework, minimum standards and guidelines for applicants.

This feedback will help shape the regulatory proposals needed to support the Framework.

As the proposals include the making of Regulations under the Misuse of Drugs Act, in accordance with the Act, the Department will be consulting directly with the Advisory Council on the Misuse of Drugs.

In addition, the Department will also be consulting directly with interested parties including the Manx National Farmers' Union, the Isle of Man Constabulary, prospective commercial operators and industry bodies.

Layout of the consultation paper

This consultation paper is divided into six main sections:

Part 1: Introduction

Part 2: Legislative Pathway

Part 3: Regulatory Framework

Part 4: Licence Requirements

Part 5: Fees

Part 6: Questions

Appendix 1: Draft regulations

Appendix 2: Detailed Licence requirements

Annex A: What is Cannabis, THC, CBN, CBD and Industrial Hemp?

GLOSSARY

Term	Definition
CBD	Cannabidiol
CBN	Cannabinol
DfE, Department	Department for Enterprise
DHSC	Department of Health and Social Care
EC	European Commission
ESFA	European Food Standards Agency
EU	European Union
FSA	Food Standards Authority
MHRA	Medicines and Healthcare products Regulatory Authority
THC	Tetrahydrocannabinol
UK	United Kingdom
UN	United Nations
WHO	World Health Organisation

1. INTRODUCTION

- The Department is seeking feedback to proposed Regulations which will be made under the Misuse of Drugs Act 1976 to bring a hemp, CBD and medicinal cannabis export industry to the Island.
- The DHSC previously held a public consultation in 2019 which garnered significant public, commercial and departmental input and participants indicated strong support for the creation of a framework for facilitating an export-based cannabis sector.
- This consultation address only issues related to an export industry and does not consider any changes to domestic legality of prescription medicinal cannabis or the legality of non-medical use of cannabis in the Isle of Man. The consultation does not consider related activities for the domestic sales or consumption of cannabis-derived products.
- Feedback is specifically requested on the framework, the regulatory regime, the interoperability of regulators and the licence fee structure.
- As proposed, the Department does not believe that these amendments allow any conduct in the Isle of Man that is not already permissible in the United Kingdom under the Misuse of Drugs Act 1971 (as amended). The Isle of Man Government is engaged in active conversations with the UK Government to ensure the proposed regulatory and legislative changes comply with the UN Single Convention on Narcotic Drugs (1961) which is extended to the Isle of Man and establishes a framework to prevent abuse and diversion of controlled narcotics while supporting the availability of such drugs for medicinal purposes.
- The cannabis plant has been used in society for centuries. In recent years, a growing body of research has emerged related to potential health benefits of cannabis, leading to the development of new products to meet consumer demand for these uses.
- Consumers and commercial cannabis operators are increasingly calling for clear guidance for the oversight of these products to ensure confidence in the supply chain, including safeguards that inform consumers of the ingredients, potency and legal distribution of cannabis-derived products.
- The Department sees an opportunity to create a framework for a well-regulated licensing structure to serve this need for today's and tomorrow's cannabis-derived products. In doing so, The Isle of Man can be a leading and trusted jurisdiction in licensing cannabis products.
- Reports[1] suggest that the European medicinal cannabis market will grow to nearly US$4 billion and that the CBD market will grow to nearly US$1.6 billion by 2025.
- The Department believes there may be an opportunity to create a well-regulated and safe export industry with the potential to create up to 250 direct Isle of Man jobs by 2025, the potential to generate up to £11.5 million in wages and potential exchequer benefit of £3 million per annum, based upon the Island's current fiscal environment.
- The objective is to facilitate, through a world class regulatory structure, a new cannabinoid cultivation and processing industry for export whilst safeguarding the Island's reputation, the health and safety of our community and our commitment to encourage sustainable economic activity in harmony with our natural resources.
- The Isle of Man has an opportunity to secure a share of this growing industry by filling a gap in the market for clear regulatory guidance and oversight of this new industry and leveraging the Island's historic success in building gold-standard regulations for complex emerging industries,

[1] Brightfield Group (European Cannabis Report and European CBD Report, April 2020)

most notably as it has done in the e-Gaming sector but also building on the strengths the Island has achieved in its Ship Registry and Aircraft Registry regimes.

- The European Parliament voted in February 2019 to improve access to medical cannabis, and research its public health effects, urging the European Commission and Member States to address regulatory, financial and cultural barriers which burden scientific research and invites them to properly fund research.
- This presents the Isle of Man with an opportunity to provide the right regulatory framework for businesses to establish on-island and address markets within the EU as they develop and mature.
- If developed, the industry could also have positive impacts on several existing sectors on the Isle of Man through indirect jobs, such as in financial and professional services, and could therefore contribute to securing opportunities for the Island's existing workforce.
- Background information on Cannabis, THC, CBN & CBD, Industrial Hemp and medicinal cannabis is available at Annex (A) for reference.

2. LEGISLATIVE PATHWAY

- Under the Misuse of Drugs Act 1976, it is currently illegal in the Isle of Man to cultivate any plant of the genus Cannabis.
- However, Section 7 of the Misuse of Drugs Acts 1976 makes provision for the DHSC to make regulations enabling licences to be granted for the cultivation, harvesting and processing of cannabis plants. The Act also makes provision for DHSC to prescribe fees for such licences.
- Any Regulations made under the Act are subject to Tynwald approval.
- To bring the new sector into operation it is therefore proposed that the provisions under the Misuse of Drugs Act are used to make two sets of Regulations to:
  - Provide that it is not unlawful under the Misuse of Drugs Act 1976 for a person to produce, supply, offer to supply or possess any cannabinol or cannabinol derivatives, or to cultivate Cannabis plants, if the person does so in accordance with the terms of, and in compliance with any conditions attached to, a licence issued under these Regulations authorising the person to do so.
  - Set out fees for applications, and renewals, for the various licence types issued under the Regulations.
- These Draft Regulations are set out in Appendix 1.
- The aim has been to align the Isle of Man legislation as closely as possible to that of the UK. The Isle of Man legislation mirrors that of the UK in respect of the originating power to make lawful conduct which would otherwise be unlawful.

3. REGULATORY FRAMEWORK

- Over 30 countries produce industrial hemp and many have a regulatory framework based on granting licences or permits. Details of the regulatory frameworks vary between countries although most aim to control production to ensure that the crop, or parts of it, cannot be diverted for illegal use (as recreational cannabis). Managing the risk of diversion is done by controlling the Controlled Cannabinoid concentration of the crop and, often, by requiring the destruction of those parts of the plant (leaves and flowers) that are not required for industrial processing into fibres or foodstuff.
- In the UK, the regulatory framework is based on granting licences to individual growers, allowing both cultivation and possession so long as certain criteria are met. The licensing and compliance is overseen by the Home Office, Crime and Policing Group. Licensing is based on the following criteria:
    - Applicants are expected to site their crops sensitively but there are no mandated requirements such as distance from schools, public rights of way or vehicular access.
    - The hemp seed used must be an 'EU approved variety'. These seeds have a THC content of less than 0.2%. No testing during cultivation or processing is required to confirm THC content in the crop.
    - Those parts of the plant not covered by the licence for industrial production (i.e. the leaves and flowers) remain illegal under the Misuse of Drugs legislation and must be retted (destroyed) at the licensed location or otherwise lawfully disposed of.
    - The local police should be made aware of the growing location.
    - Licences are usually issued to cover three consecutive growing seasons – so have up to three years' validity, although single season licences can also be issued. Holders of a three year licence are required to complete and submit an 'Annual Licence Review Statement' at the start of the growing season. Completion and submission is mandatory and without submission a licence may be revoked.
    - A Disclosure and Barring Service ('DBS') check is required for each applicant and the DBS application must have been lodged before the application for a licence is submitted.
    - If a grower is growing at multiple sites on one farm, this would be covered by their licence. However, if they are growing on multiple sites outside their main property, e.g. on land rented from a neighbour or in an adjacent village, additional licences may be required subject to discussion with the Home Office.
- In the Isle of Man, the power to make Regulations and to licence activity which would otherwise be unlawful under the Misuse of Drugs Act 1976, currently rests with the DHSC.
- However, as this sector is for exportation only, DHSC have agreed that the function of licensing and regulating the new sector shall be transferred to an alternative function within Government that is better placed to consider the aspects of licensing, vetting and supervising an emerging industry.
- A single, adequately resourced, regulator will ultimately be required, however whilst the sector is maturing, an existing single regulatory body (the Regulator) is considered to be the most practical interim solution. Discussions are ongoing to identify the most appropriate Island body.
- The Regulator will be responsible for issuing licences and conducting oversight and enforcement activities including monitoring compliance with licensee obligations.

- There may be occasions where the Regulator seeks support and guidance from other entities, on and off island, to ensure the effective and efficient execution of its regulatory functions.
- It is intended that licensing fee income will, at minimum, cover all future costs (see Fees, Part 5).
- It is proposed that a robust Licensing Policy will set out all requirements for applicants. Alongside licence conditions (see Licence Requirements Part 4), all applicants will need to positively satisfy Fit and Proper[2] criteria and due diligence investigations to be successful in obtaining a licence. This may positively limit the ability for some businesses to operate within the sector in order to ensure high quality applicants and limit the perceived and real potential risks of a new industry.
- The Regulator shall issue guidance on licensing policy and requirements for market participants as set out in draft in Appendix 2.

4. LICENCE REQUIREMENTS

There are 8 licences being considered to be issued with regard to the activity of the sector including:

I. Import, Transport and Store of Seed
II. Cultivation and Harvest
III. Transport and Store of product
IV. Extraction and Processing
V. Importation
VI. Exportation
VII. Manufacture
VIII. Analysis and Testing

- This targeted set of licences seeks to provide more clarity and transparency to the regime than other jurisdictions whilst ensuring nothing which is illegal in the United Kingdom can be undertaken as a result.
- The Misuse of Drugs Act 1976 gives the power to attach specific conditions to licences. All licences will be subject to a number of standard licence conditions in addition to any specific conditions applicable to the nature of the activity being undertaken.
- An overview of each licence type and a summary of relevant conditions and requirements for applicants is set out in Appendix 2.

5. FEES

- The proposed Misuse of Drugs (Licence Fees) Regulations 2020 will prescribe fees payable for licences.
- Cost recovery specifically applies to services that the Government has a statutory (legal) authority to deliver. Fees can be charged for a service directly provided to (or directly benefiting) individuals or organisations.

[2] Fit and Proper – a test to establish persons as honest and trustworthy to engage in regulated activities

- In setting these proposed fees, the Department has taken into consideration the principles of full recovery of the direct costs associated with the specific licensed activities. Feedback from the consultation will be used to inform final decisions to be made on the proposed cost recovery regime for the Framework, which will be prescribed in regulations and subject to Tynwald approval.
- All licence fees will be payable when an application is submitted. No work on the application will commence until the Regulator has received full payment of the fee.
- In situations where an applicant requires multiple licences, a waiver of certain fees may apply. This potential waiver applies if the Regulator is reasonably satisfied that the information and documents provided for each application are sufficiently similar to reduce the work involved in assessing them. Please note that the Regulator is not obligated to grant such a waiver, even if multiple applications are approved for a prospective market provider.
- The proposed prescribed fees payable for licences will allow for the costs of assessing and issuing a licence and the costs of administering the monitoring regime to be recovered from users. The proposed licensing regime for the Framework will include fees for the following activities:
    - importation, transportation and storage of cannabis seeds
    - cultivation of industrial hemp and cannabis plant material
    - cultivation and harvest of cannabis from male seeds for research only
    - transportation and storage of cannabis-derived products or cannabis biomass
    - extraction and/or processing of cannabis biomass, and/or preparations containing controlled cannabinoids extracted from cannabis biomass
    - importation and/or exportation of cannabis biomass, preparations containing controlled cannabinoids or cannabis-derived products
    - manufacture of cannabis-derived products
    - analysis and testing of cannabinoids.

- The proposed fee for each licence is based on the direct time and costs involved with:
    - receipt of applications, and screening of applications to determine completeness of the information provided;
    - assessment of application and police vetting of applicants;
    - on-site audits related to the application;
    - monitoring that the licence holder is complying with the licence conditions.

- Indirect costs such as those for establishing the cannabis proposition, policy development and enforcement activities are not included in the calculating of the proposed fees.
- The proposed fees have been calculated based on full recovery of the direct costs associated with the specific licensed activities. Table 1 reflects the assumption that the number of annual licence holders and renewals will stabilise after four years as the industry matures.
- This calculation includes the assumption that not all applications will be approved, and every year a certain percent of licences will not be renewed. However, given this is a new industry, the Department is unable to accurately establish fees and has provided bands to seek comment on. It is difficult to predict the volume or demand for licence applications with a high degree of certainty and the Department will monitor the fees on an ongoing basis. The fees may need to be adjusted to reflect changes in regulatory costs and industry and regulatory developments.

Table 1: Proposed licence fees

Activity	Application fee	Annual fee
Importation, transportation and/or storage of cannabis seeds	£1,500 - £3,000	£2,000
Cultivation and harvest of:		
i) low-THC cannabis without use of leaves, flowers and buds	£2,000 - £3,500	£5,000 plus £5 per m2 for above 2,000m2
ii) low-THC cannabis with use of leaves, flowers and buds	£4,000 - £8,000	£5,000 plus £5 per m2 up to 2,000m2 £15 per m2 for 2,000m2 to 5,000m2 £25 per m2 for 5,000m2 to 10,000m2 £40 per m2 for above 10,000m2
iii) high-THC cannabis	£10,000 - £15,000	£25,000, plus £10 per m2 up to 2,000m2 £20 per m2 for 2,000m2 to 5,000m2 £40 per m2 for 5,000m2 to 10,000m2 £60 per m2 for above 10,000m2
iv) cannabis from male seed for research only	£6,000 - £8,000	£10,000 - £12,000
Transportation and/or storage of cannabis-derived products or cannabis biomass	£2,500 - £3,500	£2,000 - £5,000
Extraction and/or processing of cannabis biomass and/or preparations containing controlled cannabinoids extracted from cannabis biomass	£25,000 - £30,000	£30,000 - £35,000
Importation of cannabis biomass or preparations containing controlled cannabinoids and/or cannabis-derived products	£2,500 - £3,500	£1,000 - £2,000
Exportation of cannabis biomass or preparations containing controlled cannabinoids and/or cannabis-derived products	£2,500 - £3,500	£1,000 - £2,000
Manufacture of cannabis-derived products	£2,500 - £3,500	£8,000 - £12,000
Analysis and testing of cannabinoids	£2,500 - £3,500	£8,000 - £12,000

6. QUESTIONS

- Please provide contact details.

- Please let us know your proposed activity in this sector: farmer, investor, producer, testing laboratory, logistics (including import/export), research, other (please specify)

- Please provide any overall comments on the proposals in the consultation document.

- Do you think the current proposals and options in this document will meet the Government's objective of providing a regulatory framework and fees structure that supports the development of a cannabinoid industry on the Island? If no, please provide details

Regulations:

- Are the definitions contained in the Regulations clear and appropriate?

- Are the licence types set out in the Regulations clearly defined and appropriate for the development of a cannabinoid industry on the Island?

Licensing:

- What licence(s) are you interested in applying for?

- Do you think the suggested 'Fit and Proper' person criteria are appropriate?

- Do you think the proposed licence requirements are appropriate?

- Are any of the proposed licensing requirements likely to impact on your ability to apply for a licence? If yes, please provide details.

Importation, transportation and/or storage of cannabis seeds:

Cultivation and harvest of low-THC cannabis without use of leaves, flowers and buds:

Cultivation and harvest of low-THC cannabis with use of leaves, flowers and buds:

Cultivation and harvest of high-THC cannabis:

Cultivation and harvest of cannabis from male seed for research only:

Transportation and/or storage of cannabis-derived products or cannabis biomass:

Extraction and/or processing of cannabis biomass and/or preparations containing controlled cannabinoids extracted from cannabis biomass:

Importation of cannabis biomass or preparations containing controlled cannabinoids and/or cannabis-derived products:

Exportation of cannabis biomass or preparations containing controlled cannabinoids and/or cannabis-derived products:

Manufacture of cannabis-derived products:

Analysis and testing of cannabinoids:

- How many cultivation sites, of each licence type, are you planning and what would be the average size of each cultivation area?

- How likely are you to apply for a licence to manufacture cannabis products? Please provide comments on why.

- If applicable, what types of cannabis products do you intend to manufacture?

- If you are intending to manufacture medicinal cannabis products to GMP, in what timeframe (from the start of the Framework) do you think you will have products available for assessment?

- If applicable, where are your likely markets for export of medicinal cannabis?

- If applicable, what type of medicinal cannabis product would you be interested in exporting? (Eg API, starting material, finalised product)

Fees:

- Which licence(s) do you intend to apply for within the next two years?

- Based on the proposed fees, how likely are you to enter this market?

- Will the proposed fees affect your ability to cultivate cannabis or manufacture cannabis products?

- Are the proposed cultivation area cut-off levels between small-scale and large-scale cultivation appropriate? Please provide comment.

- What is your position on the following statement: 'The fee structure and approach are fair for both licence holders and the public.'

- Do you think the cost for a lost or damaged licence is fair and reasonable?

- Do you think the proposal for the Regulator to waive fees is fair and reasonable?

- Do you have any additional comments on the proposed approach to fees?

Appendix 1: Draft regulations

CANNABIS AND CANNABINOIDS (EXEMPTIONS) REGULATIONS 2020

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Statutory Document No. 20XX/XXXX

Misuse of Drugs Act 1976

CANNABIS AND CANNABINOIDS (EXEMPTIONS) REGULATIONS 2020

Approved by Tynwald:
Coming into operation in accordance with regulation 2

The [TO BE CONFIRMED], after consultation with the Advisory Council on the Misuse of Drugs[1], makes the following Regulations under sections 7, 10, 22, 31 and 33 of the Misuse of Drugs Act 1976.

PART 1 – INTRODUCTION

1 Title

These Regulations are the Cannabis and Cannabinoids (Exemptions) Regulations 2020.

2 Commencement

If approved by Tynwald, these Regulations come into operation on [TO BE CONFIRMED][2].

3 Meaning of expressions in these Regulations

Expressions appearing in these Regulations have the meanings given to them in this Part unless the context otherwise requires.

4 General interpretation

In these Regulations —

"analysis" means the process of examining a material or substance in order to establish its constituent parts;

[1] Under section 31(2) of the Misuse of Drugs Act 1976 the [TO BE CONFIRMED] shall not make any regulations under that Act except after consultation with the Advisory Council.

[2] Under section 31(3) of the Misuse of Drugs Act 1976 these Regulations shall not have effect until they have been approved by Tynwald.

"buds", in relation to a plant, means the compact growth on the plant that develops into a leaf, flower, or shoot;

"export" means the removal from the Island to another jurisdiction;

"extraction" means the process of removal, separation or isolation of chemicals or compounds from a material or substance and **"extracted"** has a corresponding meaning;

"female" (by reference to cannabis seed) means a feminised cannabis seed produced by chemical ethylene inhibition or rodelization;

"flower" means the seed-bearing part of a plant, consisting of reproductive organs (stamens and carpels);

"import" means the bringing to the Island from another jurisdiction;

"indoors", in relation to the growing of cannabis, means growing cannabis inside a structure which —

(a) has an impermeable floor;

(b) is completely roofed and walled; and

(c) has no more than 20% of its surface area constructed from glass;

"leaf" means the flattened structure of the plant which is attached to a stem directly or via a stalk;

"preparation" means one or more substances or compounds which is created, distilled, isolated, drawn, or in any other way derived, from Cannabis biomass;

"processing" means the act of changing or treating something;

"product" means a substance, preparation or extraction which is refined and prepared for sale;

"research" means the study of a subject in order to discover new information or reach a new understanding;

"rodelization" means cultivation of a female plant to a point where the growth of male pollen sacs is stimulated, causing the plant to self-pollinate; and

"testing" means the process of establishing the safety, chemical content, characteristics and/or biological fingerprint of a material or substance.

5 Meaning of "cannabis", etc.

In these Regulations—

"cannabis" (except in the expression "cannabis resin") means any plant of the genus Cannabis or any part of any such plant (by whatever name designed) except that it does not include cannabis resin or any of the following residual by-products after separation from the rest of the plant—

(a) mature stalk of any such plant; and

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(b) fibre produced from the mature stalk of any such plant;

"cannabis biomass" means harvested material of the cannabis plant;

"cannabis-derived product" means a substance, compound, preparation or extraction which is separated, created, distilled, isolated, drawn, or in any other way derived, from cannabis biomass; and

"cannabis seeds" means seeds which, when cultivated, will produce cannabis.

6 Meaning of "controlled cannabinoids"

In these Regulations **"controlled cannabinoids"** means —

(a) cannabinol,

(b) tetrahydro derivatives of cannabinol; and

(c) 3-alkyl homologues of Cannabinol or of its tetrahydro derivatives,

as identified in the Schedule.

7 Meaning of "high-THC cannabis", etc.

In these Regulations—

"high-THC cannabis" means a plant in cultivation which contains greater than 0.2% THC content by reference to the mature plant;

"high-THC cannabis biomass" means harvested cannabis plant material which contains greater than 0.2% THC content by reference to the mature plant; and

"high-THC cannabis seeds" means seeds which when cultivated will produce "High-THC cannabis".

8 Meaning of "low-THC cannabis", etc.

In these Regulations—

"low-THC cannabis" means a plant in cultivation which contains less than 0.2% THC content by reference to the mature plant;

"low-THC cannabis biomass" means harvested cannabis plant material which contains less than 0.2% THC content by reference to the mature plant**;** and

"low-THC cannabis seeds" means seeds which when cultivated will produce Low-THC Cannabis.

9 Meaning of "cultivation", etc.

(1) In these Regulations, subject to the other paragraphs in this regulation, **"cultivation"** means the act of raising plants and includes all of the steps up to, but not including, harvest and **"cultivate"** and **"in cultivation"** have corresponding meanings.

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(2) In order to cultivate cannabis there has to be an acquisition of cannabis seeds.

(3) For the purpose of these Regulations the process of cultivation includes, but is not limited to—

(a) the acquisition, transportation and storage of cannabis seeds within the Island by a party with the intention to supply them to a cultivator; and

(b) where the cultivator enters into an arrangement for their acquisition, the transportation and storage of cannabis seeds within the Island.

(4) For the purposes of these Regulations, **"cultivation"** also includes—

(a) the sowing of cannabis seeds; and

(b) the planting, growing, tending, nurturing or pruning of a cannabis plant,

but does not include the production or manufacture of any part of the cannabis plant.

(5) In these Regulations **"cultivator"** means a person who intends to undertake the cultivation of cannabis.

10 Meaning of "manufacture of a cannabis-derived product"

(1) In these Regulations **"manufacture of a cannabis-derived product"** means all of the steps taken after production, but before export or sale, including the ones specified in paragraph (2).

(2) The steps referred to in paragraph (1) are—

(a) the use or creation of a cannabis-derived product or preparation by the refining, distillation, purification and blending and mixing of one or more elements with the original cannabis-derived product or preparation;

(b) the use or creation of a cannabis-derived product or preparation by the refining, distillation, purification and blending and mixing of one or more elements with the original cannabis-derived product or preparation and another cannabis-derived product or preparation;

(c) any activity which alters the original chemical or biological property of a cannabis-derived product or preparation in its appearance, behaviour or structure;

(d) the packaging of a cannabis-derived product or preparation;

(e) the supply of a manufactured cannabis-derived product or preparation to another person; and

(f) the supply or storage of a final cannabis-derived product or preparation.

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11 Meaning of "harvest"

In these Regulations **"harvest"** means all of the steps taken after cultivation, but before production, including—

(a) the cutting, trimming or removal of any cannabis plant material;

(b) the grafting, division or transplant of a cannabis plant;

(c) the placing of a cannabis plant in a container for any purpose other than disposal; and

(d) the supply of any harvested cannabis plant material for research, production or manufacture.

12 Meaning of "pruning"

In these Regulations **"pruning"** is an activity conducted during the period of cultivation before harvesting. and includes the cutting away of dead or overgrown branches or stems in order to—

(a) encourage growth;

(b) remove superfluous or unwanted parts; and

(c) improve or maintain plant health.

13 Controlled drugs to which these Regulations apply

The controlled drugs to which these Regulations apply are specified in the Schedule.

PART 2 – LICENCES

14 Licences to produce etc. cannabinol or cannabinol derivatives

Where any person is authorised by a licence of the [TO BE CONFIRMED] issued under this regulation and for the time being in force to produce, supply, offer to supply or have in his possession any cannabinol or cannabinol derivatives, it shall not by virtue of section 4(1) or 5(1) of the Act be unlawful for that person to produce, supply, offer to supply or have in his possession any cannabinol or cannabinol derivatives (as the case may be) in accordance with the terms of the licence and in compliance with any conditions attached to the licence.

15 Cultivation under licence of cannabis plant

Where any person is authorised by a licence of the [TO BE CONFIRMED] issued under this regulation and for the time being in force to cultivate plants of the genus *Cannabis*, it shall not by virtue of section 6 of the Act be unlawful for that person to cultivate any such plant in accordance with the terms of the licence and in compliance with any conditions attached to the licence.

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16 Licences which can be issued by [TO BE CONFIRMED]

(1) Where any person is authorised by a licence of the [TO BE CONFIRMED] issued under regulation 14 or 15 and for the time being in force to produce, supply, offer to supply or to have in the person's possession any cannabinol or cannabinol derivatives or to cultivate plants of the genus *Cannabis*, it is lawful for the person to carry out any activity specified in paragraphs (2) to (9) which under section 4(1), 5(1) or 6(1) of the Act it would otherwise be unlawful for that person to do.

(2) The activity in this paragraph is the import, transport and storage of cannabis seeds.

(3) The activity in this paragraph is the cultivation and harvest of—

(a) low-THC cannabis grown from female low-THC cannabis seeds with a prohibition on the use of leaves, buds and flowers of the plant;

(b) low-THC cannabis grown from female low-THC cannabis seeds with permission to use the leaves, buds and flowers of the plant;

(c) high-THC cannabis grown indoors from female high-THC cannabis seeds; and

(d) cannabis grown indoors from male seeds for the purpose of research only.

(4) The activity in this paragraph is the transport and storage of —

(a) cannabis biomass containing controlled cannabinoids;

(b) preparations containing controlled cannabinoids extracted from cannabis biomass where the leaves, buds and flowers were intact at first extraction and processing; and

(c) any cannabis-derived product.

(5) The activity in this paragraph is the extraction and processing of —

(a) cannabis biomass containing controlled cannabinoids; and

(b) preparations containing controlled cannabinoids extracted from cannabis biomass where the leaves, buds and flowers were intact at first extraction and processing.

(6) The activity in this paragraph is the import of—

(a) cannabis biomass containing controlled cannabinoids;

(b) preparations containing controlled cannabinoids; and

(c) any cannabis-derived product.

(7) The activity in this paragraph is the export of—

(a) cannabis biomass containing controlled cannabinoids;

(b) preparations containing controlled cannabinoids; and

(c) any cannabis-derived product.

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(8) The activity in this paragraph is the manufacture of any cannabis-derived product.

(9) The activity in this paragraph is the analysis and testing of cannabinoids.

(10) A licence to engage in the cultivation and harvest of a substance or a product specified—

(a) in paragraph (3)(a) is to be known as a "low-THC cultivation and harvest licence (without use)";

(b) in paragraph (3)(b) is to be known as a "low-THC cultivation and harvest licence (with use)"; and

(c) in paragraph (3)(c) is to be known as a "high-THC cultivation and harvest licence".

17 Licence duration

Any licence issued under regulation 14 or 15 is valid for a period of one calendar year from the date of its issue, subject to being modified or revoked.

PART 3 - CONSEQUENTIAL AMENDMENTS

18 Consequential amendments

(1) The Misuse of Drugs (Miscellaneous Enactments) (Application) Order 2013[3] is amended as follows.

(2) In article 8 (other modifications of the 2001 Regulations) —

(a) after paragraph (4) insert—

"(4A) Omit regulation 5.";

(b) after paragraph (6) insert—

"(6A) Omit regulation 12.";

(c) after paragraph (9) insert—

"(9A) In regulation 19—

(a) in paragraph (1), for "regulation 5 or 8" substitute "regulation 14 of the Cannabis and Cannabinoids (Exemptions) Regulations 2020 or regulation 8"; and

(b) in paragraph (3)(b), for "regulation 5" substitute "regulation 14 of the Cannabis and Cannabinoids (Exemptions) Regulations 2020.";

(d) after paragraph (11) insert —

[3] SD 0310/13.

"(11A) In regulation 22 for "regulation 5 or 9(1)(c)" substitute "regulation 14 of the Cannabis and Cannabinoids (Exemptions) Regulations 2020 or regulation 9(1)(c).", and

(e) for paragraph (14) substitute —

"(14) In regulation 27—

(a) in paragraph (1)—

(i) for "these Regulations" substitute "the Cannabis and Cannabinoids (Exemptions) Regulations 2020 or these Regulations"; and

(ii) omit "or, subject to paragraph (1A), an accountable officer";

(b) omit paragraph (1A); and

(c) in paragraph (3) for "these Regulations" substitute "the Cannabis and Cannabinoids (Exemptions) Regulations 2020 or these Regulations".

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[TO BE CONFIRMED]

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SCHEDULE

[Regulation 13]

CONTROLLED DRUGS TO WHICH THESE REGULATIONS APPLY

These Regulations apply to the following substances and products—

(a) Cannabis;

(b) Cannabinol;

(c) Tetrahydro derivatives of Cannabinol; and

(d) 3-alkyl homologues of Cannabinol or of its tetrahydro derivatives.

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EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations provide that it is not unlawful under the Misuse of Drugs Act 1976 for a person to produce, supply, offer to supply or possess any cannabinol or cannabinol derivatives, or to cultivate Cannabis plants, if the person does so in accordance with the terms of, and in compliance with any conditions attached to, a licence issued under these Regulations authorising the person to do so, and make related provision.

They also make consequential amendment to the Misuse of Drugs (Miscellaneous Enactments) (Application) Order 2013 so as to omit equivalent provision (and cross-references to it) to that made by these Regulations in the Misuse of Drugs Regulations 2001 [SI 2001/3998] as those Regulations are applied to the Island under that Order.

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MISUSE OF DRUGS (LICENCE FEES) REGULATIONS 2020

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Statutory Document No. 20XX/XXXX

Misuse of Drugs Act 1976

MISUSE OF DRUGS (LICENCE FEES) REGULATIONS 2020

Approved by Tynwald:
Coming into operation in accordance with regulation 2

The [TBC], after consultation with the Advisory Council on the Misuse of Drugs[1], makes the following Regulations under sections 30, 31 and 38 of the Misuse of Drugs Act 1976.

PART 1 – INTRODUCTION

1 Title

These Regulations are the Misuse of Drugs (Licence Fees) Regulations 2020.

2 Commencement

If approved by Tynwald, these Regulations come into operation on [TBC][2].

3 Meaning of expressions in these Regulations

Expressions appearing in these Regulations have the meanings given to them in this Part unless the context otherwise requires.

4 General interpretation

In these Regulations—

"analysis" means the process of examining a material or substance in order to establish its constituent parts;

"buds", in relation to a plant, means the compact growth on the plant that develops into a leaf, flower, or shoot;

[1] Under section 31(2) of the Misuse of Drugs Act 1976 [tbc] shall not make any regulations under that Act except after consultation with the Advisory Council.
[2] Under section 31(3) of the Misuse of Drugs Act 1976 these Regulations shall not have effect until they have been approved by Tynwald.

"export" means the removal from the Island to another jurisdiction;

"extraction" means the process of removal, separation or isolation of chemicals or compounds from a material or substance and **"extracted"** has a corresponding meaning;

"female" (by reference to cannabis seed) means a feminised cannabis seed produced by chemical ethylene inhibition or rodelization;

"flower" means the seed-bearing part of a plant, consisting of reproductive organs (stamens and carpels);

"importation" means the bringing to the Island from another jurisdiction;

"indoors", in relation to the growing of cannabis, means growing cannabis inside a structure which—

(a) has an impermeable floor;

(b) is completely roofed and walled; and

(c) has no more than 20% of its surface area constructed from glass;

"leaf" means the flattened structure of the plant which is attached to a stem directly or via a stalk;

"preparation" means one or more substances or compounds which is created, distilled, isolated, drawn, or in any other way derived, from Cannabis biomass;

"processing" means the act of changing or treating something;

"product" means a substance, preparation or extraction which is refined and prepared for sale;

"research" means the study of a subject in order to discover new information or reach a new understanding;

"rodelization" means cultivation of a female plant to a point where the growth of male pollen sacs is stimulated, causing the plant to self-pollinate; and

"testing" means the process of establishing the safety, chemical content, characteristics and biological fingerprint of a material or substance.

5 Meaning of "cannabis", etc.

In these Regulations—

"cannabis" (except in the expression "cannabis resin") means any plant of the genus Cannabis or any part of any such plant (by whatever name designed) except that it does not include cannabis resin or any of the following residual by-products after separation from the rest of the plant—

(a) mature stalk of any such plant; and

(b) fibre produced from the mature stalk of any such plant;

"cannabis biomass" means harvested material of the cannabis plant;

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"cannabis-derived product" means a substance, compound, preparation or extraction which is separated, created, distilled, isolated, drawn, or in any other way derived, from cannabis biomass; and

"cannabis seeds" means seeds which, when cultivated, will produce cannabis.

6 Meaning of "controlled cannabinoids"

In these Regulations **"controlled cannabinoids"** means —

(a) cannabinol;

(b) tetrahydro derivatives of cannabinol; and

(c) 3-alkyl homologues of Cannabinol or of its tetrahydro derivatives,

as identified in the Schedule.

7 Meaning of "high-THC cannabis"

In these Regulations **"high-THC cannabis"** means a plant in cultivation which contains greater than 0.2% THC content by reference to the mature plant.

8 Meaning of "low-THC cannabis"

In these Regulations **"low-THC cannabis"** means a plant in cultivation which contains less than 0.2% THC content by reference to the mature plant.

9 Meaning of "cultivation", etc.

(1) In these Regulations, subject to the other paragraphs in this regulation, **"cultivation"** means the act of raising plants and includes all of the steps up to, but not including, harvest and **"cultivate"** and **"in cultivation"** have corresponding meanings.

(2) In order to cultivate cannabis there has to be an acquisition of cannabis seeds.

(3) For the purpose of these Regulations the process of cultivation includes, but is not limited to—

(a) the acquisition, transportation and storage of cannabis seeds within the Island by a party with the intention to supply them to a cultivator; and

(b) where the cultivator enters into an arrangement for their acquisition, the transportation and storage of cannabis seeds within the Island.

(4) For the purposes of these Regulations, **"cultivation"** also includes—

(a) the sowing of cannabis seeds; and

(b) the planting, growing, tending, nurturing or pruning of a cannabis plant,

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but does not include the production or manufacture of any part of the cannabis plant.

(5) In these Regulations **"cultivator"** means a person who intends to undertake the cultivation of cannabis.

10 Meaning of "harvest"

In these Regulations **"harvest"** means all of the steps taken after cultivation, but before production, including—

(a) the cutting, trimming or removal of any cannabis plant material;

(b) the grafting, division or transplant of a cannabis plant;

(c) the placing of a cannabis plant in a container for any purpose other than disposal; and

(d) the supply of any harvested cannabis plant material for research, production or manufacture.

11 Meaning of "pruning"

In these Regulations **"pruning"** is an activity conducted during the period of cultivation before harvesting and includes the cutting away of dead or overgrown branches or stems in order to—

(a) encourage growth;

(b) remove superfluous or unwanted parts; and

(c) improve or maintain plant health.

PART 2 – PRESCRIBED FEES

12 Prescribed Fees

(1) Where a licence is, under regulation 14 or 15 of the Cannabis and Cannabinoids (Exemptions) Regulations 2020, issued to a person for the first time, the fee payable is the one which is set out in the table in Schedule 2.

(2) Where a licence is, under regulation 14 or 15 of the Cannabis and Cannabinoids (Exemptions) Regulations 2020, issued to a person who has already been issued with such a licence, the fee payable is the one which is set out in the table in Schedule 3.

(3) Where a person has lost a licence issued under any of the provisions in paragraphs (1) and (2), or where such licence has been defaced or damaged, and that licence is re-issued to the person, the fee payable shall be £45.

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13 Discretion to waive a licence fee

No fee is payable in respect of a licence where the [TBC] determines that the fee should be waived.

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Minister for [TBC]

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SCHEDULE 1

[Regulation 6]

CONTROLLED CANNABINOIDS

The following substances and products, namely—

(a) Cannabis;

(b) Cannabinol;

(c) Tetrahydro derivatives of Cannabinol; and

(d) 3-alkyl homologues of Cannabinol or of its tetrahydro derivatives.

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SCHEDULE 2

[Regulation 12]

APPLICATION FEES

Table

	Cannabinoid Licence	**Fee**
1	Importation, transportation or storage of cannabis seeds	
2	Cultivation and harvest of low-THC cannabis with prohibited use of leaves, bud and flowers	
3	Cultivation and harvest of low-THC cannabis with permission to use leaves, buds and flowers	
4	Cultivation and harvest of high-THC cannabis grown indoors	
5	Cultivation and harvest of cannabis grown indoors from male seeds for research only	
6	Transportation and storage of— (a) cannabis biomass containing controlled cannabinoids; (b) preparations containing controlled cannabinoids; or (c) cannabis-derived products	
7	Extraction or processing of— (a) cannabis biomass; (b) preparations containing controlled cannabinoids; or (c) extracted from cannabis biomass	
8	Importation of— (a) cannabis biomass; (b) preparations containing controlled cannabinoids; or (c) cannabis-derived products	
9	Exportation of— (a) cannabis biomass; (b) preparations containing controlled cannabinoids; or (c) cannabis-derived products	
10	Manufacture of cannabis-derived products	
11	Analysis and testing of cannabinoids	

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SCHEDULE 3

[Regulation 13]

ANNUAL FEES

Table

	Cannabinoid Licence	**Fee**
1	Importation, transportation or storage of cannabis seeds	
2	Cultivation and harvest of low-THC cannabis with prohibited use of leaves, bud and flowers	
3	Cultivation and harvest of low-THC cannabis with permissio to use leaves, buds and flowers	
4	Cultivation and harvest of high-THC cannabis grown indoors	
5	Cultivation and harvest of cannabis grown indoors from male seeds for research only	
6	Transportation and storage of — (a) cannabis biomass containing controlled cannabinoids; (b) preparations containing controlled cannabinoids; or (c) cannabis-derived products.	
7	Extraction or processing of— (a) cannabis biomass; (b) preparations containing controlled cannabinoids; or (c) extracted from cannabis biomass	
8	Importation of— (a) cannabis biomass; (b) preparations containing controlled cannabinoids; or (c) cannabis-derived products	
9	Exportation of— (a) cannabis biomass; (b) preparations containing controlled cannabinoids; or (c) cannabis-derived products	
10	Manufacture of cannabis-derived products	
11	Analysis and testing of cannabinoids	

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EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations prescribe the fees payable in relation to a licence issued by [TO BE CONFIRMED] disapplying the prohibition against the importation or exportation of certain controlled drugs (within the meaning of the Misuse of Drugs Act 1976) or authorising the production, supply or offer to supply, possession or cultivation of such drugs.

The prescribed fees include initial application fees and annual fees. The [TO BE CONFIRMED] can also waive fees otherwise payable.

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Appendix 2: Detailed Licence requirements

This Appendix consists of nine sections, setting out the overarching licensing policy and the eight draft detailed licence requirements:

i. Cannabinoid Licensing Policy
ii. Licence to Import, Transport and Store Seed
iii. Licence to Cultivate and Harvest
iv. Licence to Transport and Store
v. Licence for Extraction and Processing
vi. Licence for Importation
vii. Licence for Exportation
viii. Licence for Manufacture of Cannabis-derived products
ix. Licence for Analysis and Testing

i. Cannabinoid Licensing Policy ("Licensing Policy")

The Regulator will adopt a robust Licensing Policy which will set out its requirements for applicants. These will include its expectations for a simple and transparent corporate structure which will enable the Regulator to identify the ultimate beneficial owners of the business; the persons who exercise control over the appointment of the management team (directors and controllers); the management team including the Money Laundering Reporting Officer ("MLRO"); and other key persons (together "officers").

The Regulator will only license corporate entities but will not license protected cell companies, incorporated cell companies or foundations.

In addition, the Licensing Policy will detail the Fit and Proper Criteria that applicants and its officers must positively satisfy to be successful in obtaining a licence for their business. The Licensing Policy will also impose a continuing obligation on licenceholders to meet the Licensing Policy and to notify the Regulator of matters relevant to the officers' fitness and propriety. Any intention to change its ownership or control structure, must be notified to the Regulator prior to making any changes, as the proposals may alter the Regulator's assessment of the licenceholder as a fit and proper person.

In determining licence applications, particularly a new business start-up, the Regulator will consider the potential risks of granting a licence; the impact of its licensing decision on the stability of the financial system of the Island; and the effect the granting of the licence could have on the reputation of the Island.

Before being granted a licence, an applicant and its officers must positively satisfy the Regulator that they are fit and proper to undertake the Cannabinoid activity. Where the Regulator is not positively satisfied, an application will be turned down. It is for the applicant and its officers to satisfy the Regulator that they are fit and proper, rather than the Regulator to prove that the applicant and its officers are not fit and proper.

In considering an officer's fitness and propriety. The Regulator will have regard to:

- whether an officer's holding of a particular role or interest would expose the applicant to undue risk;
- whether an officer's holding of a particular role or interest would otherwise hinder effective supervision; and
- whether the interests of customers or potential customers of the applicant are, or are likely to be prejudiced, by an officer's holding of a particular role or interest.

The Regulator will objectively take into consideration the cumulative effect of the information before it in relation to the fitness and propriety of the applicant and its officers, and how this could impact upon its regulatory objectives. It is possible that single matters (which, taken in isolation, would not justify a refusal to issue a licence) may, when considered alongside other matters have the cumulative effect of being sufficient to refuse to issue a licence.

The Fit and Proper Criteria consists of three main components – integrity, competence and solvency.

Integrity

In assessing the integrity of an applicant and its officers, the Regulator will consider whether any of their current or past actions or conduct indicate a lack of integrity. The applicant and its officers should co-operate in an open and honest manner with the Regulator and must promptly inform the Regulator of anything relevant to its task. Failure to do so may be relevant to an assessment of an officer's integrity. This includes the failure to complete a form or supply information required in an honest manner, or the omission of any relevant information.

As part of the vetting procedure, the applicant and its officers are required to disclose any convictions that are not spent convictions to the Regulator. Given the importance of compliance with AML/CFT legislation, when assessing fitness and propriety, the Regulator would take into consideration whether any officer associated with the applicant:

(a) has been convicted of an offence —
- under AML/CFT legislation;
- under the law of a country or territory outside the Island if the conduct giving rise to the offence would constitute an offence under sub-paragraph (i) if it had occurred in the Island;
- involving dishonesty (whether under the law of the Island or elsewhere);
- under a relevant Act; or
- of perjury or conspiracy to pervert the course of justice (whether under the law of the Island or elsewhere);

(b) is or has been the subject of any action with respect to any breach of a relevant Act (as defined) or AML/CFT legislation;

(c) has knowingly or recklessly provided misleading or false information in the application for registration; or

(d) is otherwise considered by the Regulator not to be fit and proper for reasons related to the risk of money laundering or the financing of terrorism.

The Regulator will consider all relevant circumstances, on a case-by-case basis.

Serious or repeated breaches of legislation in the Island, or in another jurisdiction, by an applicant and/or its officers will, prima facie, suggest a lack of competence and/or integrity.

The Regulator will consider, on a case-by-case basis, whether a previous conviction is relevant to its current assessment of whether an officer is fit and proper.

Competence

The applicant must be able to demonstrate that it has a proven track record and relevant competency in the cannabinoid sector and employ key persons that have relevant experience in the market including, where appropriate, detailed knowledge of the risks of the products associated with the activity. The proposed classes of cannabinoid activities and jurisdictions in which products will be offered are relevant

when assessing an applicant's competence. An applicant must be able to demonstrate the existence of adequate risk management systems and controls for the risks associated to its activities and jurisdictions in which it operates.

The applicant will be required to appoint an MLRO who can demonstrate his or her competence to undertake the role by holding relevant qualifications; having sufficient experience; and being appropriately supervised and trained to competently fulfil their functions and legal responsibilities.

The Regulator may invite individuals to attend a personal interview to clarify any issues arising and/or to form an opinion regarding an individual's competence and/or integrity.

Solvency

Solvency is more than meeting liabilities as they fall due; it includes maintaining sufficient financial resources to survive periods of market weakness and slack trading conditions. Taking account of contingent and prospective liabilities, an applicant must be, and be likely to remain, a going concern. To establish the applicant's track record of financial stability and the ability to meet the going concern requirement, where the applicant is an existing company the Regulator will require a copy of the applicant's past 2 years' audited annual financial statements. If less than 2 years have elapsed since the applicant's incorporation, it will be required to submit its annual financial statements for the relevant number of years.

In addition, the business plan submitted by the applicant must include considered and realistic financial projections for the next 2 years including clear explanation of the assumptions used. Any applicant, especially one that is a new business start-up, must demonstrate convincingly the financial viability of its proposals.

The Regulator will consider the solvency of the applicant's officers and will require evidence that funds have been provided to meet the share capital requirement e.g. evidence of funds being lodged to pay up share capital.

As part of its consideration of an application, the Regulator will require information on the source of wealth and source of funds of prospective controllers.

Business Plan

An application for a licence to conduct cannabinoid activity under the Misuse of Drugs Act 1976 ('the Act') must be accompanied by a business plan. The extent and complexity of the business plan will vary according to the scale and complexity of the proposed business and related documents may be needed to support the information included in a business plan. The applicant is encouraged to consider what is likely to be relevant to the Regulator's assessment of its application, taking into account the nature of the applicant's activities or proposed activities, as well as the Licensing Policy, however, as a minimum the business plan should include -

- a summary of the applicant's history or, for start-ups, the rationale for entering the chosen cannabinoid business area;
- the applicant's business objectives and strategy;
- the cannabinoid activities to be undertaken by the applicant and a summary of specific products to be offered;
- an analysis of the cannabinoid market being entered, the perceived opportunities and the applicant's competitive strengths;
- the marketing strategy, marketing methods and details of the markets to be targeted; including the type of client and geographical areas; and

- an estimate of the power requirements for the proposed operations and an outline of the applicants' plans for how to contribute to the goals set out in the Climate Change Bill.

Standard and Specific Licence Conditions

In addition to compliance with the Licensing Policy, all cannabinoid licences will be subject to a number of standard licence conditions in addition to any specific conditions applicable to the nature of the activity being undertaken.

Standard licence conditions will require –

a) enhanced checks to be undertaken by the Disclosure and Barring Service (formerly the Criminal Records Bureau) in respect of all individuals engaged by, or for the benefit of, the applicant (including employees, contractors and sub-contractors) and who may have access to Cannabinoids during storage and/or transportation. These checks must be obtained for drug licence purposes; name the Regulator as the interested party; and must be no more than 12 months old;

b) clear, unambiguous and comprehensive and regularly reviewed Standard Operating Procedures ("SOPs"), agreed by the Board of Directors and retained in the records of the approval meeting, which must include procedures that must be followed and which are entirely independent of the legal responsibility which pertains to the conduct and stand as an internal regime to govern individual conduct within the organisation;

c) robust systems which allow for the identification (and data storage of), key elements within the supply chain, including –

   (i) the Chain of Custody: to follow the custodianship of the plant, biomass, product etc. from importation, through extraction and processing, to product manufacture and export; and
   (ii) the Chain of Identity: in order that the Regulator will be able to follow the custodianship of a particular asset (plant, biomass, preparation or product etc.) as it passes along the supply chain to monitor the individuals and entities who interacted with the asset;

d) any thefts and/or losses of substances containing Controlled Cannabinoids are reported to the Regulator within 2 hours of discovery and, if it is appropriate that a report should be made to the police, immediately. When thefts and/or losses occur, all entities involved in ownership, custody and control must submit a headline report to the Regulator as soon as possible and, once the incident has been investigated and any new procedures implemented to prevent a similar incident from happening again, all entities involved in ownership, custody and control must submit a full incident report to the Regulator;

e) operational and security requirements to be in place which should far exceed the minimum requirements.

Specific licence conditions will require specific minimum standards for both External Structures and Perimeter Areas and Internal Structure and Zoning. Dependent on the type of licence, these may include any or all of the following -

(a) perimeter fencing; signage; controlled access; lighting; movement restrictions within the curtilage area; restricted, and recorded, access controls; visitor information/procedures/records while on the site; reporting procedures for suspicious activity and unauthorised entry;
(b) fire doors and window locks;
(c) a CCTV monitoring system which records to an independent digital hard drive and where the CCTV monitoring images are stored for a minimum of 3-12 months;

(d) Individual fob/swipe/scan card access to sensitive areas and the digital recording of such access for a minimum of 3-12 months;
(e) an intruder detection system with the area(s) where Cannabis Seeds are stored identified as a separate Zone(s), which may need to be isolated from the wider area(s) and independently alarmed;
(f) a dual path communicator alarm system, which is monitored by an off-site company which is alerted when the system is activated;
(g) Prefabricated Strong Rooms ('PSRs') for the Storage of Controlled Cannabinoids; and
(h) the use of combination locks which permit each authorised person to use a separate combination where data can be downloaded to a computer for managers to monitor the use of the lock(s) as part of an audit facility. The digital recording of such access must be retained for a minimum of 12 months.

FAILURE TO COMPLY WITH ANY STANDARD OR SPECIFIC LICENCE CONDITION MAY LEAD TO REVOCATION OR CURTAILMENT OF THE LICENCE AND IMPACT ON ANY FUTURE LICENCE APPLICATIONS.

ii. Licence to Import, Transport and/or Store Cannabis seeds

A licence permitting the holder to Import, Transport and/or Store:

(i) female seeds with a THC content of less than 0.2% by reference to the mature plant for cultivation, whether outdoor or indoor;
(ii) female seeds with a THC content above 0.2% and below 3% by reference to the mature plant, for indoor cultivation only;
(iii) female seeds with a THC content above 3% and below 10% by reference to the mature plant, for indoor cultivation only;
(iv) female seeds with a THC content above 10% and below 20% by reference to the mature plant, for indoor cultivation only;
(v) female seeds with a THC content above 20% by reference to the mature plant, for indoor cultivation only; and,
(vi) male seeds, for research purposes only.

The Purpose of the Licence

Male vs. Female Seeds

Control of all Cannabis Seeds is necessary in order to ensure control over male seeds. The male plant produces spores which emit pollen resulting in female plants "going to seed" instead of flowering. Cannabinoids are concentrated in the flowering and fruiting tops of the female plants and so male seeds must be eradicated, save for when required for research purposes in a controlled environment.

Variation in the THC strength of female seeds

As a general rule, female seeds are either 'auto flowering or feminised' and subsequently graded by their eventual THC content. Increased levels of THC, as a norm, brings with it increasing levels of other cannabinoids. Knowledge of the quantities and strengths of seeds which are being imported by market participants is a key factor in managing the supply-chain through immutable Track and Trace systems and for ensuring that losses and diversion are controlled. Male seeds must be strictly controlled to prevent the productive crop devastation that has occurred in other jurisdictions; North America being the primary example.

Anticipated Market Participants

Individual commercial cultivators of Cannabis will utilise seeds or clones to initiate each crop. Those that use seeds will require to Import, Transport and Store them, each of which requires to be licensed and monitored to ensure that losses and diversion are controlled.

Depending upon the evolution of the IOM Cannabinoid Industry, a number of seed "wholesalers" may establish themselves in order to remove the administrative and regulatory requirements from Cannabis cultivators.

Licence conditions

External Structures and Perimeter Areas

1. External doors (including fire escape doors) manufactured to the recommended standard (LPS 1175 SR4); and,
2. External windows fitted with secure locks.

Internal Structure and Zoning

3. CCTV monitoring system which record to an independent digital hard drive and where the CCTV monitoring images are stored for a minimum of 3 months;
4. Individual fob/swipe/scan card access to sensitive areas and the digital recording of such access for a minimum of 3 months;
5. The premises as a whole protected by an intruder detection system and the area(s) where the Cannabis Seeds are stored identified as a separate Zone(s), with the ability to be isolated from the wider area(s) and independently alarmed; and,
6. A dual path communicator alarm system, which is monitored by an off-site company which is alerted when the system is activated.

iii. Licence to Cultivate and Harvest

Licence types

There will be four types of licence -

a) Low-THC Cannabis grown from female Low-THC Cannabis Seeds with a prohibition on the use of leaves, buds and flowers of the plant (a Low-THC Cultivation and Harvest Licence (Without Use));
b) Low-THC with permission to use the leaves, buds and flowers of the plant (a Low-THC Cultivation and Harvest Licence (With Use));
c) High-THC Cannabis grown indoor from female High-THC Cannabis Seeds (a High-THC Cultivation and Harvest Licence);
d) Cannabis grown indoor from male Seeds, for the purpose of Research only.

a) Low-THC Cultivation and Harvest Licence (Without Use)

Licence permitting the holder to Cultivate and Harvest Low-THC Cannabis grown from female Low-THC Cannabis Seeds with a prohibition on the use of leaves, buds and flowers of the plant (a Low-THC Cultivation and Harvest Licence (Without Use)).

The Purpose of the Licence

To permit the cultivation of Cannabis for fibre, with the destruction of the flowers, leaves and buds a condition of the licence.

Potential "end product" that will be produced/created under the licence

- Hemp fibre
- Hempcrete building materials
- Clothing
- Animal Feed

Anticipated Market Participants

1. Local farming stakeholders seeking a low-cost entry into the Cannabinoid Industry.

2. UK market participants who have established businesses in cultivation for fibre and who would benefit from the structure which the Isle of Man is proposing:

    a. increased opportunity for licence variation and expansion;
    b. transparency of regulation;
    c. consistency of regulation; and,
    d. attractive corporate taxation structures.

Licence conditions

Pre-Cultivation Security

1. Once the cultivation site has been identified and the pre-planting procedures have been established all cultivators must secure the site. In doing so you must provide the Regulator with a site security plan detailing all site security measures including, but not limited to:

(a) perimeter fencing;
(b) perimeter signage;
(c) controlled perimeter access;
(d) perimeter lighting;
(e) movement restrictions within the curtilage area;
(f) restricted, and recorded, access controls;
(g) visitor information when accessing the site;
(h) visiting procedures while on the site;
(i) visitor records;
(j) reporting procedures for suspicious activity; and,
(k) reporting procedures for unauthorised entry.

b) Low-THC Cultivation and Harvest Licence (With Use)

Licence permitting the holder to Cultivate and Harvest Low-THC Cannabis grown from female Low-THC Cannabis Seeds with permission to use the leaves, buds and flowers of the plant (a Low-THC Cultivation and Harvest Licence (With Use)).

The Purpose of the Licence

To permit the cultivation of Cannabis for fibre, but with the added utilisation of the flowers, leaves and buds a condition of the licence, which are the most valuable elements of the plant.

Potential "end product" that will be produced/created under the licence

- Cannabidiol (CBD) Supplement Products
- Research material
- Cannabinoids for the Medicinal Market
- Hempcrete building materials
- Clothing
- Animal Feed

Anticipated Market Participants

1. Local farming stakeholders seeking a low-cost entry into the Cannabinoid Industry, with the added profitability through the sale of the flowers, leaves and buds to on-Island market participants who are involved in the Extraction and Processing of Cannabinoids.

2. UK market participants who have established businesses in cultivation for fibre, who are prohibited from utilising the flowers, leaves and buds through the approach of the UK Home Office, and who would benefit from the structure which the Isle of Man is proposing:

    (a) Significantly increasing their profitability through the monetisation of the most valuable element of their crop, rather than a requirement to oversee its destruction;
    (b) increased opportunity for licence variation and expansion;
    (c) transparency of regulation;
    (d) consistency of regulation; and,
    (e) attractive corporate taxation structures.

Licence conditions

Pre-Cultivation Security

1. Once the cultivation site has been identified and the pre-planting procedures have been established all cultivators must secure the site. In doing so you must provide the Regulator with a site security plan detailing all site security measures including, but not limited to:

    a) perimeter fencing;
    b) perimeter signage;
    c) controlled perimeter access;
    d) perimeter lighting;
    e) movement restrictions within the curtilage area;
    f) restricted, and recorded, access controls;
    g) visitor information when accessing the site;
    h) visiting procedures while on the site;
    i) visitor records;
    j) reporting procedures for suspicious activity; and,
    k) reporting procedures for unauthorised entry.

c) High-THC Cultivation and Harvest Licence

Licence permitting the holder to Cultivate and Harvest High-THC Cannabis grown indoor from female High-THC Cannabis Seeds (a High-THC Cultivation and Harvest Licence) where the THC content, by reference to the whole plant, is:

(a) above 0.2% and below 1%;
(b) above 1% and below 3%;
(c) above 3% and below 10%;
(d) above 10% and below 20%;
(e) above 20% and below 30%; and,
(f) above 30%.

The Purpose of the Licence

To permit the indoor cultivation of high-strength (THC) Cannabis, which also contains increased levels of other cannabinoids.

The Cannabinoids are extracted from the cultivated biomass and utilised in the production of numerous food products, food supplements, topicals and ingestibles.

Potential "end product" that will be produced/created under the licence

- Cannabidiol (CBD) Products
- Cannabis Based Products for Medicines Uses (CBPM's)
- Research Purposes and Clinical trials
- Export products or isolates

Anticipated Market Participants

The world cannabis industry has created significant corporate entities with backgrounds and experience in this and other sectors. Few companies are truly fully vertically integrated (i.e. control their own

supply-chain from cultivation to end-product), most preferring to cover more limited elements proximate to their historic core experience. The most significant industry participants will always be involved in at least one of two core areas:

- the cultivation and harvesting of whole-plant cannabis; and,
- the extraction and processing of cannabinoids from the same.

The Isle of Man is attractive to companies based in Europe and the Americas because:

- the licence structure and licence opportunities are overt and clear, in distinct contrast to the UK and Europe;
- the regulatory regime is unified and cohesive rather than disjointed and contradictory, in contrast to the UK and Europe;
- the jurisdiction is safe, secure and is seen as having a track-record in leading at the forefront of regulated activity;
- its geographic location offers a good bridge to "Western" markets as Western and Eastern Europe, as well as (West) Asia and Africa all open up to acceptance of cannabinoids as food ingredient and health and wellbeing products;
- it is adjacent to the world's largest single cannabinoid market for uncontrolled cannabinoids (the UK); and,
- it has attractive corporate structure benefits.

Licence conditions

External Structure and Perimeter Areas

1. A perimeter fence & lockable/ access control gates (local planning regulations permitting);
2. Perimeter surveillance e.g. detector-activated CCTV which is recorded and where the CCTV monitoring images are stored for a minimum of 12 months, with the ability to provide remote access to interested parties, such as the Regulator;
3. An electronic access control system with a clear audit trail e.g. swipe cards or fobs used by all staff and the digital recording of such access for a minimum of 12 months;
4. External doors (including fire escape doors) manufactured to the recommended standard (LPS 1175 SR4); and,
5. External windows fitted with secure locks and alarmed.

Internal Structure and Zoning

6. CCTV monitoring system which record to an independent digital hard drive and where the CCTV monitoring images are stored for a minimum of 12 months, with the ability to provide remote access to interested parties, such as the Regulator;
7. Individual fob/swipe/scan card access to sensitive areas and the digital recording of such access for a minimum of 12 months;
8. The premises as a whole (or the individual elements thereof) to be protected by an intruder detection system and the area(s) where the High-THC Cannabis Biomass and/or Preparations containing Controlled Cannabinoids are stored identified as a separate Zone(s), with the ability to be isolated from the wider area(s) and independently alarmed;
9. A dual path communicator alarm system, which is monitored by an off-site company which is alerted when the system is activated; and,
10. The alarm system to be monitored by an off-site company which is alerted when the system is activated. The company which receives the alert may undertake to notify the police in the event of an alarm activation.

Prefabricated Strong Rooms (PSRs) for the Storage of Controlled Cannabinoids

11. Controlled Cannabinoids should be held in a PSR which is formed from panels that are bolted or welded together depending on the supplier. PSRs can be constructed to virtually any size consistent with the scale of a licensee's business and can be equipped internally with racking to hold multiple pallets of stock and to permit forklift operations; and,
12. The PSRs should be protected by an intruder alarm system that has a circuit that is separate from the main circuit for the premises;

Combination locks

13. Combination locks which permit each authorised person to use a separate combination are required, as is an audit facility which enables data to be downloaded to a computer for managers to monitor the use of the lock(s). The digital recording of such access should be retained for a minimum of 12 months; and,
14. The combinations should only be known to those persons authorised to operate the lock.

Securing Access Mechanisms: Keys, Swipe Cards, Fobs etc.

15. Licensees should apply the same levels of security controls to all access mechanisms as they would to contents contained within the area/zone to which the mechanism permits access, since failure to do so compromises the security arrangements and undermines the value of the security arrangements to the area/zone. Access to individual access mechanisms should be audited and recorded, with a witnessed key signing in/out procedure.

d) Cannabis grown indoor from male Seeds, for the purpose of Research only

Licence permitting the holder to Cultivate and Harvest Cannabis grown indoor from male Seeds, for the purpose of Research only.

The Purpose of the Licence

Market participants will strive for greater knowledge to fuel the increasing demands for the understanding of the human endocannabinoid system and the cannabinoids which fuel it. The licence allows market participants the ability to advance their research and development projects in respect of plant genetic, cannabinoid production and cannabinoid usage.

Potential "end product" that will be produced/created under the licence

- Research Purposes
- Strain development
- Seed Banking

Anticipated Market Participants

Large commercial market participants who have significant research and development functions tasked with increasing their knowledge-base. Academic and medical research facilities which must operate within the UK under restrictive individual UK licences where the Isle of Man licence will facilitate the conduct of scientific research for academic rather than commercial purposes.

Licence conditions

External Structure and Perimeter Areas

1. A perimeter fence & lockable/ access control gates (local planning regulations permitting);
2. Perimeter surveillance e.g. detector-activated CCTV which is recorded and where the CCTV monitoring images are stored for a minimum of 12 months, with the ability to provide remote access to interested parties, such as the Regulator;
3. An electronic access control system with a clear audit trail e.g. swipe cards or fobs used by all staff and the digital recording of such access for a minimum of 12 months;
4. External doors (including fire escape doors) manufactured to the recommended standard (LPS 1175 SR4); and,
5. External windows fitted with secure locks and alarmed.

Internal Structure and Zoning

6. CCTV monitoring system which record to an independent digital hard drive and where the CCTV monitoring images are stored for a minimum of 12 months, with the ability to provide remote access to interested parties, such as the Regulator;
7. Individual fob/swipe/scan card access to sensitive areas and the digital recording of such access for a minimum of 12 months;
8. The premises as a whole (or the individual elements thereof) to be protected by an intruder detection system and the area(s) where the High-THC Cannabis Biomass and/or Preparations containing Controlled Cannabinoids are stored identified as a separate Zone(s), with the ability to be isolated from the wider area(s) and independently alarmed;
9. A dual path communicator alarm system, which is monitored by an off-site company which is alerted when the system is activated; and,
10. The alarm system to be monitored by an off-site company which is alerted when the system is activated. The company which receives the alert may undertake to notify the police in the event of an alarm activation.

Prefabricated Strong Rooms (PSRs) for the Storage of Controlled Cannabinoids

11. Controlled Cannabinoids should be held in a PSR which is formed from panels that are bolted or welded together depending on the supplier. PSRs can be constructed to virtually any size consistent with the scale of a licensee's business and can be equipped internally with racking to hold multiple pallets of stock and to permit forklift operations; and,
12. The PSRs should be protected by an intruder alarm system that has a circuit that is separate from the main circuit for the premises.

Combination locks

13. Combination locks which permit each authorised person to use a separate combination are required, as is an audit facility which enables data to be downloaded to a computer for managers to monitor the use of the lock(s). The digital recording of such access should be retained for a minimum of 12 months; and,
14. The combinations should only be known to those persons authorised to operate the lock.

Securing Access Mechanisms: Keys, Swipe Cards, Fobs etc.

15. Licensees should apply the same levels of security controls to all access mechanisms as they would to contents contained within the area/zone to which the mechanism permits access, since failure to do so compromises the security arrangements and undermines the value of the security arrangements to the area/zone. Access to individual access mechanisms should be audited and recorded, with a witnessed key signing in/out procedure.

iv. Licence to Transport and Store

Licence types

There will be three types of licence to Transport and Store;

a) Cannabis Biomass containing Controlled Cannabinoids
b) Preparations containing Controlled Cannabinoids extracted from Cannabis Biomass where the leaves, buds and flowers were intact at first extraction and processing
c) Cannabis-derived Products

a) Licence to Transport and Store Cannabis Biomass containing Controlled Cannabinoids

The Purpose of the Licence

To control and regulate the transportation and storage of Cannabis Biomass containing Controlled cannabinoids in order to ensure that only those who are approved to do so can gain access to, and control over, a commodity which contains controlled drugs, ensuring that losses and diversion are minimised.

Anticipated Market Participants

Market participants who hold other conduct licences, as well as general transportation and haulage companies who expand their existing businesses in order to service the new market.

Licence conditions

External Structure and Perimeter Areas

1. A perimeter fence & lockable/ access control gates (local planning regulations permitting);
2. Perimeter surveillance e.g. detector-activated CCTV which is recorded and where the CCTV monitoring images are stored for a minimum of 3 months, with the ability to provide remote access to interested parties, such as the Regulator;
3. An electronic access control system with a clear audit trail e.g swipe cards or fobs used by all staff and the digital recording of such access for a minimum of 12 months;
4. External doors (including fire escape doors) manufactured to the recommended standard (LPS 1175 SR4); and,
5. External windows fitted with secure locks.

Internal Structure and Zoning

6. CCTV monitoring system which record to an independent digital hard drive and where the CCTV monitoring images are stored for a minimum of 12 months, with the ability to provide remote access to interested parties, such as the Regulator;
7. Individual fob/swipe/scan card access to sensitive areas and the digital recording of such access for a minimum of 3 months;
8. The premises as a whole (or the individual elements thereof) to be protected by an intruder detection system and the area(s) where:

    a) Controlled Cannabis Biomass;
    b) Preparations containing Controlled Cannabinoids;
    c) Cannabis-derived Products containing Controlled Cannabinoids; and,
    d) Uncontrolled Cannabinoids,

are stored identified as a separate Zone(s), with the ability to be isolated from the wider area(s) independently alarmed;

9. A dual path communicator alarm system, which is monitored by an off-site company which is alerted when the system is activated; and,
10. The alarm system to be monitored by an off-site company which is alerted when the system is activated and the company which receives the alert may undertake to notify the police in the event of an alarm activation.

Prefabricated Strong Rooms (PSRs) for the Storage of Cannabinoids

11. All Cannabinoids should be held in a PSR which is formed from panels that are bolted or welded together depending on the supplier. PSRs can be individual for different categories of Cannabinoids (Controlled and Uncontrolled), or segregated internally for the respective storage requirements. PSRs can be constructed to virtually any size consistent with the scale of a licensee's business and can be equipped internally with racking to hold multiple pallets of stock and to permit forklift operations; and,
12. The PSRs should be protected by an intruder alarm system that has a circuit that is separate from the main circuit for the premises.

Combination locks

13. Combination locks which permit each authorised person to use a separate combination are required, as is an audit facility which enables data to be downloaded to a computer for managers to monitor the use of the lock(s). The digital recording of such access should be retained for a minimum of 12 months; and,
14. The combinations should only be known to those persons authorised to operate the lock.

Securing Access Mechanisms: Keys, Swipe Cards, Fobs etc.

15. Licensees should apply the same levels of security controls to all access mechanisms as they would to contents contained within the area/zone to which the mechanism permits access, since failure to do so compromises the security arrangements and undermines the value of the security arrangements to the area/zone. Access to individual access mechanisms should be audited and recorded, with a witnessed key signing in/out procedure.

b) Licence to Transport or Store Preparations containing Controlled Cannabinoids extracted from Cannabis Biomass where the leaves, buds and flowers were intact at first extraction and processing

Transport and/or store Preparations containing Controlled Cannabinoids extracted from Cannabis Biomass where the leaves, buds and flowers were intact at first extraction and processing

The Purpose of the Licence

To control and regulate the transportation and storage of Controlled Cannabinoids in order to ensure that only those who are approved to do so can gain access to, and control over, a commodity which contains controlled drugs, ensuring that losses and diversion are minimised.

Anticipated Market Participants

Market participants who hold other conduct licences, as well as general transportation and haulage companies who expand their existing businesses in order to service the new market.

Licence conditions

External Structure and Perimeter Areas

1. A perimeter fence & lockable/ access control gates (local planning regulations permitting);
2. Perimeter surveillance e.g. detector-activated CCTV which is recorded and where the CCTV monitoring images are stored for a minimum of 3 months, with the ability to provide remote access to interested parties, such as the Regulator;
3. An electronic access control system with a clear audit trail e.g swipe cards or fobs used by all staff and the digital recording of such access for a minimum of 12 months;
4. External doors (including fire escape doors) manufactured to the recommended standard (LPS 1175 SR4); and,
5. External windows fitted with secure locks.

Internal Structure and Zoning

6. CCTV monitoring system which record to an independent digital hard drive and where the CCTV monitoring images are stored for a minimum of 12 months, with the ability to provide remote access to interested parties, such as the Regulator;
7. Individual fob/swipe/scan card access to sensitive areas and the digital recording of such access for a minimum of 3 months;
8. The premises as a whole (or the individual elements thereof) to be protected by an intruder detection system and the area(s) where:

    (a) Controlled Cannabis Biomass;
    (b) Preparations containing Controlled Cannabinoids;
    (c) Cannabis-derived Products containing Controlled Cannabinoids; and,
    (d) Uncontrolled Cannabinoids,

    are stored identified as a separate Zone(s), with the ability to be isolated from the wider area(s) independently alarmed;
9. A dual path communicator alarm system, which is monitored by an off-site company which is alerted when the system is activated; and,
10. The alarm system to be monitored by an off-site company which is alerted when the system is activated and the company which receives the alert may undertake to notify the police in the event of an alarm activation.

Prefabricated Strong Rooms (PSRs) for the Storage of Cannabinoids

11. All Cannabinoids should be held in a PSR which is formed from panels that are bolted or welded together depending on the supplier. PSRs can be individual for different categories of Cannabinoids (Controlled and Uncontrolled), or segregated internally for the respective storage requirements. PSRs can be constructed to virtually any size consistent with the scale of a licensee's business and can be equipped internally with racking to hold multiple pallets of stock and to permit forklift operations; and,
12. The PSRs should be protected by an intruder alarm system that has a circuit that is separate from the main circuit for the premises.

Combination locks

13. Combination locks which permit each authorised person to use a separate combination are required, as is an audit facility which enables data to be downloaded to a computer for

managers to monitor the use of the lock(s). The digital recording of such access should be retained for a minimum of 12 months; and,

14. The combinations should only be known to those persons authorised to operate the lock.

Securing Access Mechanisms: Keys, Swipe Cards, Fobs etc.

15. Licensees should apply the same levels of security controls to all access mechanisms as they would to contents contained within the area/zone to which the mechanism permits access, since failure to do so compromises the security arrangements and undermines the value of the security arrangements to the area/zone. Access to individual access mechanisms should be audited and recorded, with a witnessed key signing in/out procedure.

c) Licence to Transport and/or Store Cannabis-derived Products

Transport and/or store Cannabis-derived Products.

The Purpose of the Licence

To control and regulate the transportation and storage of Cannabis-derived Products in order to ensure that only those who are approved to do so can gain access to, and control over, a commodity which may (depending upon the world market to which it is to be supplied) contain controlled drugs, ensuring that losses and diversion are minimised.

Anticipated Market Participants

Market participants who hold other conduct licences, as well as general transportation and haulage companies who expand their existing businesses in order to service the new market.

Licence conditions

External Structure and Perimeter Areas

1. A perimeter fence & lockable/ access control gates (local planning regulations permitting);
2. Perimeter surveillance e.g. detector-activated CCTV which is recorded and where the CCTV monitoring images are stored for a minimum of 3 months, with the ability to provide remote access to interested parties, such as the Regulator;
3. An electronic access control system with a clear audit trail e.g swipe cards or fobs used by all staff and the digital recording of such access for a minimum of 12 months;
4. External doors (including fire escape doors) manufactured to the recommended standard (LPS 1175 SR4); and,
5. External windows fitted with secure locks.

Internal Structure and Zoning

6. CCTV monitoring system which record to an independent digital hard drive and where the CCTV monitoring images are stored for a minimum of 12 months, with the ability to provide remote access to interested parties, such as the Regulator;
7. Individual fob/swipe/scan card access to sensitive areas and the digital recording of such access for a minimum of 3 months;
8. The premises as a whole (or the individual elements thereof) to be protected by an intruder detection system and the area(s) where:

    (a) Controlled Cannabis Biomass;

(b) Preparations containing Controlled Cannabinoids;
(c) Cannabis-derived Products containing Controlled Cannabinoids; and,
(d) Uncontrolled Cannabinoids,

are stored identified as a separate Zone(s), with the ability to be isolated from the wider area(s) independently alarmed;

9. A dual path communicator alarm system, which is monitored by an off-site company which is alerted when the system is activated; and,
10. The alarm system to be monitored by an off-site company which is alerted when the system is activated and the company which receives the alert may undertake to notify the police in the event of an alarm activation.

Prefabricated Strong Rooms (PSRs) for the Storage of Cannabinoids

11. All Cannabinoids should be held in a PSR which is formed from panels that are bolted or welded together depending on the supplier. PSRs can be individual for different categories of Cannabinoids (Controlled and Uncontrolled), or segregated internally for the respective storage requirements. PSRs can be constructed to virtually any size consistent with the scale of a licensee's business and can be equipped internally with racking to hold multiple pallets of stock and to permit forklift operations; and,
12. The PSRs should be protected by an intruder alarm system that has a circuit that is separate from the main circuit for the premises.

Combination locks

13. Combination locks which permit each authorised person to use a separate combination are required, as is an audit facility which enables data to be downloaded to a computer for managers to monitor the use of the lock(s). The digital recording of such access should be retained for a minimum of 12 months; and,
14. The combinations should only be known to those persons authorised to operate the lock.

Securing Access Mechanisms: Keys, Swipe Cards, Fobs etc.

15. Licensees should apply the same levels of security controls to all access mechanisms as they would to contents contained within the area/zone to which the mechanism permits access, since failure to do so compromises the security arrangements and undermines the value of the security arrangements to the area/zone. Access to individual access mechanisms should be audited and recorded, with a witnessed key signing in/out procedure.

v. Licence for Extraction and/or Processing

Licence types

There will be two types of licence for Extraction and/or Processing;

a) Cannabis Biomass containing Controlled Cannabinoids
b) Preparations containing Controlled Cannabinoids extracted from Cannabis Biomass where the leaves, buds and flowers were intact at first extraction and processing

a) Licence for Extraction and/or Processing of Cannabis Biomass containing Controlled Cannabinoids

Extraction and/or processing of Cannabis Biomass containing Controlled Cannabinoids where:

(a) the Cannabis Biomass was cultivated on the Isle of Man; and/or,
(b) the Cannabis Biomass was not cultivated on the Isle of Man.

The Purpose of the Licence

To control and regulate the extraction and processing of Controlled Cannabinoids from Cannabis Biomass, in order to ensure that only those who are approved to do so can gain access to, and control over, a commodity which contains controlled drugs, ensuring that losses and diversion are minimised.

Potential "end product" that will be produced/created under the licence

- 3rd Party Distillation, Isolate Creation and purification
- Removal and separation of controlled cannabinoids
- Achieving on Island Minimum standards for Base Ingredients

Anticipated Market Participants

The world cannabis industry has created significant corporate entities with backgrounds and experience in this and other sectors. Few companies are truly fully vertically-integrated (i.e. control their own supply-chain from cultivation to end-product), most preferring to cover more limited elements proximate to their historic core experience. The most significant industry participants will always be involved in at least one of two core areas:

- the cultivation and harvesting of whole-plant cannabis; and,
- the extraction and processing of cannabinoids from the same.

The Isle of Man is attractive to companies based in Europe and the Americas because:

- the licence structure and licence opportunities are overt and clear, in distinct contrast to the UK and Europe;
- the regulatory regime is unified and cohesive rather than disjointed and contradictory, in contrast to the UK and Europe;
- the jurisdiction is safe, secure and is seen as having a track-record in leading at the forefront of regulated activity;
- its geographic location offers a good bridge to "Western" markets as Western and Eastern Europe, as well as (West) Asia and Africa all open up to acceptance of cannabinoids as food ingredient and health and wellbeing products;
- it is adjacent to the world's largest single cannabinoid market for uncontrolled cannabinoids (the UK); and,

- it has attractive corporate structure benefits.

Licence conditions

External Structure and Perimeter Areas

1. External doors (including fire escape doors) manufactured to the recommended standard (LPS 1175 SR4); and,
2. External windows fitted with secure locks.

Internal Structure and Zoning

3. CCTV monitoring system which record to an independent digital hard drive and where the CCTV monitoring images are stored for a minimum of 3 months;
4. Individual fob/swipe/scan card access to sensitive areas and the digital recording of such access for a minimum of 3 months;
5. The premises as a whole protected by an intruder detection system and the area(s) where Controlled Cannabinoids are stored identified as a separate Zone(s), with the ability to be isolated from the wider area(s) and independently alarmed.
6. A dual path communicator alarm system, which is monitored by an off-site company which is alerted when the system is activated.

b) Licence for Extraction and/or Processing of Preparations containing Controlled Cannabinoids extracted from Cannabis Biomass where the leaves, buds and flowers were intact at first extraction and processing

Extraction and/or processing of Preparations containing Controlled Cannabinoids extracted from Cannabis Biomass where the leaves, buds and flowers were intact at first extraction and processing where:

(a) the Cannabis Biomass was cultivated on the Isle of Man; and/or,
(b) the Cannabis Biomass was not cultivated on the Isle of Man.

The Purpose of the Licence

To control and regulate the extraction and processing of Controlled Cannabinoids from Cannabis Biomass, in order to ensure that only those who are approved to do so can gain access to, and control over, a commodity which contains controlled drugs, ensuring that losses and diversion are minimised.

Potential "end product" that will be produced/created under the licence

- The creation of Primary Ingredients for export and on Island Product Manufacture
- Cannabinoid Isolates
- Controlled Isolates
- Full and Broad Spectrum Extractions

Anticipated Market Participants

The world cannabis industry has created significant corporate entities with backgrounds and experience in this and other sectors. Few companies are truly fully vertically-integrated (i.e. control their own supply-chain from cultivation to end-product), most preferring to cover more limited elements proximate to their historic core experience. The most significant industry participants will always be involved in at least one of two core areas:

- the cultivation and harvesting of whole-plant cannabis; and,
- the extraction and processing of cannabinoids from the same.

The Isle of Man is attractive to companies based in Europe and the Americas because:

- the licence structure and licence opportunities are overt and clear, in distinct contrast to the UK and Europe;
- the regulatory regime is unified and cohesive rather than disjointed and contradictory, in contrast to the UK and Europe;
- the jurisdiction is safe, secure and is seen as having a track-record in leading at the forefront of regulated activity;
- its geographic location offers a good bridge to "Western" markets as Western and Eastern Europe, as well as (West) Asia and Africa all open up to acceptance of cannabinoids as food ingredient and health and wellbeing products; and,
- it is adjacent to the world's largest single cannabinoid market for uncontrolled cannabinoids (the UK).

Licence conditions

External Structure and Perimeter Areas

1. External doors (including fire escape doors) manufactured to the recommended standard (LPS 1175 SR4); and,
2. External windows fitted with secure locks.

Internal Structure and Zoning

3. CCTV monitoring system which record to an independent digital hard drive and where the CCTV monitoring images are stored for a minimum of 3;
4. Individual fob/swipe/scan card access to sensitive areas and the digital recording of such access for a minimum of 3 months;
5. The premises as a whole protected by an intruder detection system and the area(s) where Controlled Cannabinoids are stored identified as a separate Zone(s), with the ability to be isolated from the wider area(s) and independently alarmed;
6. A dual path communicator alarm system, which is monitored by an off-site company which is alerted when the system is activated.

vi. Licence for Importation

Licence types

There will be three types of licence for Importation;

a) of Cannabis Biomass containing Controlled Cannabinoids
b) of Preparations containing Controlled Cannabinoids
c) of Cannabis-derived Products

a) Licence for Importation of Cannabis Biomass containing Controlled Cannabinoids

Importation of Cannabis Biomass containing Controlled Cannabinoids.

The Purpose of the Licence

To permit market participants who hold a relevant additional licence to import Cannabis Biomass for deployment directly in their business, or indirectly via their up-stream supply-chain.

Potential "end product" that will be produced/created under the licence

- 3rd Party Distillation, Isolate Creation and purification
- Removal and separation of controlled cannabinoids
- Protection of on Island Minimum standards for Base Ingredients

Anticipated Market Participants

Market Participants who hold a relevant additional licence:

- Extraction and Processing licence (direct deployment);
- Manufacture of Cannabis derived Products licence (indirect deployment).

Licence conditions

Linked Conduct and Licences

1. The Importation of Cannabis Biomass is inevitably allied to its Transport and/or Storage.
2. Any entity which is engaged in the Importation of Cannabis Biomass, and who undertakes its Transportation and/or Storage, will be required to hold a Cannabis Biomass Transport and/or Storage Licence in addition to the Licence authorising its Importation.

The mechanics of the Importation of Cannabis Biomass

3. No Cannabis Biomass, even when imported under Licence, should be exposed to uncontrolled and unregulated environments and there must be a verifiable chain of custody for the imported consignment at all times.
4. In consideration of these requirements, the mechanics of Importation should ensure that:
    (a) The Importation is organised through the commercial operations of a Registered Importation Agent within the Isle of Man;
    (b) The Registered Importation Agent holds a Licence authorising the Importation of Cannabis Biomass; and,
    (c) That the Imported consignment is retained within the secure custody of the Registered Importation Agent prior to collection by, or on behalf of, the Licence-holding Importing Consignee.

b) Licence for Importation of Preparations containing Controlled Cannabinoids

Importation of Preparations containing Controlled Cannabinoids.

The Purpose of the Licence

To permit market participants who hold a relevant additional licence to import Cannabis Biomass for deployment directly in their business, or indirectly via their up-stream supply-chain.

Potential "end product" that will be produced/created under the licence

- 3rd Party Distillation, Isolate Creation and purification
- Removal and separation of controlled cannabinoids
- Protection of on Island Minimum standards for Base Ingredients
- The creation of Primary Ingredients for export and on Island Product Manufacture
- Cannabinoid Isolates
- Controlled Isolates
- Broad Spectrum Extractions
- Full Spectrum Extractions

Anticipated Market Participants

Market Participants who hold a relevant additional licence:

- Extraction and Processing licence (direct deployment);
- Manufacture of Cannabis derived Products licence (indirect deployment).

Licence conditions

Linked Conduct and Licences

1. The Importation of Controlled Cannabinoids is inevitably allied to their Transport and/or Storage.
2. Any entity which is engaged in the Importation of Controlled Cannabinoids, and who undertakes their Transportation and/or Storage, will be required to hold a Controlled Cannabinoid Transport and/or Storage Licence in addition to the Licence authorising their Importation.

The mechanics of the Importation of Controlled Cannabinoids

3. No Controlled Cannabinoids, even when imported under Licence, should be exposed to uncontrolled and unregulated environments and there must be a verifiable chain of custody for the imported consignment at all times.
4. In consideration of these requirements, the mechanics of Importation should ensure that:
   (a) The Importation is organised through the commercial operations of a Registered Importation Agent within the Isle of Man;
   (b) The Registered Importation Agent holds a Licence authorising the Importation of Controlled Cannabinoids; and,
   (c) That the Imported consignment is retained within the secure custody of the Registered Importation Agent prior to collection by, or on behalf of, the Licence-holding Importing Consignee.

c) Licence for Importation of Cannabis-derived Products

Importation of Cannabis-derived Products.

The Purpose of the Licence

To enable to Isle of Man to monetise the conduct of market participants who wish to gain a commercial benefit through the importation of complete (or near-complete) products which could, with minimal economic benefit to the Isle of Man, then themselves benefit from the Isle of Man "Cannabinoid Kite Mark".

Potential "end product" that will be produced/created under the licence

- Identification of and/or Removal and separation of controlled cannabinoids
- On Island Analytics, Testing and Minimum Standards Compliance
- Protection of on Island Minimum standards for Base Ingredients

Anticipated Market Participants

Market Participants who hold a relevant additional licence:

- Extraction and Processing licence (direct deployment);
- Manufacture of Cannabis derived Products licence (indirect deployment); and,
- Brands who hold no other connection to the Isle of Man.

Licence conditions

Linked Conduct and Licences

1. The Importation of Cannabis-derived Products is inevitably allied to their Transport and/or Storage.
2. Any entity which is engaged in the Importation of Cannabis-derived Products, and who undertakes their Transportation and/or Storage, will be required to hold a Cannabis-derived Products Transport and/or Storage Licence in addition to the Licence authorising their Importation.

The mechanics of the Importation of Controlled Cannabinoids

3. No Cannabis-derived Products, even when imported under Licence, should be exposed to uncontrolled and unregulated environments and there must be a verifiable chain of custody for the imported consignment at all times.
4. In consideration of these requirements, the mechanics of Importation should ensure that:
    (a) The Importation is organised through the commercial operations of a Registered Importation Agent within the Isle of Man;
    (b) The Registered Importation Agent holds a Licence authorising the Importation of Cannabis-derived Products; and,
    (c) That the Imported consignment is retained within the secure custody of the Registered Importation Agent prior to collection by, or on behalf of, the Licence-holding Importing Consignee.

vii. Licence for Exportation

Licence types

There will be three types of licence for Exportation;

a) of Cannabis Biomass containing Controlled Cannabinoids
b) of Preparations containing Controlled Cannabinoids
c) of Cannabis-derived Products

a) Licence for Exportation of Cannabis Biomass containing Controlled Cannabinoids

Exportation of Cannabis Biomass containing Controlled Cannabinoids.

The Purpose of the Licence

To permit the exportation of Cannabis cultivated on the Isle of Man to other jurisdictions.

Anticipated Market Participants

Market Participants who hold a Cannabis Cultivation licence.

Licence conditions

Linked Conduct and Licences

1. The Exportation of Cannabis Biomass is inevitably allied to its Transport and/or Storage.
2. Any entity which is engaged in the Exportation of Cannabis Biomass, and who undertakes its Transportation and/or Storage, will be required to hold a Cannabis Biomass Transport and/or Storage Licence in addition to the Licence authorising its Exportation.

The mechanics of the Exportation of Controlled Cannabinoids

3. No Cannabis Biomass, even when exported under Licence, should be exposed to uncontrolled and unregulated environments and there must be a verifiable chain of custody for the Exported consignment at all times.
4. In consideration of these requirements, the mechanics of Exportation should ensure that:
    (a) The Exportation is organised through the commercial operations of a Registered Exportation Agent within the Isle of Man;
    (b) The Registered Exportation Agent holds a Licence authorising the Exportation of Cannabis Biomass; and,
    (c) That the Exported consignment is retained within the secure custody of the Registered Importation Agent prior to collection by, or on behalf of, the Licence-holding Importing Consignee.

b) Licence for Exportation of Preparations containing Controlled Cannabinoids

Exportation of Preparations containing Controlled Cannabinoids

The Purpose of the Licence

To permit the exportation of Preparations containing Controlled Cannabinoids to other jurisdictions.

Potential "end product" that will be produced/created under the licence

- Cannabidiol (CBD) Extracts
- Ingredients for Cannabis Based Products for Medicines Uses (CBPM's)
- Research Purposes and Clinical trials
- Ingredients or isolates for North American Markets

Anticipated Market Participants

Market Participants who hold an Extraction and Processing licence.

Licence conditions

Linked Conduct and Licences

1. The Exportation of Controlled Cannabinoids is inevitably allied to their Transport and/or Storage.
2. Any entity which is engaged in the Exportation of Controlled Cannabinoids, and who undertakes their Transportation and/or Storage, will be required to hold a Controlled Cannabinoid Transport and/or Storage Licence in addition to the Licence authorising their Exportation.

The mechanics of the Exportation of Controlled Cannabinoids

3. No Controlled Cannabinoids, even when exported under Licence, should be exposed to uncontrolled and unregulated environments and there must be a verifiable chain of custody for the Exported consignment at all times.
4. In consideration of these requirements, the mechanics of Exportation should ensure that:
    (a) The Exportation is organised through the commercial operations of a Registered Exportation Agent within the Isle of Man;
    (b) The Registered Exportation Agent holds a Licence authorising the Exportation of Controlled Cannabinoids; and,
    (c) That the Exported consignment is retained within the secure custody of the Registered Importation Agent prior to collection by, or on behalf of, the Licence-holding Importing Consignee.

c) Licence for Exportation of Cannabis-derived Products

Exportation of Cannabis-derived Products.

The Purpose of the Licence

To permit the exportation of Cannabis-derived Products to other jurisdictions.

Potential "end product" that will be produced/created under the licence

- Cannabidiol (CBD) Products
- Cannabis Based Products for Medicines Uses (CBPM's)
- Research Purposes and Clinical trials
- Controlled cannabinoid products or isolates for North American Markets

Anticipated Market Participants

Market Participants who hold a Manufacture of Cannabis-derived Products licence.

Licence conditions

Linked Conduct and Licences

1. The Exportation of Cannabis-derived Products is inevitably allied to their Transport and/or Storage.
2. Any entity which is engaged in the Exportation of Cannabis-derived Products, and who undertakes their Transportation and/or Storage, will be required to hold a Cannabis-derived Products Transport and/or Storage Licence in addition to the Licence authorising their Exportation.

The mechanics of the Exportation of Controlled Cannabinoids

3. No Cannabis-derived Products, even when exported under Licence, should be exposed to uncontrolled and unregulated environments and there must be a verifiable chain of custody for the Exported consignment at all times.
4. In consideration of these requirements, the mechanics of Exportation should ensure that:
    (a) The Exportation is organised through the commercial operations of a Registered Exportation Agent within the Isle of Man;
    (b) The Registered Exportation Agent holds a Licence authorising the Exportation of Cannabis-derived Products; and,
    (c) That the Exported consignment is retained within the secure custody of the Registered Importation Agent prior to collection by, or on behalf of, the Licence-holding Importing Consignee.

viii. Licence for Manufacture of Cannabis-derived Products

Manufacture of Cannabis-derived Products.

The Purpose of the Licence

To control and regulate the manufacture of Cannabis-derived Products.
To enable the effective monetisation of a licensed Isle of Man "Cannabinoid Kite Mark".

Potential "end product" that will be produced/created under the licence

- Cannabidiol (CBD) Products
- Cannabis Based Products for Medicines Uses (CBPM's)
- Research Purposes and Clinical trials
- Export products or isolates

Anticipated Market Participants

Manufacturers of cannabinoid products do so on their own behalf, or on behalf of other market participants (Brands) under Contract Manufacturing (Co-Man) or Contract Packing (Co-Pack) agreements.

The Isle of Man is attractive to manufacturing companies based in Europe and the Americas because:

- the licence structure and licence opportunities are overt and clear, in distinct contrast to the current international situation;
- the regulatory regime is unified and cohesive rather than disjointed and contradictory;
- the jurisdiction is safe, secure and is seen as having a track-record in leading at the forefront of regulated activity;
- its geographic location offers a good bridge to "Western" markets as Western and Eastern Europe, as well as (West) Asia and Africa all open up to acceptance of cannabinoids as food ingredient and health and wellbeing products;
- it is adjacent to the world's largest single cannabinoid market for uncontrolled cannabinoids (the UK); and,
- it has attractive corporate structure benefits.

Licence conditions

Linked Conduct and Licences

1. The Manufacture of Cannabis-derived Products is inevitably allied to their Testing and Analysis.
2. Any entity which is engaged in the Manufacture of Cannabis-derived Products, and which undertakes their Testing and Analysis, will be required to hold a Testing and Analysis of Cannabinoids Licence in addition to the Licence authorising their Manufacture.
3. Manufactured Cannabis-derived Products must be subjected to an agreed Testing and Analysis program. Where a Manufacturer is not licensed to conduct Testing and Analysis, they must ensure that they engage with a licensed entity to fulfil the necessary obligations.

External Structure and Perimeter Areas

4. A perimeter fence & lockable/ access control gates (local planning regulations permitting);

5. Perimeter surveillance e.g. detector-activated CCTV which is recorded and where the CCTV monitoring images are stored for a minimum of 12 months, with the ability to provide remote access to interested parties, such as the Regulator;
6. An electronic access control system with a clear audit trail e.g. swipe cards or fobs used by all staff and the digital recording of such access for a minimum of 12 months;
7. External doors (including fire escape doors) manufactured to the recommended standard (LPS 1175 SR4); and,
8. External windows fitted with secure locks and alarmed.

Internal Structure and Zoning

9. CCTV monitoring system which record to an independent digital hard drive and where the CCTV monitoring images are stored for a minimum of 12 months, with the ability to provide remote access to interested parties, such as the Regulator;
10. Individual fob/swipe/scan card access to sensitive areas and the digital recording of such access for a minimum of 12 months;
11. The premises as a whole (or the individual elements thereof) to be protected by an intruder detection system and the area(s) where the Cannabis Biomass and/or Controlled Cannabinoid Preparations is/are stored identified as a separate Zone(s), with the ability to be isolated from the wider area(s) independently alarmed.;
12. A dual path communicator alarm system, which is monitored by an off-site company which is alerted when the system is activated; and,
13. The alarm system to be monitored by an off-site company which is alerted when the system is activated. The company which receives the alert may undertake to notify the police in the event of an alarm activation.

Prefabricated Strong Rooms (PSRs) for the storage of Controlled Cannabinoids

14. Controlled Cannabinoids should be held in a PSR which is formed from panels that are bolted or welded together depending on the supplier. PSRs can be constructed to virtually any size consistent with the scale of a licensee's business and can be equipped internally with racking to hold multiple pallets of stock and to permit forklift operations; and,
15. The PSRs should be protected by an intruder alarm system that has a circuit that is separate from the main circuit for the premises.

Combination locks

16. Combination locks which permit each authorised person to use a separate combination are required, as is an audit facility which enables data to be downloaded to a computer for managers to monitor the use of the lock(s). The digital recording of such access should be retained for a minimum of 12 months; and,
17. The combinations should only be known to those persons authorised to operate the lock.

Securing Access Mechanisms: Keys, Swipe Cards, Fobs etc.

18. Licensees should apply the same levels of security controls to all access mechanisms as they would to contents contained within the area/zone to which the mechanism permits access, since failure to do so compromises the security arrangements and undermines the value of the security arrangements to the area/zone. Access to individual access mechanisms should be audited and recorded, with a witnessed key signing in/out procedure.

ix. Licence for Analysis and Testing of Cannabinoids

Analysis and Testing of Cannabinoids.

The Purpose of the Licence

To regulate and control the testing of cannabinoids and Cannabis-derived Products to ensure that standards on the Isle of Man, and for Isle of Man originating products are at the height of what is achievable.

Potential "end product" that will be produced/created under the licence

- De Minimum Levels for the Isle of Man Kitemark
- Consumer safety
- Industry Leader

Anticipated Market Participants

Independent market participants who specialise in scientific analysis, whether commercial or academic.

Market participants who hold another relevant licence:

- Extraction and Processing licence; and,
- Manufacture of Cannabis-derived Products licence.

Licence conditions

External Structure and Perimeter Areas

1. A perimeter fence & lockable/ access control gates (local planning regulations permitting);
2. Perimeter surveillance e.g. detector-activated CCTV which is recorded and where the CCTV monitoring images are stored for a minimum of 12 months, with the ability to provide remote access to interested parties, such as the Regulator;
3. An electronic access control system with a clear audit trail e.g swipe cards or fobs used by all staff and the digital recording of such access for a minimum of 12 months;
4. External doors (including fire escape doors) manufactured to the recommended standard (LPS 1175 SR4); and,
5. External windows fitted with secure locks and alarmed.

Internal Structure and Zoning

6. CCTV monitoring system which record to an independent digital hard drive and where the CCTV monitoring images are stored for a minimum of 12 months, with the ability to provide remote access to interested parties, such as the Regulator;
7. Individual fob/swipe/scan card access to sensitive areas and the digital recording of such access for a minimum of 12 months;
8. The premises as a whole (or the individual elements thereof) to be protected by an intruder detection system and the area(s) where the Cannabis Biomass and/or Controlled Cannabinoid Preparations is/are stored identified as a separate Zone(s), with the ability to be isolated from the wider area(s) independently alarmed;
9. A dual path communicator alarm system, which is monitored by an off-site company which is alerted when the system is activated; and,

10. The alarm system to be monitored by an off-site company which is alerted when the system is activated. The company which receives the alert may undertake to notify the police in the event of an alarm activation.

Prefabricated Strong Rooms (PSRs) for the storage of Controlled Cannabinoids

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12. The PSRs should be protected by an intruder alarm system that has a circuit that is separate from the main circuit for the premises.

Combination locks

13. Combination locks which permit each authorised person to use a separate combination are required, as is an audit facility which enables data to be downloaded to a computer for managers to monitor the use of the lock(s). The digital recording of such access should be retained for a minimum of 12 months; and,
14. The combinations should only be known to those persons authorised to operate the lock.

Securing Access Mechanisms: Keys, Swipe Cards, Fobs etc.

15. Licensees should apply the same levels of security controls to all access mechanisms as they would to contents contained within the area/zone to which the mechanism permits access, since failure to do so compromises the security arrangements and undermines the value of the security arrangements to the area/zone. Access to individual access mechanisms should be audited and recorded, with a witnessed key signing in/out procedure.

Annex (A) : What is Cannabis, THC, CBN, CBD and Industrial Hemp?

Cannabis

The Plant

Cannabis is a genus of the family Cannabaceae and is a flowering plant. The main species is widely considered to be Sativa and there are three subspecies; Cannabis Sativa, Indica and Ruderalis. Depending on the geographical location the plant can be bush like, tall or even a shrub.

Cannabis is a "highly sexed" plant meaning that there are males and females. The females produce flowers in order to engender their pollination and "go to seed" upon having been pollinated. The Cannabinoids (see later) are to be found within the flowering and fruiting tops of the female cannabis plant.

History

There is evidence that cannabis extracts were used by the Chinese as a herbal remedy since the first century AD. Cannabis comes from the flowering tops and leaves of the hemp plant. For centuries this plant has been widely cultivated around the world for its fibres, and indeed the word *canvas*, which is a material made from woven hemp fibres, takes its name from cannabis.

Chemical Nature

Cannabis a complex plant which comprises over 400 chemical entities and at least 140 individual Cannabinoids of which Cannabidiol ('CBD') and Tetrahydrocannabinol ('THC') are presently the most well know. THC is actually a variation of its lesser-known relative, Cannabinol ('CBN').

Prohibition

Cannabis is the most widely used "recreational drug" worldwide (based upon its psychoactive properties when smoked or ingested – predicated mainly upon the presence of THC).

Research

Due to its prohibited nature scientific research into the properties of Cannabis have not flourished until more recent times and, through that research it is also now recognised as having medicinal qualities.

Tetrahydrocannabinol (THC) and Cannabinol (CBN)

Tetrahydrocannabinol ('THC') and Cannabinol ('CBN') are the two main psychotropic elements of the cannabis plant. THC is the chemical responsible for most of cannabis's psychological effects and acts much like the cannabinoid chemicals made naturally by the body.

Cannabinoid receptors are concentrated in certain areas of the brain associated with thinking, memory, pleasure, coordination and time perception. THC attaches to these receptors and activates them and affects a person's memory, pleasure, movements, thinking, concentration, coordination, and sensory and time perception.

THC is one of many compounds found in the resin secreted by glands of the marijuana plant. More of these glands are found around the reproductive organs of the plant than on any other area of the plant.

As a result of their psychotropic properties CBN and THC are controlled drugs in many countries (including the United Kingdom).

Cannabidiol (CBD)

CBD is a mildly psychoactive cannabinoid, which has been increasingly popular as a food supplement, taken for its perceived health and wellness benefits.

CBD products that are available globally differ dramatically in composition.

Different countries regulate psychoactive cannabinoids (THC and CBN) differently

In the UK and EU, CBD products cannot contain the psychotropic cannabinoids (THC and CBN) because they are narcotics and manufacturers must demonstrate that they have been removed.

The principle of THC and CBN as controlled narcotics is not necessarily the case in other jurisdictions, where there are permissible levels, and it is important to understand that there is no such thing as a "standard CBD Product". They are all different and some are lawful in one country and not another. This is why a highly regulated export industry will be able to ensure that products are sent only to those jurisdictions where the specific product is permitted to be sold legally.

Cannabidiol (CBD) Products

There are four main types of CBD products/preparations:

I. Full Spectrum;
II. Broad Spectrum;
III. Isolate; and,
IV. Reconstituted isolates.

Full Spectrum-based Products

In these products the full range of cannabinoids are present. All of the cannabinoids, along with Terpenes (that which gives a plant its taste, colour and scent) are extracted using various methods of extraction and processing to create an "oil".

This "oil" contains the psychotropic cannabinoids (THC and CBN), along with the mildly psychoactive cannabinoids, including CBD and a host of other cannabinoids of which most people are unfamiliar: CBG, CBC and CBV (the list goes on).

We are still learning about these cannabinoids and whilst many claim that they have medicinal benefits individually or collectively (known as the entourage effect), there is much research still to be done.

Due to the intended presence of THC and CBN, Full Spectrum products would be classified as controlled drugs within many jurisdictions (including the United Kingdom).

Broad Spectrum-based Products
A Full Spectrum extract "oil" can be further purified to remove the psychotropic cannabinoids (THC and CBN), to leave the non-psychotropic cannabinoids (CBD etc.). This further refined "oil" has therefore had the controlled cannabinoids (THC and CBN) removed, but all of the other cannabinoids remain. As

a result of the removal* of the controlled psychotropic cannabinoids, a Broad Spectrum cannabinoid product would not be controlled under misuse of drugs legislation in many jurisdictions (including the United Kingdom).

> * *It is to be noted that the removal of the controlled cannabinoids is a technical process and can only be verified through the application of specialised analysis and testing procedures, which are now available to market participants and regulators.*

Isolated-based Products

Further purification, separation and distillation of a Broad Spectrum preparation results in a series of isolated (i.e. individual) cannabinoids. These isolated cannabinoids (for these purposes Isolated CBD) can then be added to oils and food products to produce a "CBD Product" which is absent of the other cannabinoids, terpenes and other botanical material.

Recreated Isolate Products

A number of isolated cannabinoids can be re-combined to produce a multi cannabinoid product which is seen as having the benefits of the Broad Spectrum product/preparation, but is also known to have an absence of unwanted elements (which may be terpenes and flavonoids).

Industrial hemp

Hemp is a plant which belongs to the species Cannabis sativa. Industrial hemp is grown for commercial use as a fibre or as a foodstuff. Hemp is one of a number of plant species that can be used for fibre production. Other fibre-rich species that can be grown in the British Isles include flax, miscanthus and cereal straw (as a by-product of arable cropping). Fibre cropping is an opportunity for economic development that would support sustainable farming and have less impact on the environment than current alternative products based on petrochemicals. Uses of hemp fibre include production of textiles, clothing, paper, animal bedding, insulation materials, building materials and biodegradable plastics. Hemp seeds can be used in animal food and as a food supplement for humans. Hemp seeds can be cold-pressed to yield oil which can also be used as a food supplement.

Hemp is a variety of Cannabis sativa. However, hemp varieties contain very low levels of the chemical THC and, therefore, do not have the psychoactive properties of cannabis used for recreational use.

Novel Foods authorisation

In the European Union and United Kingdom, any business wishing to manufacture and sell a "CBD Product" must seek authorisation as a Novel Food.

Such an application requires the submission of a comprehensive application to the Food Standards Agency ('FSA') (in the UK) and the European Food Standards Agency ('EFSA') (in the 26 Member States), detailing the composition of the product, its manufacturing process from biomass to end product and both a toxicology assessment and details of the bio-availability of the product.

Cannabis-derived products and Cannabis-based medicinal products

All products which are created utilising elements, compounds and substances derived from the cannabis plant are "Cannabis-derived" products. However, in order to be a Cannabis-based medicinal product, then the product must be approved in the relevant jurisdiction as a medicine or medical product and to

be so, it is usually necessary for it to have undergone medical trials which have been evaluated and peer reviewed and the results approved-of for the efficacy of the product (i.e. the then medicine). Only then is a product authorised as a medicinal product.

For example:

a. in the United Kingdom medicines are regulated by the Medicines and Healthcare Products Regulatory Authority ('MHRA') and medicinal claims (including any sought to be made for a CBD Product) are only permitted if they are authorised by that agency following their review of submitted data in respect of clinical trials;

b. in contrast, the FSA regulate foods and no health claims are permitted unless the chemical composition of the product allows permitted health claims to be made within that chemical composition.

Presently in the UK:

a. there are only two products for which medicinal claims can be made (they being the only two products which have undergone and passed clinical trials);

b. there are no health claims which can be made for as a CBD food ingredient; but,

c. if vitamins and minerals and added to the CBD Product, then health claims can be made in respect of those additional ingredients.

The progress of research is such that it is anticipated that further advances will be made in respect of clinical trials and health research which will increase the evidence for and proven efficacy of cannabinoids as beneficial to health.

Isle of Man
Government
Reiltys Ellan Vannin