Dear Doctor.

Application for Approval to Prescribe a Non-pharmaceutical Grade Medicinal Cannabis Product under Regulation 22 of the Misuse of Drugs Regulations 1977

Thank you for agreeing to complete this application for a medicinal cannabis product on behalf of our Greencross member. We have put together three documents for to assist you to successfully complete the Application process.

Please find attached:

Schedule 1: The formal application form as can be found on the MOH website.

Schedule 2: The rewritten application form for your ease, deleting the notes from the MOH.

Schedule 3: The precedent letter to attach to the Application answering the questions posed at Paragraph 5 of the formal MOH Application form.

This precedent letter is based on the successful Application letter from the CCDHB to the MOH in respect of Alex Renton.

In the absence of you or your patient having already researched the appropriate cannabis product you wish to prescribe, we suggest that you contact experienced medical practitioners in the USA or elsewhere to determine this. One cannabis specialist doctor who has been willing to offer consultations in this regard has been Dr Frankel from Greenbridge Medical Services, Santa Monica USA whose experience is over fifteen years. Details to arrange a consultation in this regard can be found here: http://www.greenbridgemed.com/contact-us/

Please do not hesitate to contact me if you have any queries.

Yours faithfully,

RMA Purchas
Solicitor
GreenCross NZ

rosie@greencross.org.nz

Schedule 1

Application for APPROVAL TO PRESCRIBE A NON-PHARMACEUTICAL GRADE MEDICINAL CANNABIS PRODUCT under Regulation 22 of the Misuse of Drugs Regulations 1977

A completed and signed copy of this form must be submitted for each application for Ministerial approval to prescribe a non-pharmaceutical grade medicinal cannabis product for a specified patient

IMPORTANT INFORMATION FOR APPLICANTS
Applications to prescribe non-pharmaceutical grade cannabis products are considered by the Minister on a case by case basis. Please review the criteria that guide the Minister in assessing applications listed on the Medicines Control section of the Ministry of Health website.

1. PRODUCT

Name of the product:

Do you have a Certificate of Analysis?

- ☐ No
- ☐ Yes – please attach details

Please attach any evidence of potential benefits of the use in the product in the condition(s) to be treated and known adverse effects.

2. PATIENT DETAILS

Full name of patient:

Full street address:

Date of Birth:

NHI Number:

NOTE: PATIENT INFORMED CONSENT
The patient should be advised that the use of the product is on a trial basis and if reassessment indicates no benefit, the treatment will be stopped.

The patient **must** sign the patient informed consent section below for this application to be valid. This indicates that the patient is willing to use a non-pharmaceutical grade product, that is, a product which has not been manufactured to the international standards required for medicines. In addition the product does not have consent for distribution as a medicine in New Zealand or in other countries. This means that the product has not been assessed by a government regulatory authority to determine that it is acceptably safe and effective as a medicne.

As this is a cannabis-based product, if the product is abused or diverted then the application and approval is no longer valid and future applications will be declined.

3. PATIENT INFORMED CONSENT

"I, the patient named above, am willing to use the product named in this application and I am aware that this product has not been manufactured to pharmaceutical grade nor has it been approved for distribution as a medicine in New Zealand. I have been fully informed of the potential dangers associated with its use. I am aware that if the product is abused or diverted then this application and approval is no longer valid and that future applications will be declined."

Signature of above named patient *Date*

4. APPLICANT DETAILS

NOTE: APPLICANT ELIGIBILTY AND POTENTIAL EXCLUSION CRITERIA
The application can be made by a specialist or the Chief Medical Officer of the District Health Board.

The patient history must be completed by a specialist who is managing the condition that the product is to treat. The specialist must be registered with the New Zealand Medical Council as a specialist in the scope of practice appropriate to the management of the condition to be treated.

Specialists appropriate to the specified condition are likely to be oncologists, neurologists, anaesthetists and palliative care specialists.

Health professionals with a documented history of abuse or diversion of controlled drugs, or who have had their rights to prescribe controlled drugs limited under the Misuse of Drugs Act 1975 may be ineligible to prescribe. The applicant should not have any previous complaints against them for drug or alcohol abuse, and Medicines Control (Ministry of Health) should have no outstanding investigations or concerns about their prescribing pattern of drugs of misuse.

Full name:

NZ Medical Council number:

Full practice address:

Phone: Fax: Email:

5. PATIENT HISTORY *(please note that the boxes expand as needed)*

5.1 Details of patient history:

5.2 Is the patient hospitalised?

- ☐ No
- ☐ Yes – please provide details:

5.3 Does the patient have any other medical conditions?

- ☐ No
- ☐ Yes – please provide details:

5.4 Have other standard treatment options been trialled in this patient and proven either ineffective in treating the condition and/or controlling symptoms?

- ☐ No
- ☐ Yes – please provide details:

NOTE: FAILURE OF CONVENTIONAL MEDICINES OR CURRENTLY AVAILABLE TREATMENTS
To be eligible for approval to prescribe a non-pharmaceutical grade cannabis product the patient **must** have trialled adequate doses of conventional treatments for the condition for appropriate periods of time without sufficient therapeutic benefit, or the standard treatments are not tolerated by the patient, or are contraindicated in the patient.

5.5 Is the use of a cannabis product contraindicated in this patient

- ☐ No
- ☐ Yes – please provide details of contraindication(s) and proposed patient management plan:

5.6 Is this patient taking any medicines known to interact with cannabis products?

- ☐ No
- ☐ Yes – please provide details of interaction(s) and proposed patient management plan:

5.7 Does this patient have a documented history of abuse or diversion of controlled drugs (see note below)?

- ☐ No
- ☐ Yes – please provide details of history and proposed patient management plan:

NOTE: HISTORY OF ABUSE OR DIVERSION
Approval may be declined if the patient has a documented history of abuse or diversion of controlled drugs, or in the event that during the course of treatment with cannabis product should such circumstance arise.

5.8 Please provide details of the proposed protocol for treatment cessation in the event of lack of efficacy, adverse reactions, or if abuse/diversion has been identified:

5.9 Please provide details of the proposed protocol for the disposal of unwanted or unused cannabis product:

6. ENDORSEMENT AND CONFIRMATION

I, the patient's specialist, and/or the Chief Medical Officer of the applicable District Health Board apply for Ministerial approval to use a non-pharmaceutical grade cannabis product in the above named patient and confirm that the information supplied is true and correct.

We have conducted an analysis of the potential risks and benefits of the non-pharmaceutical grade product in the above named patient and we consider the risk-benefit balance to be positive in this patient.

Signature of patient's specialist *Date*

Signature of Chief Medical Officer
of District Health Board (not mandatory
if signed by specialist) *Date*

Schedule 2

Application for
APPROVAL TO PRESCRIBE A NON-PHARMACEUTICAL GRADE MEDICINAL CANNABIS PRODUCT
under Regulation 22 of the Misuse of Drugs Regulations 1977

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1. PRODUCT

Name of the product**:**

Do you have a Certificate of Analysis?

- ☐ No
- ☐ Yes – please attach details

Please attach any evidence of potential benefits of the use in the product in the condition(s) to be treated and known adverse effects.

2. PATIENT DETAILS

Full name of patient: _____

Full street address: _____

_____

_____

_____

Date of Birth: _____

NHI Number: _____

3. PATIENT INFORMED CONSENT

"I, the patient named above, am willing to use the product named in this application and I am aware that this product has not been manufactured to pharmaceutical grade nor has it been approved for distribution as a medicine in New Zealand. I have been fully informed of the potential dangers associated with its use. I am aware that if the product is abused or diverted then this application and approval is no longer valid and that future applications will be declined."

_____ _____

Signature of above named patient *Date*

4. APPLICANT DETAILS

Full name of Specialist or
Chief Medical Officer of DHB: _____

NZ Medical Council number: _____

Full practice address: _____

_____

_____

_____

Phone: _____ Fax: _____

Email: _____

5. PATIENT HISTORY

5.1 Details of patient history: ***See attached letter***

5.2 Is the patient hospitalised?

- ☐ No
- ☐ Yes – please provide details: ***See attached letter***

5.3 Does the patient have any other medical conditions?

- ☐ No
- ☐ Yes – please provide details: ***See attached letter***

5.4 Have other standard treatment options been trialled in this patient and proven either ineffective in treating the condition and/or controlling symptoms?

- ☐ No
- ☐ Yes – please provide details: ***See attached letter***

5.5 Is the use of a cannabis product contraindicated in this patient

- ☐ No
- ☐ Yes – please provide details of contraindication(s) and proposed patient management plan: ***See attached letter***

5.6 Is this patient taking any medicines known to interact with cannabis products?

- ☐ No
- ☐ Yes – please provide details of interaction(s) and proposed patient management plan: ***See attached letter***

5.7 Does this patient have a documented history of abuse or diversion of controlled drugs (see note below)?

- ☐ No
- ☐ Yes – please provide details of history and proposed patient management plan: ***See attached letter***

5.8 Please provide details of the proposed protocol for treatment cessation in the event of lack of efficacy, adverse reactions, or if abuse/diversion has been identified: ***See attached letter***

5.9 Please provide details of the proposed protocol for the disposal of unwanted or unused cannabis product: ***See attached letter***

6. ENDORSEMENT AND CONFIRMATION

I, the patient's specialist, and/or the Chief Medical Officer of the applicable District Health Board apply for Ministerial approval to use a non-pharmaceutical grade cannabis product in the above named patient and confirm that the information supplied is true and correct.

We have conducted an analysis of the potential risks and benefits of the non-pharmaceutical grade product in the above named patient and we consider the risk-benefit balance to be positive in this patient.

_____ _____

Signature of patient's specialist *Date*

_____ _____

Signature of Chief Medical Officer *Date*

of District Health Board
(not mandatory if signed by specialist)

Schedule 3

[Applicant Sender's Details]

[date]

Dr Stewart Jessamine
Medsafe, Ministry of Health
PO Box 5013
WELLINGTON 6145

Stewart_Jessamine@MOH.govt.nz

Dear Dr Jessamine

Re: Application for [cannabis product being applied for] for [Name and address of patient]

This document is the attached letter referred to in the Application for Approval to Prescribe a Non-pharmaceutical Grade Medicinal Cannabis Product under Regulation 22 of the Misuse of Drugs Regulations 1977 to which this letter is annexed.

I would be grateful if the Ministry of Health would consider allowing the prescription of a [cannabidiol / tetrahydrocannabinol] agent for this patient.

[Patient name] is [age] and suffers from [medical condition(s)].

[Provide details and history of his medical condition].

[example for seizures:
Patient name is x years old who presented to [clinic/hospital] with recurrent seizures. He quickly developed refractory status epilepticus and thereafter super-refractory status epilepticus and has a working diagnosis of New Onset Refractory Status Epilepticus (NORSE). This is a syndromic description of refractory status epilepticus pattern occurring after what appears to be a reasonably non-specific illness. The aetiology of this illness is poorly understood but is thought most likely to be related to an autoimmune mechanism. He has received multiple treatment attempts with various anti-epileptic drugs including [details]. He has been on the ketogenic diet for [time] in an attempt to control his seizures. Most recently we have tried treatment with ketamine but have had only limited success and unfortunately [patient] has returned to his refractory seizure pattern. Despite the best efforts of our

neurological services we have been unable to establish any control over his refractory multifocal seizures.]

The other standard treatment options been trialled in this patient and proven either ineffective in treating the condition and/or controlling symptoms. [Detail treatments tried.]

[Patient name] [and his family] hold strong beliefs in the value of complementary healing mechanisms. They have researched cannabidiol /tetrahydrocannbinols extensively and believe that these may be of use in [patient name's] situation. You will be aware there is increasing support for cannabis derivatives for the treatment of [medical condition].

[Although the evidence for this is primarily [anecdotal/limited to small groups of individuals or animal studies] there is more interest in this following the widespread use of medicinal cannabis in certain states of the United States of America, Canada, Israel and Europe.]

The trend in the literature for [medical condition] is that these agents have a role to play in the treatment of [medical condition]. There is some evidence to support a role for cannabidiol / tetrahydrocannabinols in [medical condition] in animal models. The medical literature outlining their benefits in treating [medical condition] in humans is [cite].

We have consulted widely with specialists within the DHB, elsewhere in New Zealand and internationally. The consensus is that with all the agents that have been trialled and the lack of success, an alternative and unproven treatment as requested by the family could be considered. We believe that it is not likely to cause harm and in the current clinical situation we think it could be considered as a theoretical potential adjunct to the current treatment.

The medical ethics is that given no treatment has yet been successful in a sustained manner, the use of this medication in other similar medical conditions, and given the patient's strongly held beliefs, the treatment could be considered ethically appropriate. This is solely in the current scenario where more conventional therapies are proving ineffective and not to any wider use of cannabis derivatives in other clinical settings or other complementary therapies in general.

[Patient's name] and family are aware that the treatment is not a standard medically recognised treatment for [medical condition] and it is their wish to pursue this option. They are aware that if the medicine was to be administered that it would fall outside of the normal parameters of treatment of [medical condition] and they are happy to sign documentation to that effect.

The agent that is considered is called [name of medicine]. This is a preparation of cannabidiol and tetrahydrocannabinol. There are a number of distributors in the [United States] and elsewhere. The agents have a total CBD composition of about [%] with a percentage of THC of [%]. The dosing is described as [ ] ml [ ] times per day administered [describe how].

We have no reason to believe that this would interfere with any other aspect of [patient's] care. We acknowledge that this is not considered standard treatment in New Zealand however other treatments are proving ineffective. [Patient] [Patient's family] have given this careful and considered thought and given the probable lack of harm from their use, we support the consideration of this treatment for [patient's] medical condition.

The proposed protocol for the disposal of unwanted or unused cannabis product is that [Patient name] will return all unwanted or unused cannabis product to this medical practice for disposal in the ordinary accepted methods, being [provide details].

I would be happy to provide any clinical details or further questions that arise out of this directly and would be grateful for your urgent consideration.

Yours faithfully,

[Specialist's name]