Office of Hon Peter Dunne

MP for Ohariu
Minister of Internal Affairs
Associate Minister of Health
Associate Minister of Conservation

23 AUG 2016

Mr Gregory Soar
mailto:fyi-request-4018-fbd0bb97@requests.fyi.org.nz

Ref: H201603024

Dear Mr Soar

Response to your request for information

Thank you for your request of 18 May 2016 to Hon Peseta Sam Lotu-liga, Associate Minister of Health, under the Official Information Act 1982 (the Act). You requested information relating to the reported statement about access to cannabis products, that:

> "We reiterate our strong commitment to improving access…by appropriately addressing barriers in this regard including legislation".

You have asked:

- if barriers to improving access to cannabis have been addressed
- about progress in terms of a review of the legislation
- if there has been a delay to any proposed legislative changes, the reason for the delay
- whether there will be a call for improved medical training to support easier access to cannabis products
- whether Sativex will be placed into Misuse of Drugs Regulations 22(2) to improve access to cannabis products.

Your request has been forwarded to me for response as access to cannabis-based products falls under my delegation as Associate Minister of Health.

A process already exists for the prescription of cannabis-based products if a patient's specialist considers it clinically appropriate. I have set out the process below, for your information.

Access to cannabis-based products
Ministerial approval of applications to prescribe cannabis is a requirement under the Misuse of Drugs legislation. Misuse of Drugs Regulation 22 requires a prescriber to obtain Ministerial approval to supply, prescribe and administer cannabis products.

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The Regulation 22 requirements are not specific to cannabis, they apply to a range of controlled drugs (Class A, B1, B2 and C1 with some exceptions, principally morphine).

Ministerial approval to prescribe products covered by Regulation 22 can be delegated to the Ministry of Health (the Ministry) and this has occurred for pharmaceutical grade products. As you will be aware, Sativex is the only pharmaceutical grade product that has been approved by Medsafe for use in New Zealand.

Approval for non-pharmaceutical grade cannabis-based products is not delegated to the Ministry. These approvals are considered by me, following evaluation of the application by Ministry officials and informed by their recommendations.

Recent consultation by the Ministry found that prescribers with experience in applying for approval to prescribe cannabis-based products consider the process sound and do not find the application process a barrier.

Pharmaceutical grade and non-pharmaceutical grade products
While the existing process allows access to both pharmaceutical and non-pharmaceutical grade cannabis products, pharmaceutical products are preferred by clinicians. This is because pharmaceutical grade products are manufactured to specified standards, have known composition (so dosages can be calculated with accuracy), are contaminant-free, and most importantly, have efficacy data to inform clinical decisions about prescribing.

The guidelines to assess applications to prescribe a non-pharmaceutical grade product are more rigorous than the guidelines to prescribe pharmaceutical grade products. This reflects the lack of authoritative quality and safety data and the lack of robust efficacy data for these products.

You can find out more about the guidelines to assess applications to prescribe on the Ministry's website (www.health.govt.nz) by searching 'prescribing cannabis-based products'.

Access to cannabis-based products: review of the legislation and current processes
We have already made progress in reviewing how controlled drugs are used for legitimate purposes. A need to review the Misuse of Drugs regulations, including Regulation 22, has been identified, to ensure that they are fit for purpose for current medical and pharmacy practice. The review is part of the National Drug Policy Action Plan and is expected to be completed by the end of the 2017/18 year.

The Ministry is currently reviewing the process that clinicians are required follow to obtain approval to prescribe Sativex. The aim of the review is to identify opportunities to streamline current requirements.

In addition, as noted above, the Ministry recently undertook external consultation on the guidelines used to support decisions on applications for Ministerial approval to import, prescribe and administer cannabis-based products.

The document outlining the key themes from this consultation is available on the Ministry's website on the *Changes to terminology around applications for cannabis-based products* page.

Sativex and Misuse of Drugs Regulation 22(2)

You have specifically asked whether Sativex will be added to Regulation 22(2) which would exempt it from the requirement for Ministerial approval to supply, prescribe and administer cannabis products. As noted above, the Misuse of Drugs Regulations will be reviewed as part of the National Drug Policy Action Plan. Specific amendments to the Regulations, such as the one you propose, will be considered as part of that review.

Medical training to prescribe cannabis products

The external consultation on the guidelines specifically asked about professional education and knowledge of cannabis products. Feedback from clinicians consulted was that medical specialities where there is early efficacy data for the use of cannabis products, such as neurology, pain management and palliative care, are aware of the current research. A number of medical organisations have developed guidelines on the use of cannabis. These guidelines are listed in Appendix 4 of the *External Consultation on Guidelines to Assess Applications for Ministerial Approval to Prescribe Cannabis-based Products* document, available on the Ministry's website.

The decision to use or trial a particular product is a clinical one. Clinicians are required professionally and ethically to make robust prescribing decisions based on an assessment of the risks and benefits of a particular product for each individual patient.

I am not releasing or withholding any documents under your request because there are no documents covered by it. Therefore I am refusing your request under section 18(e) of the Act as the documents alleged to contain the information requested do not exist. However, I trust this information above fulfils your information needs.

Yours sincerely

Hon Peter Dunne
Associate Minister of Health