2022-11

REPLY BY THE PRESIDENT OF
THE COMMITTEE *FOR* HEALTH & SOCIAL CARE
TO A QUESTION POSED BY DEPUTY ST PIER PURSUANT TO RULE 14 OF THE
RULES OF PROCEDURE

1. **On 6th January 2022, the Economic and International Affairs Scrutiny Panel of the States Assembly in Jersey, produced a report entitled "Regulations for the licensing production and export of Medicinal Cannabis in Jersey" (Report - Regulations for the licensing production and export of Medicinal Cannabis in Jersey - 6 January 2022.pdf (gov.je)**

   Could the Committee for Health & Social Care advise what, if any, lessons and recommendations from that report it believes may have application to the licensing regime in the Bailiwick of Guernsey?

   The Committee *for* Health & Social Care ('C*f*HSC') considered the key findings and recommendations of the report soon after its publication as a bench marking exercise as it strives to uphold good governance standards in this relatively new industry. The C*f*HSC was encouraged to read that the model and operation of the Bailiwick of Guernsey Cannabis Agency ('BGCA') has been highlighted by the Government of Jersey's Scrutiny Panel as a recommended format to follow. While the Minister for Health and Social Services is the sole member of the Jersey Cannabis Agency, the cross-Committee approach already taken by the BGCA has negated some of the recommendations provided.

   The BGCA has provided a briefing paper to C*f*HSC on the findings and outcomes of the States of Jersey Scrutiny Report and key outcomes are detailed in Table 1. Where interlinked Key Findings and Recommendations have been identified, they have been grouped accordingly (irrespective of sequential numbering). C*f*HSC acknowledges that this is an early stage for both the commercial sector and the regulation of this field, however, it is very positive to note that systems are already in place that address the significant issues that were highlighted in the report as recommendations for the States of Jersey to implement.

   The BGCA regularly liaises with the cannabis industry and will continue to develop and refine the guidance which is already publicly available on the States of Guernsey website. Lessons can always be taken from reviews of this nature and C*f*HSC is grateful for the opportunity to compare our systems with those of other jurisdictions. The resources and fee structures associated with regulation of the cannabis industry will continue to be reviewed to ensure that they cover costs incurred by the States of Guernsey whilst also considering the impact on the industry and the economic benefits that the sector brings to the Bailiwick.

Table 1 – C*f*HSC Comments on the States of Jersey's Scrutiny Panel Findings

	Recommendation (R) / Key finding (KF)	**C*f*HSC comment**
	Regulations	
R2	The Council of Ministers should implement Jersey's own detailed and specific regulations for the medicinal cannabis industry. This work should be carried out immediately with a clear timeline set in place with the Legislative Drafting Office.	Guernsey's legislation broadly mirrors that of Jersey. Whilst there is not specific, stand-alone legislation regarding Cannabis Based Products Medicinal (CBPM / medicinal cannabis), it is paramount to acknowledge that cannabis (of any THC and cannabidiol profile) is a controlled drug and must be licensed and handled accordingly as any controlled drug. Provisions in relation to cannabis and CBPM are detailed within the Misuse of Drugs (Bailiwick of Guernsey) Ordinance, 1997. A licence(s) must be issued to cultivate, produce, possess and / or supply cannabis and the licence conditions must reflect the nature of the product and the risk that is posed. The licence conditions should also stipulate proportionate controls that must be in place to mitigate these risks and ensure that the product is handled in an appropriate manner (e.g. including requiring EU GMP, MHRA etc. approvals where this is necessary and proportionate).
	Licence Application	
R3	The Council of Ministers should ensure that the medicinal licence application process includes a full business case setting out the reasoning behind the project, the project and operational costs and timescales and clearly define all benefits both financial and non-financial to Jersey. A business case template should be developed with immediate effect.	Whilst the current application process does not expressly request that information is provided on "all benefits both financial and non-financial" to the Bailiwick of Guernsey, all of the other information is already required. The BGCA has provided guidance on the States of Guernsey website of the nature of material that should be provided with an application e.g. company background and business overview information is requested as part of the application process. This guidance continues to be reviewed and updated. If the States of Jersey produce a business case template then this will be reviewed and local guidance will be amended if it is felt that there are any omissions or additions of benefit.
R6	The Council of Ministers should ensure the licence fee for the cultivation, production and export of medicinal cannabis is	Guernsey's fees are broadly similar to those in Jersey. Fees are set by C*f*HSC and were formulated in accordance with the Policy & Resource Committee guidance.

	reviewed immediately and benchmarked against the minimum required resource to regulate this industry in Jersey. This should be carried out with immediate effect.	Fee structures will be reviewed annually (and can also be reviewed on an ad hoc basis). C*f*HSC have requested that a review is carried out after 12 months (from the current fees being set) to ensure that the fees are appropriate to cover costs incurred by the States of Guernsey whilst also considering the impact on the industry and the economic benefits that the sector brings to the Bailiwick. The BGCA will also raise any concerns regarding licence fees and resources (should they arise) during routine reporting to the Committee.
	Planning and the Environment	
KF8	The current application procedure for a medicinal cannabis licence requires the submission of an "Economic Impact Assessment" (EIA). However, unlike the form of EIA submitted with a planning application, the EIA accompanying an application for a medical cannabis licence is not available to the public and there is no procedure for the public to then make representations relating to a licence application.	Officers from the BGCA are consulted on Planning applications in relation to current or proposed sites for cannabis cultivation and comments are provided accordingly. It is a prerequisite of a valid licence application that the applicant provides confirmation that the site holds the relevant planning use class. The Development and Planning Authority (DPA) are consulted on all cannabis licence applications and their comments are considered and (where appropriate) incorporated within licence conditions. A guidance document for applicants has been developed which details considerations in relation to planning matters (e.g. lighting, odour, noise etc.) and conditions are also included within licences to specify these matters and to provide auditable and enforceable parameters. Within planning legislation locally, an EIA refers to an Environmental Impact Assessment. It is unlikely that an Environmental Impact Assessment would be appropriate for a cannabis site although this is within the remit of the DPA. It is equally unlikely that an Economic Impact Assessment would be required as part of a planning application although this matter is again within the remit of the DPA. A licence application must include details of the company's background and the nature and purpose of the business that is to be undertaken. They must also provide details of the products that they intend to cultivate and / or process and details of what will be supplied and who to. Whilst this does not constitute a formal Economic Impact Assessment, the BGCA will consider the information
R7	The Council of Ministers should ensure that all Environmental Impact Assessments submitted as part of a medicinal cannabis licence application are made public and, a process introduced that allows both the public and key stakeholders to comment on any such EIA prior to the approval of any licence with immediate effect.	
R8	The Council of Ministers should ensure that officers of the Planning and Environment Department are solely responsible for the assessment and approval of any EIA submitted with a medicinal cannabis licence application prior to the Jersey Cannabis Agency (JCA) determining the application with immediate effect.	

		provided and determine whether sufficient details have been provided to demonstrate that there is a valid reason for cultivation / production, a market for the product and a route to market. Given the nature of the current legislation and the reason for holding this information, it is currently not deemed that this information is available in the public domain. The BGCA is considering what information is publicly available (including whether there should be a public register of licence holders) and will be consulting with Data Protection Officers to consider aspects that are impacted by the current regime. If an Environmental Impact Assessment (EIA) is required as part of the Planning application process then it will be held on public record. If an EIA is submitted as part of the application process then this would not be available to the public but it would be shared with stakeholders during the licence consultation process.
	Security	
R9	The Council of Ministers should ensure that prior to a medicinal cannabis licence being issued, a detailed plan for site security should be set out within any licence application. No cultivation of cannabis should begin on site until all the approved security measures are implemented and signed off by the JCA and penalties put in place to ensure compliance.	This is a prerequisite of a valid licence application. Licence conditions do and will ensure that no cannabis shall be cultivated, stored, processed or otherwise on a site without the necessary site security, with appropriate risk assessments and assurance, being in place and having been approved by the BGCA.
R10	The Council of Ministers should ensure that a specialised training programme is delivered to Customs and Immigration officers in relation to handling the import and export of medicinal cannabis products. A training plan should be developed within 6 months of the presentation date of this report.	Guernsey Border Agency (GBA) is responsible for the training and competence of their officers. GBA is responsible for ensuring the border controls are in place for the importation and exportation of cannabis and cannabis products. Import and export certificates are issued by BGCA officers who are competent in this regard. The BGCA regularly liaises with GBA officers and both parties sit on the Misuse of Drug and Alcohol (MDAG) group. BGCA has no concerns regarding the competence of GBA officers to discharge their legal duties.
R11	The Council of Ministers should ensure the Responsible Person who is nominated by the licence applicant at	The competence and fitness of an applicant to hold a licence is assessed as part of their application and the applicant is expected to detail their background and

	application stage should hold the relevant qualifications to undertake this role. This should include relevant experience in both the science and biological industry and in the disposal of hazardous waste materials. This should be made part of the licence application process and carried out with immediate effect.	experience in the field. A successful applicant will also need to demonstrate that the licence holder has suitable staff to support them and carry out the licensable activities. The BGCA believes that there is no singular, specific qualification which would ensure that an applicant is competent, and this may be achieved in a variety of different ways, supported by a spectrum of staff. The competence of an applicant is also reviewed during the site visit when they will be questioned on various technical aspects of their application and the proposed processes.
	European Union Good Manufacturing Practice (EU/GMP) certification	
R12	To protect the quality and reputation of produce grown in Jersey, the Council of Ministers should ensure there is a requirement to apply for EU/GMP accreditation prior to receiving a medicinal cannabis licence to cultivate, process or export cannabis products. This should be monitored by a designated body (JCA) with key milestones in place to ensure the process is being followed and the licence holder is taking the relevant steps to achieve this. This should form part of the licence application process criteria and should be carried out with immediate effect.	There would not be a route to market for a medicinal product without an appropriate marketing authorisation. This would therefore impact the licence decision. It would be a business decision to determine if this would be EU/GMP (EMA) or UK/GMP (MHRA). There are possible scenarios where the respective EU and UK reference products might be qualitatively and quantitatively identical and therefore suitable for parallel submission. Good manufacturing practice (GMP) is the minimum standard that a medicines manufacturer must meet in their production process. Medicines and Healthcare products Regulatory Agency (MHRA) carries out inspections to check if manufacturing and distribution sites comply with GMP when assessing an application for a UK Marketing Authorisation. Product related inspections can also be requested by the EMA. MHRA and European Medicines Agency (EMA) have published guidance on GMP. Medicines (Human and Veterinary) (Bailiwick of Guernsey) Law, 2008 (submarine.gg) Legislation recognises EMA and MHRA marketing authorisation. C*f*HSC is responsible for the licences/certificates held but exercises it functions in consultation with the MHRA.

	Overall Responsibility	
KF20	The Jersey Cannabis Agency does not have clearly defined Terms of Reference and is reliant solely on the Memorandum of Understanding (MoU) currently in place with the Government of Jersey (with the Minister for Health and Social Services as the sole representative of the GoJ) and the UK Home Office.	The BGCA does not have specific Terms of Reference with C*f*HSC. Legislation clearly states the legal framework and scope within which the Licensing Authority (and thus also the BGCA) can operate. When constituted, the role of the BGCA was defined. BGCA officers have specific legal authorisations and this defines and limits the activities that can be undertaken. Regular Committee briefings and feedback have defined the reporting process between BGCA and the Committee. It is acknowledged that there may be some merit in formalising Terms of Reference between BGCA and the Committee although this is not considered a matter of necessity.
R16	The Council of Ministers should ensure the remit of the Jersey Cannabis Agency is expanded to include both the monitoring function of the medicinal cannabis industry, and compliance with security, quality of production, clear moral conduct of people working in the industry and issuance of trade licences. The monitoring function would also include ensuring Customs and Excise and the States of Jersey Police are well informed about the process of the medicinal cannabis industry and are trained to be attentive to illicit drug importation and possession. This should be carried out with immediate effect.	The BGCA already has responsibility for routine and reactive compliance assessments in relation to licensed site activities. The BGCA liaise with BLE over site security and other compliance considerations. It should also be highlighted that licence conditions place notification requirements on the licensee which ensure that issues of significance must be reported to BGCA (e.g. actual and attempted break ins, theft, loss of product etc.).