MINISTRY OF HEALTH
MANATŪ HAUORA

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PO Box 5013
Wellington 6145
New Zealand
T+64 4 496 2000

13 April 2015

Mr Pete Hollier
fyi-request-2579-99c0c83c@requests.fyi.org.nz

Ref: H2001500915

Dear Mr Hollier

Response to your request for official information

Thank you for your request of 13 March 2015 under the Official Information Act 1982 (the Act) for information about medicinal cannabis. You requested:

- Copies of all correspondence between the Ministry of Health, the Prime Minister, the Minister of Justice, the Minister of Health, and both Associate Ministers of Health with regards to the recent review of medicinal cannabis.
- All correspondence covering the initiation, reasoning, outline and objectives for the review of medical cannabis between the above mentioned parties.
- Copies of all correspondence between the above parties which occurred during the completion of the review of medical cannabis.
- Copies of correspondence between the above mentioned parties which occurred during a review of the medical marijuana review results and subsequent discussions regarding this topic.

The Ministry does not hold any correspondence between the Prime Minister and the Minister of Justice concerning the recent review of medicinal cannabis. Please find attached the documents that relate to your request, which are listed in the table below.

Title of document	Date
Email - Briefing – Medicinal Cannabis	28 January 2015
Email - Medicinal Cannabis Meeting 11am 5 Feb, Lev 11 Bowen House	3 February 2015
Health Report – HR20150106 Medicinal Cannabis	16 February 2015
Aide Memoire - Medicinal Cannabis - talking points 20150197	27 February 2015
Email - Signed HR	17 February 2015
Email - Medicinal cannabis – comments from Minister Coleman	5 March 2015

I have decided to withhold information in Health Report (16 February) HR20150106 under:

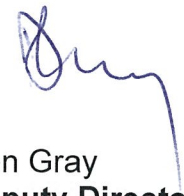
- s9(2)(a) of the Act to protect the privacy of natural persons
- s9(f)(iv) of the Act to maintain the constitutional conventions for the time being which protect the confidentiality of advice tendered by Ministers of the Crown and officials.

I have decided to withhold information in one email titled 'Medicinal cannabis – comments from Minister Coleman' (5 March 2015) under:

- s9(f)(iv) of the Act to maintain the constitutional conventions for the time being which protect the confidentiality of advice tendered by Ministers of the Crown and officials.

I trust this information fulfils your request. You have the right, under section 28 of the Act, to ask the Ombudsman to review my decision to withhold information under this request.

Yours sincerely



Don Gray
Deputy Director-General
Policy Business Unit

Encl:

From: Michael Johnson <Michael.Johnson@parliament.govt.nz>
To: Briefings <Briefings@moh.govt.nz>,
Cc: Stella Li <Stella.Li@parliament.govt.nz>, Adrian Portis <Adrian.Portis@parliament.govt.nz>, Don Mackie <Don_Mackie@moh.govt.nz>, "stewart_jessamine@moh.govt.nz" <stewart_jessamine@moh.govt.nz>
Date: 28/01/2015 12:43 p.m.
Subject: Briefing - Medicinal Cannabis

Hi

Can I please request a briefing for Minister Coleman and Dunne please on our current position with regards to medicinal cannabis, potential next steps and developments. I think we should also include some background on international context.

I am aware that Minister Dunne is considering a roundtable discussion with Ministers and relevant agencies (Medsafe and Pharmac, others?) following a meeting he had yesterday (Adrian can fill in detail) and so this should be included as an option for Ministers to consider.

Timeline for this please is two weeks

Michael.

Michael Johnson I Senior Advisor - Health I Office of the Hon Dr Jonathan Coleman
Minister of Health, Minister for Sport and Recreation
6.4 Beehive, Parliament Buildings, Private Bag 18041, Wellington 6160, New Zealand
T: 04 817 9860 I M: 021 870 190 I E: michael.johnson@parliament.govt.nz

Sent by:
Adrian.Portis@parliament.govt.nz

03/02/2015 12:45 p.m.

To: "Hannah_Cameron@moh.govt.nz" <Hannah_Cameron@moh.govt.nz>, "stewart_jessamine@moh.govt.nz" <stewart_jessamine@moh.govt.nz>, "jenny.langton@pharmac.govt.nz" <jenny.langton@pharmac.govt.nz>,
cc: Michael Johnson <Michael.Johnson@parliament.govt.nz>,
bcc:

Subject: Medicinal Cannabis Meeting 11am 5 Feb, Lev 11 Bowen House

Hi All

Just confirming this meeting.

Attending will be Medsafe, PHARMAC and policy officials.

Minister Dunne has decided that any relevant issues on this topic should be discussed separately with NZMA.

Suggest discussion (and briefing) be divided in two:
medicines (eg Sativex) processes and whether there is scope for making these less onerous for consumers and health professionals.
therapeutic (eg plant material and oil) uses, overseas approaches, evidence of efficacy and delivery mechanisms (eg smoking, ingesting, vaporisors).

Ministers have noted concerns that NZ may be falling behind in recognising health benefits of cannabis derived products, that those with legitimate claims to Sativex (and future similar products) are not getting access.
If the legal status of cannabis has meant market-driven development has been hindered to-date – if so is this an area where the government should play more of a role (as per the Law Commission's rec 10.140)?

Thanks
Adrian

Adrian Portis | Private Secretary - Health
Office of Hon Peter Dunne | Associate Minister of Health
Tel: DDI 04 817 6727 | Mobile: 021 413 072

Sent by:
Michael.Johnson@parliament.govt.nz

17/02/2015 09:18 a.m.

To: Paula Martin <Paula_Martin@moh.govt.nz>, "hannah_cameron@moh.govt.nz" <hannah_cameron@moh.govt.nz>,
cc: Adrian Portis <Adrian.Portis@parliament.govt.nz>, Stewart Jessamine <stewart_jessamine@moh.govt.nz>,
bcc:

Subject: Signed HR

Hi

Signed report with Minister Coleman's comments.

So the report to Ministers in June obviously very important.

My only other question is do we have a standard set of simple talking points for Ministers on the subject and current position

Cheers

Michael

Michael Johnson I Senior Advisor - Health I Office of the Hon Dr Jonathan Coleman
Minister of Health, Minister for Sport and Recreation
6.4 Beehive, Parliament Buildings, Private Bag 18041, Wellington 6160, New Zealand
T: 04 817 9860 I M: 021 870 190 I E: michael.johnson@parliament.govt.nz

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17022015091427-0001.pdf

Sent by:
Michael.Johnson@parliament.govt.nz

05/03/2015 08:07 a.m.

To: "hannah_cameron@moh.govt.nz" <hannah_cameron@moh.govt.nz>,
cc: Paula Martin <Paula_Martin@moh.govt.nz>, Don Mackie <Don_Mackie@moh.govt.nz>, Adrian Portis <Adrian.Portis@parliament.govt.nz>,
bcc:

Subject: Briefing

Hi

Please see Minister's comments re NSW

Cheers

Michael

Michael Johnson I Senior Advisor - Health I Office of the Hon Dr Jonathan Coleman
Minister of Health, Minister for Sport and Recreation
6.4 Beehive, Parliament Buildings, Private Bag 18041, Wellington 6160, New Zealand
T: 04 817 9860 I M: 021 870 190 I E: michael.johnson@parliament.govt.nz

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MINISTRY OF HEALTH
MANATŪ HAUORA

1 6 FEB 2015
DISPATCHED

Health Report number: 20150106
File number: AD10-05-1
Action required by: routine

Medicinal Cannabis

To:	Hon Dr Jonathan Coleman (Minister of Health)
Copy to:	Hon Peter Dunne (Associate Minister of Health)

Purpose

This paper responds to your request for a briefing on medicinal cannabis, international developments and possible next steps.

Key points

- Medicinal cannabis means one of two things: a pharmaceutical grade cannabinoid medicine; or an unprocessed or partially-processed cannabis product (eg. leaf cannabis) used for medicinal purposes.
- New Zealand regulates medicinal cannabis products as medicines and requires robust evidence of safety and efficacy. To date the only cannabinoid medicine available in New Zealand is Sativex. Approval to prescribe Sativex has been given for 48 patients.
- Of the patients who have been prescribed Sativex, two patients have been funded by ACC and the remainder are self-funding. Sativex is not currently funded by PHARMAC and costs approximately $1000 per month per patient.
- It is difficult to quantify the level of unmet need for access to Sativex by patients who would clinically benefit. Some patients whose prescribers have approval to prescribe Sativex have not filled the prescription it is likely that other patients' prescribers have not even applied due to the cost of the drug, and the administrative burden.
- Despite the lack of robust clinical data and evidence of patient benefit a number of jurisdictions permit personal use of unprocessed or partially-processed cannabis products on compassionate grounds.
- The Australian states of New South Wales and Victoria have announced initiatives which signal a move towards permitting personal use of unprocessed or partially-processed cannabis products for particular patient groups such as, adults with a terminal illness or AIDS.
- The Ministry's project to review legitimate uses of controlled drugs will review the current regulation of controlled drug therapies, potentially including cannabis-based medicines.

Contacts
Paula Martin, Acting DDG, Policy Business Unit 021 825 691
Hannah Cameron, Manager, Sector & Services Policy 021 783 574

Paula Martin
Acting Deputy Director-General
Policy Business Unit

Minister's signature

Date: 4.2.15.

Minister's feedback on quality of report

Very poor (1)	Poor (2)	Neutral (3)	Good (4)	Very good (5)

Medicinal Cannabis

1. There are two approaches for regulation of cannabis products for medicinal purposes. The first is the approved medicines route where safety and efficacy standards are required, as for any pharmaceutical product.

2. A second approach is to permit personal use of unprocessed or partially-processed cannabis products (eg. leaf cannabis), for people with particular medical conditions. Unprocessed or partially-processed cannabis products do not meet the approved medicines requirements because of the lack of clinical data showing safety and efficacy, and the challenges with controlling the dose or potency.

3. Government policy is that the use of unprocessed or partially-processed cannabis is not permitted. Only a cannabinoid pharmaceutical such as Sativex could be approved for therapeutic use. This is consistent with the approach in the United Kingdom.

Approved medicines route

4. Approval and access to controlled drug products in New Zealand has three aspects.

   a. *Approval of the medicine by Medsafe.* This involves assessment of the safety and efficacy of medicines and compliance with a quality manufacturing process. Medicines are approved for a particular set of indications, but for many drugs there are other recognised indications not applied for in New Zealand. Controlled drug products require licences for import and supply (to protect the supply chain from diversion for illicit uses).

   b. *A prescriber who has the ability to prescribe the medicine.* Some controlled drugs require Ministerial approval prior to a prescription being written. For some drugs, a general permission has been issued to prescribe under certain conditions for example, pseudoephedrine can be prescribed by medical practitioners.

   c. *Funding* of the medicine via PHARMAC, ACC or privately by the individual patient.

Sativex

5. There is currently a very limited range of cannabinoid medicines being produced by pharmaceutical companies. To date Sativex, a medicine which contains a fixed combination of two of the active ingredients derived from cannabis, is the only approved cannabinoid medicine available in New Zealand. Sativex is approved to treat extreme spasticity linked with multiple sclerosis. Approval to prescribe Sativex is considered on a case-by-case basis.

6. To date, the Ministry has considered 49 applications to prescribe Sativex for multiple sclerosis and a variety of off-label conditions including chronic pain and Dravet Syndrome. Approval has been given for 48 patients. s 9 (2) (a)
   Of the 48 approvals given to date, two of patients have been funded by ACC, all other patients are self-funding their treatment.

7. Sativex is not currently funded by PHARMAC and costs approximately $1000 per month per patient. Under PHARMAC's Named Patient Pharmaceutical Assessment (NPPA) policy applications can be made for funded treatment for an individual, outside of the Schedule decision-making process. PHARMAC has received eight NPPA applications for Sativex, none of which have been successful.

NZ requirements for clinical trials of medicinal cannabis

8. The Ministry of Health is not aware of any application to date to run a medicinal cannabis clinical trial in New Zealand. The rules to conduct a clinical trial of a medicinal cannabis in New Zealand are the same as that required for any clinical trial but with the additional requirements of licences and Ministerial approval.

9. The Law Commission's 2011 Report on the Misuse of Drugs Act recommended that the Government consider undertaking or supporting clinical trials into the efficacy of raw cannabis for pain relief. The Government's 2011 response stated that while it didn't oppose genuine research it

didn't believe it was the Government's role to actively initiate or support such trials. This response does not however, preclude researchers applying for funding for medicinal cannabis clinical trials from the Health Research Council and the Marsden Fund, or other entities, such as NGOs.

Findings from overseas medicinal cannabis clinical trials

10. To date clinical trials of unprocessed or partially-processed cannabis products have suffered from limited participant numbers and lack of data on long term effects. Results can't be compared across trials because they have used different products in different patient groups.

11. A 2013 review of randomised controlled trials of any cannabis intervention in adults with HIV or AIDS, compared with placebo or with a known effective treatment concluded that evidence for the efficacy and safety of cannabis and cannabinoids is lacking.

12. A 2012 review of medicinal cannabis research supported by the Center for Medicinal Cannabis Research at the University of California, concluded that evidence is accumulating that cannabinoids may be useful medicine for certain indications.

Access to unprocessed or partially-processed medicinal cannabis products overseas

13. The countries that allow the medicinal use of unprocessed or partially-processed cannabis include: Belgium, the Czech Republic, The Netherlands, Israel, Canada, and 20 States of the United States of America and the District of Columbia. In some cases, such as The Netherlands and Israel, provision is made for the prescription of a pharmaceutical grade leaf cannabis product. In other countries, such as the USA, people are allowed to join "compassion clubs" to buy small quantities of raw leaf cannabis or to cultivate a small number of plants.

14. These jurisdictions have, in one form or other, decriminalised use of unprocessed or partially-processed cannabis products for personal medicinal use. There are different parameters around the range of health conditions where cannabis use is permitted and different regulatory approaches to production, supply and possession.

Australian developments

15. There have been a number of recent developments in Australia signalling a move towards permitting the medicinal use of unprocessed or partially-processed cannabis.

16. A 2013 New South Wales Senate General Purpose Standing Committee report into the use of cannabis for medicinal purposes recommended that access to cannabis pharmacotherapies continue via the current regulatory regime (ie. through the Therapeutics Goods Administration) and that further clinical trials be conducted. It also recommended changing the law to allow people with a terminal illness or AIDS to be able to possess and use small quantities of unprocessed or partially-processed cannabis without prosecution. To date, no amendment to the State legislation has occurred.

17. In late 2014 the NSW Government announced it would invest $A9m over the next five years to support medicinal cannabis clinical trials examining the benefits for children with severe drug-resistant epilepsy, terminally ill adults, and chemotherapy patients who suffer nausea and vomiting as a result of their treatment.

18. In December 2014 the Victorian Government asked the Victorian Law Reform Commission to review and report on options for changes to the *Drugs, Poisons and Controlled Substances Act 1981* and associated Regulations to allow people with terminal or life-threatening illnesses to be treated with medicinal cannabis. The Commission will report by August 2015.

Next steps

19. Despite the lack of clinical data showing efficacy for unprocessed or partially-processed cannabis products some population groups strongly believe that they are effective and that access should be permitted. Allowing personal possession and use for patients with severe medical conditions where conventional treatments are not effective or with terminal illness would be based primarily on compassionate grounds.

20. The challenge jurisdictions face when permitting medicinal use of unprocessed or partially-processed cannabis is to develop a regulatory regime for production, manufacture, sale and supply that is robust, workable for patients and health professionals and efficient to run. This is a particular issue in jurisdictions which choose to retain restrictions around personal supply and use of cannabis.

21. While the medicines approval process is appropriate for the pharmaceutical grade products some of the Misuse of Drugs Act provisions which limit the use of controlled drugs have been designed to restrict illicit use rather than allow a potential legitimate medicinal use.

S 9 (f)(iv)

END.

please keep me informed on developments in NSW & Victoria (see final bullet point)

Ministry of Health Aide Memoire

To:	Hon Dr Jonathan Coleman, Minister of Health
From:	Paula Martin, Acting Deputy Director-General, Policy Business Unit
Date:	27 February 2015 **Report number:** 20150197

Medicinal Cannabis – talking points

Purpose

1. This paper responds to your request following the briefing *Medicinal Cannabis* (HR 20150106) for a standard set of talking points.

Talking points

2. All cannabis products are classified as controlled drugs under the Misuse of Drugs Act 1975.
3. Medicinal cannabis refers to one of two things: a pharmaceutical grade cannabinoid medicine; or an unprocessed or partially-processed cannabis product (eg. leaf cannabis) used for medicinal purposes.
4. Pharmaceutical grade cannabinoid medicines follow the medicines approval route where safety and efficacy standards are required, as for any pharmaceutical product.
5. Government policy is that the use of unprocessed or partially-processed cannabis is not permitted.
6. Unprocessed or partially-processed cannabis products do not meet the approved medicines requirements because of the lack of clinical data showing safety and efficacy. To date clinical trials using these products have suffered from limited participant numbers and lack of data on long term effects.
7. The Government is not opposed to the trial and development of cannabis-based medicines if they can be shown to be safe and effective.
8. Processes are in place if a research institution or pharmaceutical company wants to conduct research or hold clinical trials on the effectiveness of a cannabinoid medicine.
9. Sativex, a mouth spray containing THC and cannabidiol, is the only cannabis preparation currently approved for use in New Zealand. Approval for Sativex to be prescribed is considered on a case-by case basis.
10. Some of the Misuse of Drugs Act 1975 provisions which limit the use of controlled drugs have been designed to restrict illicit use rather than allow legitimate medicinal use.
11. The Ministry is reviewing the controls on legitimate (therapeutic and industrial) use of controlled drugs within the Misuse of Drugs Act. This review will include the licensing, prescribing and classification of controlled drugs for legitimate purposes.
12. The timing of this project is intended to allow some or all of the changes to be progressed via the new regulatory framework for therapeutic products (which will replace the Medicines Act 1981). Legislation is expected to be introduced in 2016.

Factual notes

Sativex

- As at 15 February 2015, approval to prescribe Sativex has been given for 48 patients for multiple sclerosis and a variety of off-label conditions including chronic pain and Dravet Syndrome.

- Sativex is not currently funded by PHARMAC and costs approximately $1000 per month per patient.

International approaches to unprocessed or partially-processed cannabis products

- The countries that allow the medicinal use of unprocessed or partially-processed cannabis include: Belgium, the Czech Republic, the Netherlands, Israel, Canada, and 20 States of the United States and the District of Columbia.

- In late 2014 the New South Wales Government announced it would invest $A9m over the next five years to support medicinal cannabis clinical trials. In December 2014 the Victorian Government asked the Victorian Law Reform Commission to review and report on options for legislative change to allow people with terminal or life-threatening illnesses to be treated with unprocessed or partially-processed cannabis.

Contact person: Hannah Cameron, Manager, Sector & Services Policy, 021 783 574