Hon Andrew Little

Minister of Health
Minister Responsible for the GCSB
Minister Responsible for the NZSIS
Minister for Treaty of Waitangi Negotiations
Minister Responsible for Pike River Re-entry
Lead Coordination Minister for the Government's Response to the Royal Commission's Report into the Terrorist Attack on the Christchurch Mosques

25 October 2022

Josiah Spackman

By email: josiah@skyman.co.nz
Ref: ALOIA267

Dear Josiah

Response to your request for official information

Thank you for your request under the Official Information Act 1982 (the Act) on 14 September 2022 for information about the Medicinal Cannabis Scheme. Please find a response to each part of your request below.

> *When setting up the Medicinal Cannabis Scheme with the commencement of the Misuse of Drugs (Medicinal Cannabis) Regulations 2019, were there any targets, KPIs or indicators that the Minister had in mind for 1, 2, 5 or 10 years that would indicate that the legislative changes were providing the desired outcomes to the benefit of patients?*
>
> *Likewise, what numbers / targets / KPIs of products would indicate a "successful" industry for license holders (for example in terms of dry flower shipped locally, exported, or number of products registered under the New Zealand Minimum Quality Standards - NZ MQS)?*

No targets or key performance indicators were established. The Regulatory Impact Statement (RIS) for the Medicinal Cannabis Scheme included some estimates of the potential size of the domestic and export markets. The RIS is publicly available at: https://www.treasury.govt.nz/sites/default/files/2019-12/ria-moh-mcs-dec19.pdf.

> *Is the minister aware that 100% of all natural / dried flower products are imported, and that two years on there has not been a single locally grown natural product to market under the current regulations?*

To date, all dried products which have been verified as meeting the minimum quality standard have been grown outside of New Zealand. However, there are several locally grown and manufactured medicinal cannabis dosage products which have been verified as meeting the minimum quality standard (MQS).

The Medicinal Cannabis Agency assesses all applications received for verification of products against the MQS, however, does not actively seek or source products for verification.

Private Bag 18041, Parliament Buildings, Wellington 6160, New Zealand
+64 4 817 8707 | a.little@ministers.govt.nz | beehive.govt.nz

Was the minister aware that when creating the regulations that 200 CFU's for inhilation would be some of (if not THE) strictest in the world by an order of magnitude (As per European Pharmacopoeia section 5.1.4) for Medicinal Cannabis flower?

At the time of the introduction of the Scheme, industry was consulted on the MQS, and these were put in place following assessment of the feedback.

The limits which products for inhalation are required to meet with respect of microbial contamination, are described in the European Pharmacopeia. These limits are the same or similar to limits described in other recognised pharmacopeia, such as the United States Pharmacopeia (USP) and British Pharmacopeia (BP).

The limits are in place to ensure that the product is of a sufficient quality, including ensuring that it does not introduce quantities of bacteria into the lungs, which could lead to infection.

Is the minister aware that 100% of all currently imported flower products have had to be gamma irradiated in order to meet the 200 CFU/g limitation?

Your statement is incorrect. To date, Manatū Hauora (the Ministry of Health) has verified seven imported dried flower products, two of which are irradiated. Medicinal cannabis products are required to meet the limitations outlined in the European Pharmacopeia, depending on their route of administration. Gamma irradiation is one (but not the only) method for achieving these limits for inhalation products.

Was there any advice regarding the impact of those regulations on dried flower products, especially in comparison to other countries regulations (such as 10,000 CFU/g for inhilation for most of the USA or 500,000 CFU/g for Canada)?

What advice was provided to the Minister around the implications of the NZ MQS, in regards to the requirements that products / dried flower / starter material meet the NZ MQS prior to being exported, and how this would greatly harm license holders capacity to export?

The Misuse of Drugs (Medicinal Cannabis) Regulations 2019 (the Regulations) were developed with guidance and consultation from several parties including industry, the public, government, and medical experts. Advice to the Minister around the impact on dried flower products in comparison with other countries and the implications of products, dried flower and starting material having to meet the minimum quality standard prior to export was provided as part of the RIS for the Medicinal Cannabis Scheme. This RIS was reviewed by a panel with representatives from the Treasury Regulatory Quality Team and the Ministry of Health. The RIS included the feedback received from all external stakeholders after public consultation on the establishing of the Medicinal Cannabis Scheme. This consultation included different options towards the regulation of dried products and the implications of the minimum quality standard on medicinal cannabis products for supply and export. The current Regulations are the result of the feedback received. Please refer to the RIS linked above.

What advice was provided to the Minister around the implications of repeatability trials and how it would require license holders (cultivators / manufacturers) to hold on to potentially hundreds of thousands (if not millions) of dollars worth of product for months (if not a year or more) while these trials took place?

Private Bag 18041, Parliament Buildings, Wellington 6160, New Zealand
+64 4 817 8707 | a.little@ministers.govt.nz | beehive.govt.nz

‘Repeatability trials’ is not a term used within the Regulations or as part of the MQS. As such, this part of your request is refused under section 18(e) of the Act, as the information requested does not exist.

> *What were the key reasons that batch-testing / labelling for each product batch was not adopted instead, both as a method of streamlining any products under NZ MQS and as a method of providing the most accurate labelling for patients?*

The Regulations require medicinal cannabis products to be manufactured in a Good Manufacturing Practice (GMP) certified facility. The code of GMP requires that any product must be fully tested to ensure it meets its desired specifications before the product is allowed to be released for supply. This ensures that every batch is consistently produced and complies against set specifications.

Medicinal cannabis products are required to meet the MQS imposed by Part 1 of the Regulations. The MQS include certain tests with the associated specifications. The MQS requires a representative sample of three batches of a product to be submitted to verify it meets these specifications listed.

In addition, the MQS require these products to meet the labelling requirements as outlined in specific sections of the Medicines Regulations 1984 (as specified in the Regulations).

> *Is the Minister aware that pharmacies cannot currently even list what products they have in-stock, let alone the price of them publicly?*
>
> *Is the Minister currently aware of how Medsafes advertising restrictions prevent patients from making informed decisions, and has resulted in "price gouging"?*

With the exception of Sativex, medicinal cannabis products are unapproved medicines. Under the Medicines Act 1981, unapproved medicines are not permitted to be advertised. Should pharmacies publicly list unapproved medicines and their prices, this would be a form of advertising.

It should be noted that even when an approval is granted for a product under the Medicines Act 1981, medicines which are also classified as controlled drugs under the Misuse of Drugs Act 1975 are still unable to be advertised to the public.

> *When the Omicron outbreak began, the Govt took steps it deemed "reasonable" to prevent price gouging on RAT tests. Given what we are seeing now with medicinal cannabis products, is a 40% price variation between pharmacies on the exact same product acceptable to the Minister or the Ministry of Health, either for Medicinal Cannabis products or any other medicine?*
>
> *What steps is the Minister currently taking, and going to take, to stop this from occurring as we are seeing now?*

Whilst the Medicinal Cannabis Agency verifies medicinal cannabis products, it does not regulate or have control over commercial decisions, such as the price an individual pharmacy charges a patient for a medicinal cannabis product.

Private Bag 18041, Parliament Buildings, Wellington 6160, New Zealand
+64 4 817 8707 | a.little@ministers.govt.nz | beehive.govt.nz

Does the minister find it acceptable that the regulations have inadvertently required gamma irradiation to meet the Eu Ph 5.1.4 levels?

Under what circumstances would the minister consider further amendment to the current legislation regarding Eu Ph 5.1.4 limits?

Under what circumstances would the Minister seek to amend legislation so that the NZ MQS standards would not apply to exports, and cultivators / manufacturers would only have to adhere to the destination country legislation for their products?

Under what circumstances would the Minister seek to amend legislation to instead permit per-batch testing, labelling, and the removal of the repeatability trials?

How many dried flower products did the Minister expect to have been available for patients after 2 or 3 years?

How many extract / oil-based products did the Minister expect to have been available for patients after 2 or 3 years?

I do not accept the premise of these parts of your request. While the Act allows New Zealanders to ask Ministers and government agencies for information, it is not a vehicle to engage in a debate with Ministers about the regulations on medicinal cannabis and cannabis products. There is no requirement under the Act for agencies to create new information, compile information they do not hold, respond to hypothetical questions, or provide or prove an opinion. The Act does not support requests where statements are put to agencies and Ministers for response, couched as a request for official information. Therefore, these parts of your request are refused under section 18(g)(i) of the Act on the grounds that the information is not held by me, and I do not consider it is held by any other agency subject to the Act.

Under section 28(3) of the Act, you have the right to ask the Ombudsman to review any decisions made under this request. The Ombudsman may be contacted by email at: info@ombudsman.parliament.nz or by calling 0800 802 602.

Yours sincerely

Hon Andrew Little
Minister of Health

Private Bag 18041, Parliament Buildings, Wellington 6160, New Zealand
+64 4 817 8707 | a.little@ministers.govt.nz | beehive.govt.nz