



Consultation response for Regulatory Framework for Cannabis-derived Products for Export

This Consultation Response paper is divided into six main parts:

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GLOSSARY

Term	Definition
CBD	Cannabidiol
CBN	Cannabinol
DEFA	Department of Environment, Food and Agriculture
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
GSC	The Gambling Supervision Commission
IOM	Isle of Man
MHRA	Medicines and Healthcare products Regulatory Authority
MMCHA	Manx Medicinal Cannabis and Hemp Association
THC	Tetrahydrocannabinol
UK	United Kingdom
UN	United Nations
WHO	World Health Organisation

1. BACKGROUND

This Consultation response is issued by the Department for Enterprise following the Consultation published on 23rd October and which closed on 19th November.

The purpose of the Consultation was to obtain views from interested parties on the details of the draft Regulatory Framework ('Framework') and the licence fee structure proposed for cannabis-derived product for export. The intention of such a Framework is to facilitate potential opportunities for new economic activity within the Isle of Man

The Department sought feedback from industry, inward investors and other interested stakeholders on the proposals, with a particular focus on:

- i. 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
- ii. The proposed licensing Framework, minimum standards and guidelines for applicants.

Key principles within the remit of the Consultation were to focus on the economic development opportunities for developing a cannabis-derived product for export and to align as closely as possible with UK policy and practice in this area. These principles were imperative to move the project at pace and to ensure any regulatory framework respects the constitutional relationship between the UK and the Isle of Man.

The Consultation did not consider any changes to the domestic prescription of medicinal cannabis, or the legality of non-medical use of cannabis in the Isle of Man, nor will this response address any comments on these issues which are outside the remit of this Consultation.

In the months preceding the Consultation, DfE collaborated with industry experts to review global best practice, and lessons learnt from other jurisdictions, in order to incorporate these learnings into our Framework.

DfE has sought to develop a detailed regulatory framework that:

- Creates a positive economic impact for the IOM;
- Closely mirrors the UK's regulatory framework to allow the cultivation, harvest, manufacturing, transportation and distribution/, import/export of hemp and cannabis-derived products;
- Provides greater clarity on distinct licensing categories, minimum requirements, and clear guidance for potential market participants; and
- Focuses on creating an export-only industry.

The Cannabis industry presents unique challenges given the history of use and regulation of cannabis products worldwide. The subject can be controversial, spanning issues around morality, economic policy, social policy, criminal justice and political considerations. Further there is lack of experience around the world in regulating this nascent industry and there is significant misinformation, bias and a lack of education about key issues related to cannabis.

We have therefore worked with external third party specialists to assist in the development of the Framework and Guidance Notes.

We have also worked closely with key IOM Government stakeholders to review the draft Framework. This has helped to identify the interdependencies, and wider implications of implementing the proposals, which touch on responsibilities of a number of Government Departments and bodies.

During the Consultation process, DfE identified the Gambling Supervision Commission as the proposed interim regulator for this new sector, with responsibility over the licensing and ongoing supervisory processes. The GSC has been involved throughout in a full review of the proposed Framework and associated Guidance Notes, prepared independently for the Department, with a view to the effective application of the proposition. The Consultation responses have and will help form the GSC's implementation of the Framework in practice.

The complexity of the issues arising from this work have impacted on the timescales for bringing a final Framework forward. However, we believe that it was important to take time to reflect the feedback received and comprehensively address issues raised so that we can be sure that we are delivering an effective Framework which will attract quality businesses to the Island enabling the development of a viable new economic sector to develop.

2. SUMMARY OF RESPONSES

We received 28 responses through the Government's consultation portal, many welcoming and supporting the majority of the proposals set out in the original Consultation Paper. Respondents represented a broad cross section of interested stakeholders in the proposed new sector. Three quarters of those who expressed an interest in licences were Isle of Man based. At least three respondents indicated their intention, at the earliest opportunity, to establish high-THC operations that extended across the full "Seed to Shelf" spectrum of licences. There was also strong interest from operators (directly and indirectly through the MMCHA) that were interested in developing the industrial hemp (low-THC without use) segment of the industry sector.

The Consultation attracted a response from one testing laboratory operator and one logistics entity, both who indicated applying for the associated 'specialist' functions that will support the industry. Other support industries that responded to the Consultation and recorded their interest in supporting this industry included a blockchain based provenance software solution company and a renewable energy supply company.

A number of respondents sought clarification on specific areas of the Framework and the manner in which licence conditions would be applied and monitored by the intended Regulator. Furthermore, some respondents stated their interpretation and sought clarification on some elements of the proposed regulations and application of the Framework. The most consistent theme in responses was in respect of the proposed licence fee structure.

Part 6 of this paper sets out how comments have been considered and addressed where appropriate.

3. OTHER FEEDBACK

A detailed summary of all feedback received and the Department's response is included in Appendix 2.

A few of the responses received raised their concerns that the proposal presented in the Consultation Paper did not, in their opinion, extend fully to allow for both the decriminalisation of cannabis and the availability of prescribed medicinal cannabis for the Isle of Man population. As noted above, the Consultation focused on the economic growth opportunities for an export sector and did not consider any changes to the domestic prescription of medicinal cannabis or the legality of non-medical use of cannabis in the Isle of Man.

Feedback was also received on the deployment of technology noting that the sector should use robust Blockchain "track and trace" systems to "assist in regulation, increase confidence amongst market participants and support the "Seed to Shelf" transparency of the products which emanate from the Island." The GSC intend to remain open minded on the nature of solutions to the track and trace requirement. The opportunity to implement a unified and standardised solution is attractive, but the GSC will not mandate licensees use a third party system and does not believe there is sufficient time to implement a central GSC-led solution without delaying the implementation of licensing.

Comment was also made on whether new primary legislation should have been brought forward. The approach taken has been to use current existing legislation (The Misuse of Drugs Act 1976) and Regulation making powers within that Act to establish the Framework. This approach will enable the new sector to be brought into operation relatively quickly. However, Government remains mindful of the possible need for new primary legislation in the future as the sector develops.

Some respondents noted that they would have hoped for speedier progress in considering the cannabis export market. For reasons stated above, DfE engaged in extensive research and worked with a large number of internal and external stakeholders. There has been significant cross-government collaboration and input, supported by additional external resources, to bring forward the proposals originally established as quickly as possible. Indeed, this Consultation has touched upon nearly every Department within Isle of Man Government. What has been of paramount importance is the need to get the Framework right.

We have also been engaging closely with the UK Home Office and continue to work constructively with them to ensure that our Framework allows for our licensed operators to meet their commercial needs in alignment with international laws relative to controlled substances. In order to address evolving international policy we will continue working closely with the Home Office, and other UK Government departments and international bodies, to benefit this new sector.

A summary of all the feedback received and the Department's responses is included in Appendix 2 to this Paper.

4. CHANGES TO THE REGULATORY FRAMEWORK

i. Legislative Pathway

The Consultation document proposed that two separate sets of draft regulations would be made under the provisions of the Misuse of Drugs Act 1976.

Following feedback, and further discussions with the Attorney General's Chambers, these will be consolidated into one set of Regulations. This will allow each licence type to be clearly set out alongside the prescribed fees for ease of reading and avoidance of repetition of definitions.

Consultation with the Attorney General's Chambers identified that the Importation of Seeds licence was not required and therefore the licence type has been removed from the proposed Regulations.

Some refining of the definitions within the Regulations has also been taken forward, to reflect feedback received during the Consultation, alongside some minor consequential amendments to the Misuse of Drugs Regulations 2001, as applied to the Isle of Man.

The main amendment to the Regulations, following the Consultation, are the fee levels proposed which is set out in further detail in Part 6 of this document.

ii. Regulator for the new sector

The Consultation document outlined that, as this sector is for exportation only, the Department for Health and Social Care had agreed that the function of licensing and regulating the new sector would be transferred to an alternative function within Government, better placed to consider the aspects of licensing, vetting and supervising an emerging industry.

It was noted that a single, adequately resourced, regulator will ultimately be required, however whilst the sector is maturing, an existing single regulatory body was considered to be the most practical interim solution.

Following consultation with the Treasury and the GSC, at the December sitting of Tynwald a transfer of functions for the sector from the DHSC to the GSC was approved.

The GSC is well suited to assume these regulatory functions given its success in creating the Island's regulatory framework for eGaming, where Isle of Man Government was at the forefront of creating a gold standard regulatory regime for the emerging sector.

The Commission has significant experience in a number of the functions that will be required for the emerging sector, such as vetting of interested parties, oversight of licence holders and implementing stringent controls.

Cannabis is an emerging global sector, and the GSC will look to foster, recruit and retain the necessary expertise within the industry in order to provide a world-class regulatory regime for the sector. This will include drawing on the expertise of the UK Government to ensure that the Island continues to comply with its international obligations.

iii. Licence Requirements

There were limited comments from respondents regarding specific licence requirements with many noting that they were awaiting the full details of specific guidance for licensable activity from the Regulator.

As noted above, following Tynwald approval, the GSC will become the regulator for the sector. The GSC intends to take a risk-based approach to the licensing of the sector. However, with the exception of the low-THC without use licences, there will be a requirement across all licence types for applicants to meet a fit and proper test, demonstrating competence and integrity to operate in the sector.

The GSC will be developing clear guidance documents for the new sector which will ensure that applicants understand the minimum requirements for each licensable activity. However, noting the feedback which expressed concern about the prescriptive nature of some of the proposed solutions to risks (such as the types of locks suitable for security) the Guidance Notes will establish the requirement for applicants to demonstrate how they will achieve those minimum standards. The GSC's approach is to typically recognise the risk and review both the documentary evidence and the physical manifestation of the minimum standards in practice.

Feedback from the Consultation indicated a significant benefit for outdoor growers to be able to plant a test crop during 2021. The GSC recognises that any delay in licensing may cause crops to be planted later than ideal undermining any conclusions growers might draw in respect of the Isle of Man's suitability for the outdoor crop.

For this reason and for 2021 only, the GSC will offer provisional licences for low-THC without use of flower, leaf and bud outdoor growing based upon applicants' declarations of integrity, with the licensee's confirmation (following GSC's due diligence checks) being a condition for continued cultivation. This is the only solution that will allow growers the lead-time require to realistically address a 2021 season and strikes a pragmatic balance between risk and opportunity.

For 2021 low-THC without use licences, no male plants will be permitted to be cultivated and no parts of the plant containing cannabinoids will be harvested for use. The GSC will seek to allow growers to test their crops for key yields (THC, CBD etc.) prior to destruction. Any fibres and herds yielded by female plants may be processed as growers see fit.

The GSC believes the indoor growing of high-THC cultivars represents a significantly higher risk for the misuse of drugs and therefore applications will be subject to enhanced security and, unlike the 2021 low-THC without use crop, will not benefit from immediate licensing. Rather, applicants will need to demonstrate competence and integrity, will need to have demonstrably legal routes to market for their products, will need to demonstrate that their funding is compatible with the Isle of Man's laws and, if intending to move products off the Isle of Man will need to supply credible assurances on product labelling that the GSC will test.

5. CHANGES TO THE FEES

The majority of respondents to the Consultation provided clear feedback that the proposed fee structure was unsuitable and, for a number of proposed operating models, uneconomical. The Department has given full consideration to the feedback received from the Consultation and the following amendments will be made to the fee structure.

To answer comments from the Consultation regarding the recognition of the industrial hemp segment of the potential market and to acknowledge the UK licence fee starting position, the fee for low-THC without use of flower, leaf and bud has been significantly reduced.

Feedback was also received in respect of fees being based on cultivation area which highlighted that the proposed basis was uneconomical across cultivation of low-THC with or without use. Comparisons with other jurisdictions were raised to highlight the potentially very high fees for large cultivation areas and the suggested commercial response was a much smaller island-based industry centred on head office functions only. The purpose of introducing the Framework is to encourage and support a broad based industry for all aspects of operations to create the best employment opportunities in a quality, well regulated, sector. As a result the proposed area-based cultivation fees will be removed from the fee structure.

The proposed fee structure was originally based around an Application fee and a subsequent Annual fee, but, following feedback this will be amended to a First year and Ongoing annual fee.

Significant feedback was received in respect of a lack of ability to package licences in the original proposal set out in the Consultation Paper. A number of applicants noted that if they were looking at multiple licences added together this would total a large combined fee. In response to that issue, a fee cap has been introduced to provide certainty to applicants where they seek a package of licences to allow them to operate from 'seed to shelf'.

Feedback was received that encouraged setting significantly higher fees for the sector. However, as set out in the Consultation document, the Department, in setting these proposed fees, has taken into consideration the principles of full recovery of the direct costs associated with the specific licensed activities. The revised fee structure also meets this objective and the GSC will have the ability to amend prescribed fees to reflect changes in regulatory costs and industry and regulatory developments.

The revised fee structure is set out in Table 1 below.

Table 1: Proposed licence fees

	Original proposed schedule		Final schedule	
Activity	Application Fee	Annual Fee	First year fee	Ongoing annual fee
Importation, transportation and/or storage of cannabis seeds	£1,500 – £3,000	£2,000	N/A	N/A
Licence for low-THC cannabis cultivation without use (of leaves, flowers and buds)	£2,000 - £3,000	£5,000 plus £5 per m ² (>2,000m ²)	£500	£250
Licence for low-THC cannabis cultivation with use (of leaves, flowers and buds)	£4,000 - £8,000	£5,000 plus £5 per m ² (<2,000m ²) £15 per m ² (2,000m ² to 5,000m ²) £25 per m ² (5,000m ² to 10,000m ²) £40 per m ² (>10,000m ²)	£10,000	£5,000
Licence for high-THC cannabis cultivation	£10,000 - £15,000	£25,000 plus £10 per m ² (<2,000m ²) £20 per m ² (2,000m ² to 5,000m ²) £40 per m ² (5,000m ² to 10,000m ²) £60 per m ² (>10,000m ²)	£45,000	£35,000
Licence for cultivation of cannabis using male plants (for research only)	£6,000 - £8,000	£10,000 - £12,000	£20,000	£12,000
Licence for transportation and/or storage	£2,500 - £3,500	£2,000 - £5,000	£5,000	£2,500
Licence for extraction	£25,000 - £30,000	£30,000 - £35,000	£22,500	£17,500
Licence for importation into the Isle of Man	£2,500 - £3,500	£1,000 - £2,000	£10,000	£7,500
Licence for exportation from the Isle of Man	£2,500 - £3,500	£1,000 - £2,000	£10,000	£7,500
Licence for manufacturing cannabis-derived products	£2,500 - £3,500	£8,000 - £12,000	£22,500	£15,000
Licence for operating a test laboratory	£2,500 - £3,500	£8,000 - £12,000	£12,500	£8,000

Fee cap calculation:

Where a class of licence is issued for the first time, the fee payable is the “First year fee”. Subsequent applicable period fees are the “Ongoing annual fee”. Total fees are capped at £62,500 and the cap is

calculated on a rolling basis as the cap value minus any licence sums already paid in the previous 364 days.

The rolling basis of the cap offers three benefits over calendar year based caps, or caps that operate at the point of initial licensing:

- i. The rolling cap always applies remaining cap discounts automatically (the GSC will calculate the discount when new licences are added to a licensee's collection of licences).
- ii. The rolling cap means that a licensee can choose the most suitable time to increase the range of activities they wish to operate, without losing unused portions of the cap.
- iii. The rolling cap means that a licensee is not obliged to make an all-or-nothing decision when first applying for a licence in roster to benefit from the cap.

The rolling cap means that there will come a point where adding a new licence is free and the only requirement will be demonstrating to the GSC that the licensee has the competence to discharge the regulatory obligations of the new licence.

6. NEXT STEPS

Given the responses received to the Consultation, the Department has progressed with the Regulations proceeding through legal review and to Tynwald, with a view to introducing legislation in January 2021.

At the December sitting Tynwald approved the Transfer of Functions Order, which establishes the Gambling Supervision Commission (GSC) as the launch regulator for licensing and supervising adherence by the regulated entities to the Framework. The GSC intend to issue the final Regulations and publish the Guidance Notes needed to support the enactment of the Regulations and to prepare to consider licence applications.

It is anticipated that the GSC will begin considering initial applications in February 2021 and issue the first approvals before April 2021. Given the outdoor harvest cycles and the interest amongst some local farmers to test crops, the GSC will initially prioritise applications for outdoor cultivation in order to meet the critical timeframe.

The GSC will then prioritise the applications related to the higher-value, medicinal market and anticipate approving applicants in this sector during Q2 2021.

Appendix 1: List of Representative Groups to which this Response paper will be sent

Manx National Farmers' Union

Manx Medicinal Cannabis and Hemp Association

National Pharmacy Association

European Industrial Hemp Association

Isle of Man Post Office

Relevant Isle of Man Government Departments

Specific individual private sector respondents

Appendix 2: Summary of responses received

<p>Question: Please let us know your proposed activity in this sector: farmer, investor, producer, testing laboratory, logistics (including import/export), research, other (please specify).</p>
<p>Summary of feedback: A wide range of applicants responded to the Consultation including direct investors, farmers/cultivators, logistic operators, manufacturers/producers, testing and research laboratories. One response was provided by a geothermal energy plant operator.</p>

<p>Question: Please provide any overall comments on the proposals in the consultation document.</p>	
Summary of feedback:	Response:
Overall, the proposal represents a sizeable opportunity for the Isle of Man to establish as a strategic location within the European cannabis sector.	Noted.
<p>Lots of positive and sensible aspects, a few we disagree with...</p> <p>Positive: clear and transparent, aligned with UK legal principles crucial for inter-governmental relations Negative: fee structure incorrect, some disproportionate rules, lack of clarity over scope boundary specifically with regard to interface with MHRA requirements and associated medicinal regs, some overly prescriptive aspects e.g. types of lock used Missing: information regarding banned substances and specific testing requirements</p>	<p>Comments made regarding the fee structure are addressed in Part 5 of this Response Paper.</p> <p>Matters raised regarding the specific details within the Guidance Notes will be taken into consideration by the GSC at the time of their drafting most likely in early 2021.</p>
The proposals in the Consultation Document appear measured, balanced and focused on providing a workable regulatory framework for development of cannabis based businesses within the IoM	Noted.
The IOM is clearly serious about entering the medicinal cannabis arena - as a Manx based business we applaud and fully support this initiative. The proposals appear well thought through - our only comments would be that the initially fee structure appears overly complex and costly!	Noted. Comments regarding our fee structure have been addressed and we have revised the activities and associated fees as appropriate. These changes are set out in Part 5 of this Response Paper.
Overall the framework would provide a sensible regulatory regime for the island.	Thank you for your comments.

It is a shame to see a single department led regulatory proposal instead of a multi-departmental legislative change...	The scope of this Consultation has been, from the initial release, only in respect of the potential economic activity of a new export industry. The Department for Enterprise has acted as departmental sponsor and existing legislative provisions have been utilised to bring the sector into operation as quickly as possible.
Very positive to see clear regulatory structure.	Thank you for your comments.
We believe that the proposed legislation and regulatory regime is well structured and its proposed introduction is well timed, if a little later than previously expected. The structural design allows the Island to take advantage of the opportunity presented by multiple factors, which offer it the ability to maximise its potential to the full...	Thank you for your comments.
The proposal looks good, fees need to be discussed.	Thank you for your comments. Comments regarding our fee structure have been addressed and we have revised the activities and associated fees as appropriate. These changes are set out in Part 5 of this Response Paper.
Proposed framework is 80% there but there are a few matters which are fundamentally flawed, which if not corrected will make a significant proportion of the proposed IOM cannabis industry and therefore the financial and biosphere opportunity commercially unviable. The general areas which are unworkable, as drafted are: <ul style="list-style-type: none"> • One size fits all nature of the proposed regulations. Hemp and medicinal cannabis are vastly different products with vastly different risks, which needs to be reflected in the regulations. Any legislation needs to treat all hemp matters as distinctly separate from medicinal cannabis products/activities, with each having their own regulatory and operational framework • Proposed regulatory changes regarding the purchase and importation of cannabis/ hemp seeds • Proposed regulations regarding hemp cultivation and transportation are excessive • Pricing framework for all hemp related activities is uncommercial • The variety of separate licences that are proposed for the cannabis and hemp industries are excessive and a number should be combined, even from a practicality point of view, i.e. importation + cultivation + transportation 	Thank you for your comments. Comments regarding the treatment of Hemp vs medicinal cannabis in the licence fees, the licence activities and the guidelines have been considered and where appropriate amendments have been made. The Framework has, through the establishment of low-THC and high-THC cultivation licences, provided for the different products of Hemp, and cannabis derived medicinal products. The availability and variety of licences within the Framework has been on the basis of specialist advice given represented industry's requirements. The Framework provides clarity over licensable activities and flexibility for potential applicants, which outweigh any possible administrative burden. The variety of licences provides for specialised companies to focus on just parts of the value chain. For those that plan to manage all aspects, a cap has been introduced to make the overall licensing cost reasonable.

<p>Question: 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.</p>	
Summary of feedback:	Response:
<p>A large number of the respondents commented on the inappropriate nature of the fee structure with regard the low-THC and industrial hemp crops. At the levels proposed in the Consultation Paper, respondents indicated that there was little of no operating margin for the businesses and hence few if any licences would be applied for.</p> <p>As well as inappropriate (too high) licence fees for industrial hemp, concern was raised at the level of regulatory compliance required to be demonstrated by applicants. Together, these issues could restrict and perhaps be a barrier to that industry segment developing.</p>	<p>Significant revision has been made to the fee structure and, to a lesser extent, the licence activities to address the sense of a less than level playing field between cultivators of industrial hemp and cannabis containing controlled cannabinoids. These changes are set out in Part 5 of this Response Paper.</p>
<p>The licence fees proposed were seen by some respondents to act as a significant barrier to entry for 'craft' cultivators who may, each on a small scale, enter the market focused on high quality product. Suggestions regarding the use of 'thresholds or licence fee caps' for multiple licence applications were also raised by respondents.</p>	<p>There was no evidence from the responses to the Consultation that there was a 'craft' segment of the market interested in establishing under the proposition. The requests for thresholds or licence fee caps in circumstances where multiple licences are applied for by one entity have been taken on board in the final fee structure and the manner of its application. These changes are set out in Part 5 of this Response Paper.</p>
<p>I believe that the current licensing structure encourages companies to move key parts of the supply chain 'off-island'.</p>	<p>Noted. The licence fees have been amended to ensure that cultivation of low and high-THC cultivars is economically viable. Fees are raised on the basis of covering the Regulator's operating costs only.</p>
<p>The fee structure will heavily restrict the amount of businesses choosing the island and therefore the jobs created.</p> <p>There is an important point regarding the scope of the regulator and if/how it will interface with the MHRA that is unclear from this document.</p>	<p>The licence fee structure has been amended following the Consultation process feedback received. These changes are set out in Part 5 of this Response Paper.</p> <p>Noted. The manner in which the Regulator will interact with the MHRA and any other regulatory body depends on the operational scope of the other regulator. The GSC will consider the impact of the interoperability on its own procedures and reflect that within the Guidance Notes.</p>
<p>We.....believe that as an island with a long and proven history worldwide for farming and agricultural excellence that the different canna products cultivated here will, within a few years of harvesting be amongst the very best in the world.</p>	<p>Noted. The changes to the licence fee structure have been made to ensure the right fiscal environment for this cultivation to take place.</p>

The framework needs to focus on providing a cannabis industry on the island that allows for the full use of cannabinoids but doesn't restrict the development of viable markets for the fibre and ships.	Noted. Changes to the licence fee structure have been made to ensure that there can be an economically viable low-THC without use industry segment. These changes are set out in Part 5 of this Response Paper.
It may meet the Government objectives of providing a regulatory framework, but we need distinction between high-THC and low or no THC. The proposals that would cover low or no THC do not work.	Noted. As well as amending the licence fee structure to allow for low or no THC cultivation to be economically viable, the accompanying guidelines for that activity when published will take account of the lower associated regulatory risks.

Regulations:

Question: Are the definitions contained in the Regulations clear and appropriate?	
Summary of feedback:	Response:
<p>A significant majority of the respondents to the Consultation agreed that the definitions within the Regulations were clear and appropriate. The following points require a specific response.</p> <p>A common theme from a number of responses related to the defined limits to the stages 'Cultivation', 'Production' and 'Manufacture' and the need to establish clear process boundaries between each stage to ensure that the associated Guidelines are distinct. One respondent was particularly concerned that while the regulations for 'Import', 'Export' and 'Transport & store' licences had some commonality, the underlying guidelines and conditions are materially different.</p>	<p>Noted. At this stage of the legislative drafting process, the primary focus is on the completion of the Regulations. Work continues simultaneously on the underlying Guidance Notes and the GSC welcome feedback and will action the discrepancies in their next iteration.</p>
<p>The definition of legal THC levels within CBD of 0.2% was questioned by a couple of respondents who pointed out that the EU (on 23/10/20) approved a level of 0.3% and suggested the IOM regulations followed suit.</p>	<p>Due to the constitutional connection between the IOM and the UK, and the UK's responsibility for the IOM under the UN's Single Convention on Narcotic Drugs, the Isle of Man is seeking to maintain parity with the UK rather than follow the newly revised EU's definition at this time.</p>
<p>One Consultation response identified the need for any testing laboratory on the Island to hold ISO17025 accreditation as a mark of assurance over the lab's accuracy, rather than standards ISO9001 and ISO22000.</p>	<p>Noted. The Regulator will consider the adequacy of any quality assurance certification held by licensed testing laboratories as part of its supervisory procedures. The Guidance Notes will set out the required quality assurance principles rather than specific certificates required.</p>

Three respondents raised questions regarding the need for clarity around the definition and understanding of 'biomass', suggesting that the inclusion of a more detailed definition to assist licence holders understand any differences in comparison to agricultural biomass definitions.	Noted. The terminology 'biomass' will be considered by the Regulator when drafting final versions of the Guidance Notes to ensure that the definitions used adequately addresses the matter fully.
The meaning of GMP in the way it was used in the Consultation Paper was questioned by one respondent, on the basis that there are a number of different GMPs, depending on the use of the processes final product.	It was envisaged that the term GMP in the case of cannabis derived product manufacture related to pharma GMP and the procedures established within the EuDralex Vol 4 in respect of medicinal production for human consumption. If, on further review, the drafted guidelines are misleading, then amendment will be made before finalisation.
We believe that there is a need to define the point in time at which "Production" occurs to ensure that effectively all conduct after "Cultivation" is not "Manufacture". We believe that this is necessary to ensure that the regulatory and security safeguards associated with Extraction and Processing are retained as distinct from the similar, but likely lesser, safeguards associated with Manufacture.	Noted. In revising the Guidance Notes, the Regulator will take account of comments made as a result of the Consultation process.

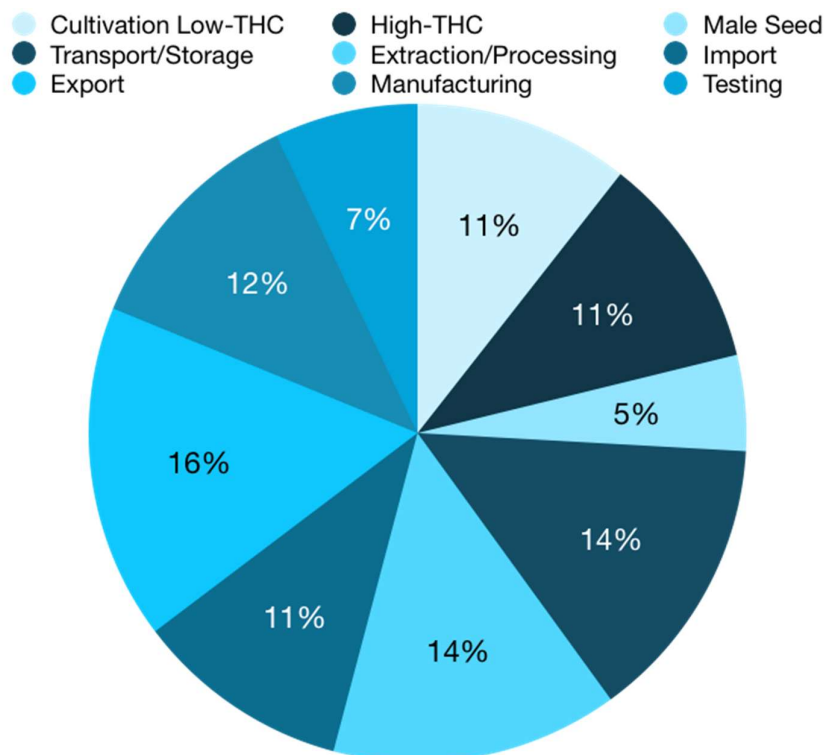
Question: Are the licence types set out in the Regulations clearly defined and appropriate the development of a cannabinoid industry on the Island?	
Summary of feedback:	Response:
Consultation responses specifically supported the creation of the separate licences seeing the benefits of flexibility within the industry supply chain and ensuring that all licenced operators can see with certainty the standards of conduct of others by way of the clear, transparent guidelines.	<p>In response to specific comments on both the quantity of licence types and the licence fees for operators that intend to carry out a number of licenceable activities, the revised Regulations raise the concept of a capped fee for multiple licences. To maintain the flexibility of the licenceable activity structure, there has been no attempt to 'best guess' what combined licence vertically integrated businesses require. However, the fees are reduced to a preset 'cap'.</p> <p>There have been amendments to the licence types as a result of some of the feedback from the Consultation process and from further discussion with other governmental stakeholders, resulting in the removal of the seed importation licence. Further clarity has been established in the fee structure for 'with' and 'without' use low-THC cultivation licences.</p>

A few Consultation respondents raised concern that the licence framework did not cater for the hemp industry to the same extent it did for the high THC medicinal cannabis products, applying similar licence conditions were felt to penalise the market segment where compliance costs are a higher percentage of the end product value.

Throughout the Framework and Regulations, the definitions used for the controlled substances and cannabis products are consistent with definitions in the UK legislation to ensure a smooth transition for UK applicants and current licence holders.

Licensing:

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



Summary of feedback: Of the 28 respondents to the Consultation, 16 specified they would be looking for at least one licence. One respondent indicated applying for a Testing licence and another was looking for the licence types that supported their logistics business.

Indications are that there is equal interest in low-THC and high-THC cultivation, suggesting good support for a broad industry sector on the Island.

We have drawn an assumption from the number of respondents that indicated an interest in multiple licence types that a significant majority of them would operate vertically integrated operations - 'seed to shelf', which creates good potential for the creation of strong employment over the medium term.

Licensing:

Question: Do you think the suggested 'Fit and Proper' person criteria are appropriate?	
Summary of feedback:	Response:
<p>There was general agreement from the respondents that the application needed to be submitted by an Isle of Man incorporated entity that therefore had Manx directors in role.</p> <p>A number of respondents to the Consultation highlighted that, given the industry's past in many jurisdictions, there are likely to be some challenges with applicants who have previous experience. One response suggested that a different test was created for the lowest risk licence activity: low-THC cultivation without use of flower, leaf and bud. One respondent stated that the proposed criteria were too strict for this industry and had been lifted from the financial services and eGaming industries which were not comparable.</p>	<p>Noted.</p> <p>After discussion with other external stakeholders (UK Home Office), changes have been made to the licensed activity of cultivation of low-THC without use of flower, leaf and bud to reduce the compliance burden for those licensed entities. No other changes are likely to be made to the quality or the standard IOM criteria demanded as a result of the Consultation.</p> <p>We understand that this may positively limit the ability for some businesses to operate within the sector but it will ensure high quality applicants and limit the perceived and real potential risks of a new industry.</p>
<p>Also, respondents suggested that requiring a 'proven track record' precluded new entrants to the industry from establishing on island. Instead, there should be recognition of having access to, rather than employing, that expertise: the application of the guidelines in this area by the Regulator should be more flexible. However, recognising that the experience may not be internalised within the applicant, the respondent suggested a condition of the licence is the requirement of the applicant to notify the Regulator when that person leaves.</p>	<p>Noted. Amendments to the underlying guidelines to assess the practicalities of applying the condition to notify will be considered.</p>
<p>The preliminary guidelines published in the Consultation Paper indicated that all persons who enter the entity's site (field or factory) including contractors and subcontractors should be checked. Practically this is not feasible to manage situations where subcontractors are required on site for essential equipment repairs.</p>	<p>Noted. This point is accepted and has been taken into consideration in the final drafting of the associated Guidance Notes in respect of the enhanced DBS checks required of applicants.</p>

Question: Do you think the proposed licence requirements are appropriate?	
Summary of feedback:	Response:
A number of respondents commented through the Consultation process that, while the licence requirements were suitable for the high-THC, medicinal cannabis product segment of the industry, the hemp industry (low-THC without use) licence required too high a standard of behaviours and operating procedures.	Having continued discussion with the UK Home Office, it became apparent that changes, in line with respondents' suggestions, would help to reduce both the Regulator's workload and the hemp cultivators' compliance burden and not affect the overall regulatory oversight of the industry by the Regulator. Guidance Notes issued in early 2021 will reflect this.
The licensable activity relating to male seed importation for research only remains in place, due in part to the decision to protect the cultivators' 'female' crops from random fertilisation from any male seed on island. Two respondents questioned the original rationale for such a decision in the Consultation, but no significant objective evidence has been provided to change the Regulator's positions on this point.	After significant consultation with associated stakeholders, independent advisers and direct research, the licensing Framework remains unchanged with regard to the treatment of male seed.
Additional licence requirements were raised by one respondent in respect of the licensed operator setting out in writing details of the upstream suppliers and buyers and the downstream partners' (retailers/wholesalers) to establish a known supply chain and provide the regulator with a base case in the application that can be checked back to the 'real world' detail. Contrary to this point, another respondent felt that the requirements around the adoption of an MLRO were overzealous for the farming/low-THC cultivation.	Noted. Although the Regulator is likely to request a business plan alongside the licence applications in which details such as upstream and downstream supply chain parties could be denoted, there is no current indication that these details will be a specific requirement of a licence application.

In general yes. There are additions which would add further clarity such as a guidance feature, a description of the regulatory and legal framework and more importantly the connection between the various jurisdictions with which the industry on Island may interact.

- Will the importation of cuttings be licensable?;
- Why is there so strict a security requirement for industrial hemp?;
- What is the rationale for the licencing of male plant?;
- What is the rationale behind the differing categories of THC in the fee structure?;
- What is the transport licenced policy based upon?;
- What happened to the Market Participation Proposal?;
- Can there be up to date clarity on what is and is not currently banned substances?;
- There are a number of other important questions that stem from this question on the Consultation document. Further work is required.

Noted. As Guidance Notes are fully developed in line with the agreed Regulations, questions raised through the Consultation process will be answered.

- Importation of cuttings falls within scope of the Import licence.
- The Framework and associated Guidance Notes have been amended to recognise the different inherent risks involved in the cultivation and production of industrial hemp/low-THC and high-THC cultivars.
- Licensing male plants allows for the outdoor growing of female plants to maximise CBD yields.
- The fees structure reflects the different associated regulatory risks between low and high-THC.
- Licensing transport ensures security of materials.
- The legal Framework doesn't allow for a separate market participation licence.
- Existing primary legislation already defines 'banned substances'.

Question: 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:

Please note: this licence category has been removed from the list of licensable activities within the Regulations, due to the scope of the current Seed Act 1921.

Summary of feedback:	Response:
I would like some clarification for importing, and storing of the seed for personal use and hope that it should be exempted.	The Consultation process related to the proposition for regulations over cannabis derived medicinal products for export and not for personal use. That is outside the Regulatory Framework.
<p>We will import seeds as part of our cultivation genetics program, therefore we will need the relevant permissions to do so. Note that we are not primarily a seed bank or genetics business.</p> <p>Q1 - is it already legal to buy cannabis seeds as they contain no controlled substances (whole hemp seeds often found in bird seed, fish bait and human supplements) so how and why is the licence required?</p> <p>Q2 - pg. 47 refers to "commercial cultivators...utilise clones", does this mean the importation of cuttings will be permissible?</p>	<p>Noted.</p> <p>The requirement to obtain a licence in order to import seeds has been removed.</p> <p>The importation of cuttings is within the scope of the Importation licence.</p>

Cultivation and harvest of low-THC cannabis without use of leaves, flowers and buds:	
<p><i>Comments submitted from the Consultation have been taken into account and amendments to the guidelines related to this licence type made, bringing the licence requirements in line with the UK position. The changes recognise the important attributes of the hemp plant in supporting climate change target achievement and the low risk operations the licence covers. To that extent, the scope of this licence has been extended to include the transportation and/or storage of the hemp.</i></p> <p><i>Licence fees have changed significantly, with the removal of area-based fees and replaced with a simple, fee comparable to the UK. These changes are set out in Part 5 of this Response Paper.</i></p> <p><i>As with all of the licence types, the fees are raised annually and the licence cover a period of three years, albeit depending on the severity of the condition breach, it can be removed.</i></p>	
Summary of feedback:	Response:
This licence does not allow male plants which are essential for seed production due to pollination of the female flowers being a precursor for seed development and seeds are a desirable non-controlled agricultural crop (as referred to by "Animal Feed" pg. 49)	Based upon feedback, the decision was taken to allow only female plants in order to maximise the revenue potential for outdoor growing.
We are steadfast in our belief that all of the Island residents benefit to a significantly greater extent from the creation of a cannabinoid industry, in contrast to a fibre industry in which the benefit will go to a very limited number of individuals.	Thank you for your comment.

Cultivation and harvest of low-THC cannabis with use of leaves, flowers and buds:	
Summary of feedback:	Response:
Whilst the flowers do contain more valuable compounds of the cannabis plant, the expected concentrations achievable outdoors, climate dependent productivity and current wholesale CBD isolate market prices mean the economic case is unlikely to stack up in the context of the licence fees.	Noted. The licence fees have been amended significantly for low-THC cultivation too take account of the economic viability of the crop grown outdoors. These changes are set out in Part 5 of this Response Paper.
There is very limited access to feminised cultivars below 0.2% THC as they are normally grown industrially and not in the way that would be required under this Framework, removing male plants. None of the OECD approved list are available commercially as feminised seeds, resulting in no compliant sources of seeds for the proposed low THC licences.	The Guidance Notes relating to seed and cutting importation will address the issue of OECD approved cultivars when issued in early 2021.

Cultivation and harvest of high-THC cannabis:	
Summary of feedback:	Response:
<p>It is unclear from the consultation document:</p> <ul style="list-style-type: none"> - what is the testing criteria? - what is the scope of the Regulator, specifically with regards to the boundary of IOMG with the MHRA? <p>We have very clear views on how we anticipate it to work but it's an important area that we'd like to understand better.</p>	<p>Noted. The interoperability between the Isle of Man Regulator and other jurisdictions' regulators will be addressed in each circumstance, under the overarching principle of minimising duplication of regulatory procedures where possible.</p>
<p>We believe that the minimum requirements should be just that and, given the importance to the industry as a whole of adequate regulation and protection from diversion, we do not believe that any credible market participant will regard the identified requirements as prohibitive to their market entry. Indeed, sensible market participants will be prepared for significantly more robust requirement if the nature and circumstances of the individual operating facility demand such.</p>	<p>Noted. We understand that the minimum requirements may positively limit the ability for some businesses to operate within the sector but it will ensure high quality applicants and limit the perceived and real potential risks of a new industry.</p>

Cultivation and harvest of cannabis from male seed for research only:	
Summary of feedback:	Response:
<p>In this context, my view is that these charges should be exempted. We need more research which will benefit the society.</p>	<p>Thank you for your comment. Any fee raised is done so to cover the Regulator's associated operating costs arising from the need for oversight of any controlled cannabinoids and the Island's international reporting responsibilities.</p>
<p>The Island should aim to be a centre of excellence for the worldwide cannabinoid industry. Intrinsic to that aim will be the ability for market participants to engage in research and development to advance their own business, and through evolution, the Island's industry as a whole.</p> <p>Having this licence separate from all other licences means that the Island can also seek to target "pure" research and development entities, rather than only those who wish to engage in research ancillary to their core business. In the light of this we would encourage the licence criteria to be amended to "cannabis from male or female seeds for research only".</p>	<p>Thank you for your comment. The intention of this class of licenceable activity is that it restricts male seeds use to research only. Any female seeds can be used for research purposes.</p>

Transportation and/or storage of cannabis-derived products or cannabis biomass containing controlled cannabinoids	
Summary of feedback:	Response:
Respondents raised comments that the scope of this licenceable activity was too broad in that it covered the transport of biomass from industrial hemp cultivation. Given this crop has no controlled cannabinoids, the suggestion is that such transport and storage does not require a licence.	The guidelines for this activity have been amended to accommodate these comments. Where a licence is granted for the cultivation of low-THC cannabis without use of flower, leaf and bud, transport and storage of resulting harvested crop will be permitted within the allowable activities of that licence.
Similarly this category seems unnecessary since it is a pre-requisite for any cannabis business in the supply chain to transport and/or store cannabis derived products or biomass. We understand if it is solely aimed at logistics companies. However if we are dealing with a legal finished product e.g. a medicine being prescribed, why could FedEx, G4S or Royal Mail not transport it without a specific licence?	As above, where the material transported or stored is derived from high-THC cannabis cultivar, a licence is required, whether the entity carrying out the activity holds a cultivation licence or not. The reason for the licence is to ensure security of material.

Extraction and/or processing of cannabis biomass and/or preparations containing controlled cannabinoids extracted from cannabis biomass:	
Summary of feedback:	Response:
Questions have arisen from the consultation process regarding the requirement of a licence to extract and/or process cannabis biomass not containing controlled cannabinoids, i.e. arising from the harvest of industrial hemp.	As with the Transport and storage licence, where a licence has been granted for the cultivation of low-THC cannabis without the use of flower, leaf and bud, the activity of extraction and/or processing of the harvested crop will be included within the permitted activities of the cultivation licence.
Unclear what the "on Island minimum standards for base ingredients" means? Also what testing criteria for banned substances are? Also nothing about the regulatory interface with the MHRA and EU GMP compliance?	Details of base ingredient minimum standards and testing criteria for banned substances will be provided in the Guidance Notes issued in early 2021. The interoperability between the Isle of Man Regulator and other jurisdictions' regulators will be addressed in each circumstance, under the overarching principle of minimising duplication of regulatory procedures where possible.
Exemption required or a separate licence for the Extraction of cannabis biomass or preparations not containing controlled cannabinoids and/or cannabis-derived products	Where extraction occurs on cannabis biomass where the flower, leaf and bud have been removed and destroyed, the cultivation licence extends to include this activity.

Importation of cannabis biomass or preparations containing controlled cannabinoids and/or cannabis-derived products:	
Summary of feedback:	Response:
A number of respondents indicated their plans to apply for a number of licences that, together, would allow them a business model serving 'from seed to shelf'. In setting out that expectation, they commented on the potential for a bundle of licences to be available, or for there to be a cap on the licence fees payable.	A fee cap has been established to respond to these requests, demonstrating commitment to vertically integrated business models that require numerous licence types to cover all of their operating activities through certainty of a maximum licence fee payable. The licence fee arrangements also ensure that multiple licence applicants do not incur increased fees in any one 12 month period as a result of multiple applications. See Part 5 of this Response Paper for further details.
Unclear what the "on Island minimum standards for base ingredients" means? Also what testing criteria for banned substances are? Also nothing about the regulatory interface with the MHRA and EU GMP compliance? We feel that particular care and attention should be paid to the testing regimes and protocols applied to imported biomass. This is particularly pertinent where standards of GAP are variable, often production is carried out outdoors and therefore subject to external factors including pesticide spray drift from adjacent crops and a whole host of persistent toxic compounds that are potentially prevalent in soil long after application. Thus testing requirement for imported biomass are likely to differ from locally indoor cultivated biomass under strictly controlled conditions.	<p>Details of base ingredient minimum standards and testing criteria for banned substances will be provided in the Guidance Notes issued in early 2021.</p> <p>The interoperability between the Isle of Man Regulator and other jurisdictions' regulators will be addressed in each circumstance, under the overarching principle of minimising duplication of regulatory procedures where possible.</p>
Exemption required or a separate licence for the Importation of cannabis biomass or preparations not containing controlled cannabinoids and/or cannabis-derived products	To ensure that the Regulator fulfils the required reporting standards to meet the Island's international obligations, importation into the Isle of Man will require a separate licence.

Exportation of cannabis biomass or preparations containing controlled cannabinoids and/or cannabis-derived products:	
<i>As noted in other responses, the concept of a licence fee cap has been established to ensure that multiple licence applicants are not financially penalised for making significant financial investment into the Island's economy. See Part 5 of this Response Paper for further details.</i>	
Summary of feedback:	Response:
Exemption required or a separate licence for the Exportation of cannabis biomass or preparations not containing controlled cannabinoids and/or cannabis-derived products	To ensure that the Regulator fulfils the required reporting standards to meet the Island's international obligations, exportation into the Isle of Man will require a separate licence.

Manufacture of cannabis-derived products:	
<p><i>The licence fee structure has been amended to better reflect the Regulator's associated costs in overseeing that specific activity and to recognise that, where manufacture is undertaken for a cannabis derived medicinal product, there will be the interaction of and costs from other regulatory bodies such as the UK MHRA. The proposed sqm basis for licence fees has been removed in response to comments made during the Consultation. These changes are set out in Part 5 of this Response Paper.</i></p>	
Summary of feedback:	Response:
Exemption required or a separate licence for the Manufacture of cannabis products derived from industrial hemp activities.	As with the Transport and storage licence, where a licence has been granted for the cultivation of low-THC cannabis without the use of flower, leaf and bud, the activity of manufacture of product derived from the harvested crop will be included within the permitted activities of the cultivation licence.

Analysis and testing of cannabinoids:	
Summary of feedback:	Response:
<p>As noted previously, testing requirements are currently unclear. A related point for clarification is there is reference to 'Biological fingerprint' in the definitions, but no reference to HPLC and GCMS which typically are the technologies of choice for the industry. In our view, DNA testing (which is implied by biological fingerprint) is an unnecessary minimum requirement that has little bearing on safety, albeit it is desirable for certain activities, notably R&D and genetics. However, testing for certain banned substances, controlled and desired cannabinoids via appropriate methods would be a reasonable requirement.</p> <p>Can this be clarified?</p>	<p>Details of testing criteria including confirmation of any references to 'biological fingerprinting' and DNA testing will be provided in the Guidance Notes issued in early 2021.</p>
<p>All testing methods for product release should be independent and aligned with UKAS and require testing of the cultivated crop to demonstrate cultivation compliance as well as the exported ingredient or finished product. Appropriate testing methods at the appropriate test points are needed to certify the custody, provenance and quality of the entire supply chain.</p>	<p>Details of testing criteria for banned substances will be provided in the Guidance Notes issued in early 2021.</p>

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

Summary of feedback: In the light of responses to the Consultation being given with no certainty of what the final fee structure would look like nor whether the area-based fees would remain in the final version, a number of the Consultation responses note their dependency upon agreement of a final fee structure.

Notwithstanding that caveat, indications given in the responses are as follows:

Outdoor industrial hemp

- test crops covering 2.5 to 5 hectares, subsequently growing to 245/300 hectares in 2022, through to 1,200/2000 hectares in 2024

Indoor (high THC)

- ranging from small 350 sqm up to 10,000 sqm

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

Summary of feedback: A number of respondents from the Consultation process showed interest in the manufacture of cannabis derived medicinal products, either as a process associated with on island cultivation and processing or related to the import of ingredients/flowers. Some of the respondents described the Isle of Man as a site to fit in with their current operating and research interests.

With the interest in the cultivation of industrial hemp, interest was shown for an on-island hemp manufacturing plant that could produce commercial end product from that crop too.

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

Pleasingly, the scope of the response to this question from the Consultation was very broad, showing the interest in the Island as a jurisdiction to create a broad based industry sector.

Industrial hemp products considered included:

- construction Hempcrete blocks
- insulation
- seed oil
- animal feeds
- protein powders
- biofuels

The scope of cannabis derived medicinal products and food /food supplements identified included:

- the Cultivation of cannabis for:
 - the medicinal “flower” market;
 - the medicinal “API” market; and,
 - the food and food supplement market.
 - The Extraction and Processing of cannabis biomass to create Preparations for deployment within:
 - the medicinal “API” market;
 - the food and food supplement market (for THC-legal jurisdictions); and,
 - the food and food supplement market (for THC-prohibited jurisdictions).
 - The Manufacture of Cannabis-derived Products for:
 - the medicinal “API” market;
 - the food and food supplement market (for THC-legal jurisdictions); and,
- the food and food supplement market (for THC-prohibited jurisdictions).

Question: 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?

Summary of feedback: There was a general consensus from the Consultation response that establishing the facilities to manufacture cannabis derived medicinal products required a timeline of approx. 12 months from initial licence grant. A further 6 to 12 months was cited by a number of respondents as the timeframe to then take seed through, cultivation, growth, harvest and production to finished product, unless the product proposed was cannabis flower dried for medicinal use.

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

Summary of feedback: The Consultation respondents identified a variety of countries that were seen to be likely market for the cannabis derived medicinal products produced on island; but the more common ones were:

- Germany
- UK
- Northern Europe

There was recognition that the landscape of permissible markets was ever changing and therefore not all respondents suggested specific countries, but more agreed the general concept of legality was key.

Question: If applicable, what type of medicinal cannabis product would you be interested in exporting? (E.g. API, starting material, finalised product)

Summary of feedback: The most popular response from the Consultation is the export of APIs, with finalised products identified as an export product.

Fees:

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

Summary of feedback: The majority of respondents who answered this question identified their intention to apply for a 'bundle' of licences that allowed for 'seed to shelf' operations. One respondent indicated the wish to applying for a testing laboratory licence, another identified licences supporting logistics operations only and two respondents suggested licences which allowed the import of preparations, manufacturer and export of finished products.

One response suggested the need for a specific hemp industry licensing Framework and indicated their willingness to work with Government to establish. However, the licensing structure proposed allows for low-THC (without the use of flower, leaf and bud) activity to address this.

Question: Based on the proposed fees, how likely are you to enter this market?	
Summary of feedback:	Response:
The proposed fee structure in the Consultation paper was not considered supportive of an industrial hemp (no flower, leaf and bud cultivation) sector. A number of respondents Consultation comments also indicated that entrance into the Manx market was dependent upon adjustment to the proposed fee schedule. Also, respondents felt that a fuller market evaluation was needed to make such a decision with some certainty.	Having listened to the Consultation comments, the fee schedule has been substantially amended: the removal of the area-based fees and establishment of single fees based upon regulatory costs; the establishment of a first year and then subsequent year fee and the recognition of the low regulatory burden of low-THC, no flower, leaf or bud cultivation in a significantly reduced fee. These changes are set out in Part 5 of this Response Paper.

Question: Will the proposed fees affect your ability to cultivate cannabis or manufacture cannabis products?	
Summary of feedback:	Response:
Overwhelmingly, the Consultation responses confirmed that, in their proposed format, the fee structure would restrict economic activity on the island across the full range of cannabis derived product manufacture from industrial hemp through to high-THC medicinal products.	The fee structure has been significantly revised to address concerns raised. The ability of the regulator to waive fees has been amended to setting a fee cap which will provide certainty of the licence costs, especially for multiple licence applicants. These changes are set out in Part 5 of this Response Paper.

Question: Are the proposed cultivation area cut-off levels between small-scale and large-scale cultivation appropriate? Please provide comment.	
<i>Please note: Where comments were made in response to this question, each was strongly against the cultivation area proposals and, as a result, the revised fee structure has removed all references to cultivation areas to provide a simplified cost base.</i>	
Summary of feedback:	Response:
The market is developing rapidly and seed yields, extraction technology and optimised bioavailability through novel drug delivery technologies will improve yields and productivity significantly over the coming months and years. More revenues will be earned from smaller amounts of biomass.	Thank you for your comment.

Question: What is your position on the following statement: 'The fee structure and approach are fair for both licence holders and the public.'	
Summary of feedback:	Response:
I think the more competitive fee structures are, the more companies will domicile manufacturing in country. As a result, this will generate more jobs and spendable income for the region. The fees are fair and competitive compared to other countries.	Thank you for your comment.
Fair - yes. However it is unlikely to encourage as much inward investment as would be possible with more sensible, industry relevant structuring.	An amendment to the licence fee structure has been devised as a result of Consultation feedback. These changes are set out in Part 5 of this Response Paper.
Better value for all stakeholders can be achieved with a fee structure that encourages a variety of cannabis businesses to locate on the island and generate a variety of jobs with a variety of skills and salary levels. This would generate more money to Treasury via ITIP, NIC and VAT from discretionary spend, as well as the multiplier effect in the local community.	Thank you for your comment. With the amended licence fee structure, the Department considers all stakeholders will benefit.
Biomass will generally become commoditised as time progresses and more widely utilised across a wide range of finished products. High THC crops will by necessity be focused on niche regulated markets or high value pharmaceutical APIs whereas Hemp is likely become the dominant crop for supplying ingredients for wellness products. It is therefore difficult to predict how this will develop....and whether the proposed structure is appropriate. Wellness market is by far and away the dominant market growth driver at the moment and should be the IoM's priority. We believe that medicinal cannabis will become dominated by national cultivators in their respective markets and therefore imports will be disadvantaged as the market matures so good to have a wider licensing base to rely on.	Thank you for your comment.
<p>We look forward to further engagement with the Regulator in order that a deeper understanding of how the following inherent aspects which will flow from the creation of an industry will be considered and developed within the more detailed licence Guidance documents that will be inevitable as we progress to implementation of the proposals:</p> <ul style="list-style-type: none"> • local employment creation; • sustainability; • environmental considerations; • energy consumption; • waste management; and, • commitment to ancillary local investment. 	Thank you for your offer to work with the Regulator. This has been taken into consideration.

Yes, broadly speaking. I believe that in general, the island should seek to develop and nurture a nascent industry in order to generate tax revenues through normal channels, rather than seeking to generate income primarily via the licensing framework	Thank you for your comment. The licence fee structure has been amended to reflect better the underlying regulatory costs.
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Question: Do you think the cost for a lost or damaged licence is fair and reasonable?
Summary of feedback: <i>Overwhelmingly respondents agreed that the cost of a lost or damaged licence is fair and reasonable. However, the GSC consider the administrative burden of recouping small costs outweighs the cost recovery and so this has been removed.</i>

Question: Do you think the proposal for the Regulator to waive fees is fair and reasonable?	
Summary of feedback:	Response:
<p>The majority of respondents to the Consultation agreed that it was fair and reasonable for the Regulator to be able to waive fees, for a variety of different reasons such as:</p> <ul style="list-style-type: none"> - to support businesses in early stage set-up - to kick start a new economic sector on the island - to recompense for any failed crops <p>as long as it was carried out equitably and transparently.</p> <p>The only other comment was that there should be a 'bundle fee' for vertically integrated businesses, with multiple licence applications.</p>	<p>To address the concerns raised from the Consultation regarding the quantum of total fee for multiple licence applicants, a fee cap has been introduced.</p> <p>Therefore the proposal for the Regulator to waive fees has been removed from the Regulations.</p> <p>These changes are set out in Part 5 of this Response Paper.</p>

Question: Do you have any additional comments on the proposed approach to fees?	
Summary of feedback:	Response:
<p>1. At this stage the DfE would benefit from more discussion with the relevant interested parties regarding the initial fees paid by the first interested parties to take a chance in this bold new market place</p> <p>2. No mention of penalties or allowances if a crop or plant exceeds its stated and expected THC content as most stated levels in specific strains of seed are approximations and are condition dependent</p>	<p>The Department considers that the Consultation process provided adequate opportunity for interested parties to engage and provide feedback on the licence fee structure.</p> <p>The Regulator expects crops that exceed the conditions allowed with the issued licence to be destroyed and will require proof and assurance that the destruction has occurred.</p>
<p>I would expect financial partnership or support from primary processors for high THC product and agree with the testing and licensing proposals. For low or no THC then there should be no licensing or fee or regulation as it's no different to growing any other agricultural output. Obviously, these are loose answers and we have to comply with UK and EU legislation for export trade including testing (in line with all legislation and other products currently tested) but I am sure you understand the meaning of my response. Low or no THC cannabis and hemp derived products is not the same as high THC products.</p> <p>As for fees in general again we support fees and regulation for the high THC products but not for low or no THC. Keeping a register of approved people would seem more sensible and more secure as licences can be forged, stolen etc. although to what end I don't know.</p>	<p>Thank you for your comment. The amendments to the licensable activity structure have been made to address these points regarding the difference between low and high-THC.</p> <p>The amendments made to the Framework look to take account of the relative risks of low and high-THC products, including industrial hemp as a crop without the use of the flower, leaf and bud.</p>
<p>The professional image and reputation of the IOM as a well managed regulated cannabinoid sector with world leading international quality standards is important. Our reputation as a jurisdiction in other industry sectors such as shipping, gaming and aviation is impressive. Therefore in the first year we propose that for pragmatic management reasons it is important the industry is carefully managed and scaled in development and does not represent as a 'free for all' to outside parties. Whilst we do not know how many applications there will be, history has shown us that if we set the guidance and regulations up correctly the industry will be long lived and we can move ahead as a prime jurisdiction supporting a regulated cannabinoid business sector.</p>	<p>Thank you for your comment. A world class regulatory framework for the industry to grow with certainty regarding the manner in which businesses will be overseen is a key objective for the Department too. We do not consider that 'cottage-based industries' nor a startup licence should have any lesser regulatory requirements as a result of size: the industry risks remain the same.</p>

<p>In order to carefully manage staged development of the Industry and to also attract investment funding we propose consideration for a limited number of licences to be offered in the first year. This provides value to the licences and supports careful sector development. We propose that notice can be given from the regulator regarding availability of new licences in 2022/23, following review and renewal of existing licences. This provides the option for second phase licences to be offered following review of Industry progress and performance in 2021.</p> <p>Phase One Licence Proposals</p> <ul style="list-style-type: none"> • Outdoor Cultivation of (Low THC with or without) Hemp any Area /Acreage = ten to fifteen licences • Indoor Cultivation (all THC levels) of any size of unit = ten to fifteen licences • New Business Start Ups = As required <p>We recommend inclusion of provision for New Business Start Up Licence opportunity - to support and incentivise our smaller local based business, sometimes termed as 'Cottage Based Industry' that provides opportunity for indoor or outdoor cultivation up to a capped limit. Bear in mind that there are already cottage based industries operating under the current rules. These will be 'pulled into' a licensing regime whether they wish to or not. Their requirements will have to be accommodated.</p>	<p>There are at present no plans to restrict the number of licences issued.</p>
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