

Brief for Ministerial Correspondence

RM folder reference No:	C-ECTF-18/173 C-ECTF-18/659
Division:	Prevention
File Ref No:	

SUBJECT: Streamlining access to medicinal cannabis

Key Issues

1. On 22 December 2017, the Honourable Greg Hunt MP, Commonwealth Minister for Health, wrote to the Honourable Steven Miles MP, Minister for Health and Minister for Ambulance Services, regarding the release of the national guidance documents for medicinal cannabis.
2. On 22 January 2018, Minister Hunt wrote to the Minister for Health and Minister for Ambulance Services regarding streamlining access to medicinal cannabis.
3. The letters announce the release of the national guidance documents in December 2017, and request ongoing engagement from the State to work with the Commonwealth Department to streamline Commonwealth and State application processes.
4. A key suggestion by the Commonwealth is to develop a single application form nationally. This would require some legal advice with regard to issues of patient confidentiality and sharing of information between the Commonwealth and State Governments.
5. The letter suggests that there is duplication in the process and that the application review undertaken and approval given by the Commonwealth may be enough in regard to determining suitability for access.
6. The second letter concludes by suggesting that at the April 2018 COAG Health Council meeting a formal announcement is made regarding overall progress in this area.
7.
8. The Commonwealth has written to all other States and Territories about this matter.
9. On the 2 March 2018 the Honourable Greg Hunt MP, Commonwealth Minister for Health, and the NSW Minister for Health Mr Brad Hazzard jointly announced that NSW would recognise the TGA's clinical approval for medicinal cannabis for NSW patients, effectively meaning the TGA is the primary decision maker for approvals in NSW.

Results of Consultation

10.
11. Commonwealth and State officers are in frequent communication with regards to streamlining the system through the working group process.

Resource Implications (including Financial)

12. Nil

Background

13. The *Public Health (Medicinal Cannabis) Act 2016* took effect on 1 March 2017.
14. The access to medicinal cannabis is an ongoing concern for a number of parties, particularly patients, consumer groups, advocates, prescribers, Queensland Health and the Commonwealth.
15.

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Attachments

16. Attachment 1: Letter of response to the Honourable Greg Hunt MP

Department Contact Officer

Dr Jeannette Young, Chief Health Officer and Deputy Director-General, Prevention Division, on telephone 3708 5190 or mobile

RTI Release

RM folder reference No:	C-ECTF-18/173 C-ECTF-18/659
Division:	Prevention
File Ref No:	

Author	Cleared by: (SD/Dir)	Content verified by: (CEO/DDG/Div Head)
Gregory Perry	Dorothy Vicenzino	Dr Jeannette Young
Director	Executive Director	Chief Health Officer and Deputy Director-General
Medicinal Cannabis Unit	Chief Medical Officer and Healthcare Regulation Branch	Prevention Division
3708 5316	3708 5245	3708 5190
Updated 6 March 2018	Xx March 2018	Xx March 2018

RTI Released

SharePoint Ref No: 18

Registration No.: C-ECTF-_____

RESPONSE:

- Minister
 - Dept. Contact required
- Action Direct
- Action Direct - Minister's Office to approve response
- DLO to action
- Hospital and Health Service
 - (HHS to provide Minister's office copy of response or details of response)
- No Response Required (Note and File)

Policy Advisor: _____

Name: Greg Hunt

Issue: Guidance documents for medicinal cannabis

- BRIEFING NOTE REQUIRED
 - Background information only

Previous Dept Ref #: _____

URGENT

INSTRUCTIONS:

CHO please advise if this response should be incorporated into C-ECTF-17/3094 or if a separate response is required.

RTI@ESU

Reviewed by: _____

Date: _____

Sent to ESU by: Larven Bae

Date: 8/1/18

ESU ONLY

Doc Type: MINMP

Brief Template: 5

Letter Template: C

Action Officer: CND Due Date: _____

Opening Paragraph: _____



**The Hon Greg Hunt MP
Minister for Health**

1 2 JAN 2018

Ref No: MC17-02799

The Hon Dr Steven Miles MP
Minister for Health and Minister for Ambulance Services
PO Box 48
BRISBANE QLD 4001

22 DEC 2017

Dear Minister

As you know, some challenges can exist for prescribers and patients in accessing evidence-based advice around the efficacy of medicinal cannabis. In late 2016 my Department commissioned a group of universities (University of Sydney, University of New South Wales, and University of Queensland) to review the existing evidence in the medical literature for the use of medicinal cannabis in various conditions. This work was largely funded by the Commonwealth Department of Health but with co-investment from three state governments, which I gratefully acknowledge.

Based on these reviews, an overview document and five condition-specific guidance documents have been developed to assist health care professionals in prescribing medical cannabis products to treat patients. These include guidance documents for palliative care, multiple sclerosis, nausea and vomiting (particularly after chemotherapy), and pain conditions and epilepsy. In addition, a plain English brochure which summarises the current evidence for medicinal cannabis for consumer and patient groups has been developed.

The materials are available on the Therapeutic Goods Administration's website at: www.tga.gov.au/access-medicinal-cannabis-products

Production of these documents was informed by five face-to-face workshops consisting of 30-60 clinicians, patient representatives and state and territory health department representatives. A range of organisations from across Australia were involved in these workshops which directed the drafting of the documents, including:

- 18 patient and consumer representative groups
- all state and territory health departments
- 15 health care professional organisations
- clinical staff from 29 hospitals and health care systems
- 14 outpatient or primary health networks.

A drafting group for each guidance document was derived from volunteers at each workshop. I thank you for your jurisdiction's participation in the process. They have also been reviewed and endorsed by the Australian Advisory Council for the Medicinal Use of Cannabis.

The documents will be used to educate and inform healthcare professionals who are interested in medicinal cannabis as a treatment option for their patients. The guidance documents outline the evidence base as it stands and will be updated into the future as more evidence is established through clinical trials and research. However, I must emphasise the documents have no status in law – that is, they are for purposes of advice only.

Overall, the advice in the guidance documents is that there are a number of areas where cannabis products have been shown to have some efficacy, such as in certain paediatric epilepsies, management of spasticity in multiple sclerosis and reduction of neuropathic (nerve) pain in some patients.

It is anticipated that there will be some disagreement with the recommendations in the various guidance documents from some stakeholders. These stakeholders may either feel they are “anti-medicinal cannabis” or alternatively may provide undue support for the use of medicinal cannabis products. Ultimately, the guidances are based on the facts and to support the patient access pathways available to treating doctors.

There are a significant number of clinical trials currently underway both within Australia and globally using medicinal cannabis products. It is planned that the guidance documents will be updated during 2018 as more evidence from these trials becomes available.

My enduring focus is to ensure that treating doctors have the most up-to-date evidence on the efficacy of medicinal cannabis products to ensure they can have confidence to treat the patients they deem may benefit from its use, and critically, to ensure patient safety.

Yours sincerely



Greg Hunt

RTI Released



Hon Steven Miles MP
Minister for Health and
Minister for Ambulance Services

1 William Street Brisbane Qld 4000
GPO Box 48 Brisbane
Queensland 4001 Australia
Telephone +61 7 3035 6100
Facsimile +61 7 3220 6231

C-ECTF-18/173

The Honourable Greg Hunt MP
Minister for Health and Minister for Sport
PO Box 6022
House of Representatives
Parliament House
CANBERRA ACT 2600

Email: Greg.Hunt.MP@aph.gov.au

Dear Minister

Thank you for your correspondence in relation to the release of the national guidance documents for medicinal cannabis and regarding timely access to medicinal cannabis and streamlining Commonwealth and State application processes

The national guidance documents are a great step forward to help doctors, pharmacists and patients gain a better understanding of the potential uses of medicinal cannabis and assist to integrate medicinal cannabis into the Australian health system. These documents are an excellent beginning and will assist doctors who are interested in utilising medicinal cannabis as a treatment option. This resource is a necessary step to develop nationally consistent education and training for doctors and pharmacists.

I understand that this is an ongoing process and as new evidence comes to light, it will be included in regular updates in the guidance documents. This will ensure that the guidance remains a relevant source of truth that can be relied upon. Queensland produced its own guidance documents as part of the development of the *Public Health (Medicinal Cannabis) Act 2016*. The Queensland Department of Health is in the process of ensuring that the Queensland document reflects the national guidance.

In the time that I have been the Minister for Health and responsible for this initiative in Queensland, I have become aware of the many issues that cause delays in delivering access to these products in Queensland and the frustration these delays cause patients.

I am advised that the Queensland Department of Health will continue to work closely with the Therapeutic Goods Administration and the Office of Drug Control and other States to improve the appropriate access for patients to medicinal cannabis, as prescribed by their treating doctor. I agree that the major impediment at this time is the overall reluctance by doctors to prescribe, as the supporting evidence of the efficacy of medicinal cannabis as a valid treatment option for patients is small. This reluctance may be exacerbated by the application processes required to apply for access to unregistered medicinal cannabis products for patients.

I support work to be undertaken to reduce red tape and to reduce as much of the duplication of applications as possible. I have requested the Queensland Department of Health provide advice on any possible improvements Queensland can put in place to reduce administrative burden on medical officers who wish to prescribe medicinal cannabis for their patients. As you are aware, the TGA and Queensland Health are working on the proposed Smartform to ensure only one application form is required.

Irrelevant information

Thank you again for bringing this matter to my attention. Should your officers require a specific contact for any further information in relation to this matter, I have arranged for Dr Jeannette Young, Chief Health Officer and Deputy Director-General, Prevention Division, on telephone (07) 3708 5190, to be available to assist.

Yours sincerely

STEVEN MILES MP
Minister for Health
Minister for Ambulance Services

RTI Release

Prepared by: Gregory Perry
Director
Medicinal Cannabis Unit
3708 5316
24 January 2018
Edited 15 February 2018
Edited 6 March 2018

Submitted through: Dorothy Vicenzino
Executive Director
Chief Medical Officer and Healthcare Regulation Branch
3708 5245
16 February 2018

Cleared by: Dr Jeannette Young
Chief Health Officer and Deputy Director-General
Prevention Division
3708 5190
19 February 2018

Cleared by: Michael Walsh
Director-General
Queensland Health

RTI Release

Gregory Perry

From: Gregory Perry
Sent: Tuesday, 13 March 2018 6:15 PM
To:
Cc:
Subject:

Pleasure look forward to getting it done

Greg

Sent from my iPhone

On 13 Mar 2018, at 5:01 pm, wrote:

Thanks for the prompt response Greg! Extremely helpful.

Kind regards

Experimental Products Section
Pharmacovigilance and Special Access Branch
<image001.png>
Therapeutic Goods Administration
Health Products Regulation Group
Australian Government Department of Health

T:

Location: Symonston GD-47

PO Box 100, Woden ACT 2606, Australia

This response is general information given to you without prejudice; it is not binding on the TGA and you should get your own independent legal advice to ensure that all of the legislative requirements are met.

From: Gregory Perry [mailto:Gregory.Perry@health.qld.gov.au]
Sent: Tuesday, 13 March 2018 5:46 PM
To:
Subject: RE: Medicinal Cannabis - Online application portal - Application form requirements [SEC=UNCLASSIFIED]

Hi and team – please see my responses below in red

Thanks

1. The legislative and regulatory provisions that relate to the SAS prescribe that another health practitioner is able to submit a SAS application/notification **on behalf of** the prescriber (i.e. to undertake the administrative task of completing the application and submitting this to the TGA). Given the system will also provide the relevant information to QLD Health upon a submission being made in the system, will QLD Health accept an application that has been

submitted by a health practitioner that is not the prescriber of the medicinal cannabis product?

Hadn't thought about this before, should be ok - but the declaration and consent are an issue – its best the applicant is the prescriber from our perspective.

2. Both PCPs and SPPs are required to submit a *Notification of Medicinal Cannabis Management Plan* at the time they notify/apply to QLD Health (please correct me if I have misinterpreted this). Upon review of the data contained within the separate medicinal cannabis management plan form, we feel it would be appropriate and more streamlined to also collect this information through the online system as part of the original application/notification (rather than requiring the prescriber to complete and submit a separate document). I note that there appears to be a high level of duplication between the *Application for a Medicinal Cannabis Approval – Medical Practitioner* and the *Notification of Medicinal Cannabis Management Plan* forms relating to the dispensing pharmacy, hence the suggestion to capture these as part of the initial submission. Would this be an acceptable approach?

The MCMP is only required if the doctor is going to store product – this is unlikely – suggest we leave this out and treat it separately. So far no doctor is showing any interest in doing this

3. Section 5 (*health condition requiring treatment with medicinal cannabis*) currently requests a breakdown of information relating to the diagnosis; symptoms/condition being treated; present and past therapies etc. As part of the TGA's requirements under the SAS, prescribers are asked to provide a clinical justification for the use of the unapproved product in line with the patient's condition. We propose that, rather than providing 7 separate fields to capture this information (as is the case currently with the QLD Health application form), to capture this information in a single field titled 'Clinical justification for use of the product'. If amenable to this proposal, we could include explanatory text to accompany this fields which references the nature of the information requested by QLD Health (i.e. "Please provide details of the diagnosis, symptoms, and present or past therapies including reasons for failure etc")

Your suggestion is fine by us

From: [REDACTED]
Sent: Tuesday, 13 March 2018 2:23 PM
To: Gregory Perry
Cc: [REDACTED]
Subject: RE: Medicinal Cannabis - Online application portal - Application form requirements [SEC=UNCLASSIFIED]

Hi Greg

Thanks for participating in Friday's teleconference with the other state and territory representatives. As we discussed, the incorporation of state and territory requirements within the Special Access Scheme (SAS) online system has been supported by the majority of the representatives. Given this support, I am now working closely with the development team to document the finer details that apply to medicinal cannabis products being prescribed in each state and territory and ensuring the system captures the required information as part of the respective application processes. We will be sure to factor in the differences between the information required of a Patient Class Prescriber (PCP) and a Single Patient Prescriber (SPP).

I have reviewed QLD Health's *Application for a Medicinal Cannabis Approval – Medical Practitioner* form which you kindly provided last week and would appreciate your advice on the following before we commence development work:

1. The legislative and regulatory provisions that relate to the SAS prescribe that another health practitioner is able to submit a SAS application/notification **on behalf of** the prescriber (i.e. to undertake the administrative task of completing the application and submitting this to

the TGA). Given the system will also provide the relevant information to QLD Health upon a submission being made in the system, will QLD Health accept an application that has been submitted by a health practitioner that is not the prescriber of the medicinal cannabis product?

2. Both PCPs and SPPs are required to submit a *Notification of Medicinal Cannabis Management Plan* at the time they notify/apply to QLD Health (please correct me if I have misinterpreted this). Upon review of the data contained within the separate medicinal cannabis management plan form, we feel it would be appropriate and more streamlined to also collect this information through the online system as part of the original application/notification (rather than requiring the prescriber to complete and submit a separate document). I note that there appears to be a high level of duplication between the *Application for a Medicinal Cannabis Approval – Medical Practitioner* and the *Notification of Medicinal Cannabis Management Plan* forms relating to the dispensing pharmacy, hence the suggestion to capture these as part of the initial submission. Would this be an acceptable approach?
3. Section 5 (*health condition requiring treatment with medicinal cannabis*) currently requests a breakdown of information relating to the diagnosis; symptoms/condition being treated; present and past therapies etc. As part of the TGA's requirements under the SAS, prescribers are asked to provide a clinical justification for the use of the unapproved product in line with the patient's condition. We propose that, rather than providing 7 separate fields to capture this information (as is the case currently with the QLD Health application form), to capture this information in a single field titled 'Clinical justification for use of the product'. If amenable to this proposal, we could include explanatory text to accompany this fields which references the nature of the information requested by QLD Health (i.e. "Please provide details of the diagnosis, symptoms, and present or past therapies including reasons for failure etc").

Please note I have attached the aforementioned application form to this email with comments for your input. Please do not hesitate to contact me if you have any questions. I look forward to hearing from you.

Kind regards

[Redacted]

[Redacted]

Experimental Products Section
Pharmacovigilance and Special Access Branch
<image001.png>
Therapeutic Goods Administration
Health Products Regulation Group
Australian Government Department of Health
T: [Redacted] | E: [Redacted]
Location: Symonston GD-47

PO Box 100, Woden ACT 2606, Australia

This response is general information given to you without prejudice; it is not binding on the TGA and you should get your own independent legal advice to ensure that all of the legislative requirements are met.

From: Gregory Perry [mailto:Gregory.Perry@health.qld.gov.au]
Sent: Tuesday, 6 March 2018 9:14 AM
To: [Redacted]

Subject: RE: Medicinal Cannabis - Online application portal - Application form requirements
[SEC=UNCLASSIFIED]

Thanks

greg

From:
Sent: Tuesday, 6 March 2018 6:09 AM
To: Gregory Perry
Cc: MCTeam
Subject: RE: Medicinal Cannabis - Online application portal - Application form requirements
[SEC=UNCLASSIFIED]

Good Morning Greg

Thanks for providing this information. As you've suggested, we'll be sure to take this into consideration once an agreed approach has been reached between the TGA and states/territories.

For now, I will feed this back to the development team to consider (noting that we are still undertaking a scoping exercise to determine whether the integration of this functionality will suit all the states and territories). I trust that the teleconference on Friday will serve as a good opportunity to further discuss prospective solutions.

Look forward to speaking with you then.

Kind regards

Experimental Products Section
Pharmacovigilance and Special Access Branch
<image001.png>
Therapeutic Goods Administration
Health Products Regulation Group
Australian Government Department of Health
T: | E:
Location: Symonston GD-47

PO Box 100, Woden ACT 2606, Australia

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From: Gregory Perry [mailto:Gregory.Perry@health.qld.gov.au]
Sent: Monday, 5 March 2018 10:35 AM
To:
Cc: MCTeam
Subject: RE: Medicinal Cannabis - Online application portal - Application form requirements
[SEC=UNCLASSIFIED]

I did think of another issue over the weekend

Qld has 2 categories of prescribers Patient class prescribers (PCP) and single patient prescribers (SPP).

PCP's do not require a Qld approval only a notification within 7 days of prescribing. Attached info

So on your application – we need to flag early that PCP's need TGA approval but can skip the Qld application requirements.

Happy to discuss

Greg

<image002.gif>

Gregory Perry

Director
Medicinal Cannabis Unit
Chief Medical Officer and Healthcare Regulation Branch
Prevention Division, **Department of Health**

p: 07 3708 5316 m: [redacted]

a: Locked Bag 21, Fortitude Valley BC QLD 4006

w: Queensland Health | e: Gregory.Perry@health.qld.gov.au

<image003.jpg> <image004.jpg> <image005.jpg> <image006.jpg>

Queensland's health vision | *By 2026 Queenslanders will be among the healthiest people in the world.*

Queensland Health acknowledges the Traditional Owners of the land, and pays respect to Elders past, present and future.

From: [redacted]
Sent: Monday, 5 March 2018 9:25 AM
To: Gregory Perry
Cc: [redacted]; MCTeam
Subject: RE: Medicinal Cannabis - Online application portal - Application form requirements
[SEC=UNCLASSIFIED]

Good Morning Greg

That is good news! Thank you for following up on this so quickly.

Kind regards

[redacted]

[redacted]

Experimental Products Section
Pharmacovigilance and Special Access Branch
<image001.png>

Therapeutic Goods Administration
Health Products Regulation Group
Australian Government Department of Health

T: [redacted] | E: [redacted]

Location: Symonston GD-47

PO Box 100, Woden ACT 2606, Australia

This response is general information given to you without prejudice; it is not binding on the TGA and you should get your own independent legal advice to ensure that all of the legislative requirements are met.

From: Gregory Perry [mailto:Gregory.Perry@health.qld.gov.au]
Sent: Monday, 5 March 2018 10:18 AM
To: [redacted]
Cc: [redacted]; MCTeam
Subject: RE: Medicinal Cannabis - Online application portal - Application form requirements [SEC=UNCLASSIFIED]

Hi [redacted] have advice regarding the declaration signoff

Its good news we do not require a signature, so a tick box to accept the declaration will suffice.

greg

<image002.gif>

Gregory Perry

Director
Medicinal Cannabis Unit
Chief Medical Officer and Healthcare Regulation Branch
Prevention Division, **Department of Health**
p: 07 3708 5316 m: [redacted]
a: Locked Bag 21, Fortitude Valley BC QLD 4006
w: Queensland Health | e: Gregory.Perry@health.qld.gov.au
<image003.jpg> <image004.jpg> <image005.jpg> <image006.jpg>

Queensland's health vision | By 2026 Queenslanders will be among the healthiest people in the world.

Queensland Health acknowledges the Traditional Owners of the land, and pays respect to Elders past, present and future.

From: [redacted]
Sent: Monday, 26 February 2018 4:18 PM
To: Gregory Perry
Cc: [redacted]; Tara
Subject: RE: Medicinal Cannabis - Online application portal - Application form requirements [SEC=UNCLASSIFIED]

Hi Greg

Thanks again for your time this afternoon and please pass on my thanks to your colleagues. I would be very appreciative if you could provide me with an updated version of the application form to use as the basis for our development.

Please do not hesitate to contact me if you have any questions in the meantime.

Kind regards

[redacted]

[redacted]

Experimental Products Section

Pharmacovigilance and Special Access Branch
<image001.png>
Therapeutic Goods Administration
Health Products Regulation Group
Australian Government Department of Health

T: [redacted]
Location: Symonston GD-47

PO Box 100, Woden ACT 2606, Australia

This response is general information given to you without prejudice; it is not binding on the TGA and you should get your own independent legal advice to ensure that all of the legislative requirements are met.

From: Gregory Perry [mailto:Gregory.Perry@health.qld.gov.au]
Sent: Monday, 26 February 2018 2:04 PM
To: [redacted]
Subject: RE: Medicinal Cannabis - Online application portal - Application form requirements [SEC=UNCLASSIFIED]

Hi [redacted] that fine for me – I will have to excuse myself at 4.25 your time – to head to another meeting

Cheers greg
<image002.gif>

Gregory Perry
Director
Medicinal Cannabis Unit
Chief Medical Officer and Healthcare Regulation Branch
Prevention Division, Department of Health
p: 07 3708 5316 m: [redacted]
a: Locked Bag 21, Fortitude Valley BC QLD 4006
w: Queensland Health | e: Gregory.Perry@health.qld.gov.au
<image003.jpg> <image004.jpg> <image005.jpg> <image006.jpg>

Queensland's health vision | By 2026 Queenslanders will be among the healthiest people in the world.

Queensland Health acknowledges the Traditional Owners of the land, and pays respect to Elders past, present and future.

From: [redacted]
Sent: Monday, 26 February 2018 12:50 PM
To: Gregory Perry
Subject: RE: Medicinal Cannabis - Online application portal - Application form requirements [SEC=UNCLASSIFIED]

Hi Greg

Thanks for the below. Would 4pm today suit? If so I'd be happy to dial you then.

Kind regards
[redacted]

[Redacted]

Experimental Products Section
Pharmacovigilance and Special Access Branch
<image001.png>

Therapeutic Goods Administration
Health Products Regulation Group
Australian Government Department of Health

T: [Redacted] | E: [Redacted]

Location: Symonston GD-47

PO Box 100, Woden ACT 2606, Australia

This response is general information given to you without prejudice; it is not binding on the TGA and you should get your own independent legal advice to ensure that all of the legislative requirements are met.

From: Gregory Perry [mailto:Gregory.Perry@health.qld.gov.au]
Sent: Monday, 26 February 2018 12:11 PM
To: [Redacted]
Subject: RE: Medicinal Cannabis - Online application portal - Application form requirements [SEC=UNCLASSIFIED]

Hi [Redacted] I have time this afternoon before 430 your time, or tomorrow morning, or before 3pm, Wednesday after 230, Thursday after 12pm your time

Thanks greg

From: [Redacted]
Sent: Monday, 26 February 2018 9:29 AM
To: Medicinal Cannabis; Gregory Perry; Susan Ballantyne; jmack@doh.health.nsw.gov.au; peter.gilfedder@doh.health.nsw.gov.au; jfizz@doh.health.nsw.gov.au; vivien.bevan@act.gov.au; Anglea AF. Fitzhenry; 'Liam.Golding@sa.gov.au'; 'Bernard.Laidlaw@sa.gov.au'; 'Martyn.England@sa.gov.au'; peter.boyles@dhhs.tas.gov.au; 'sam.halliday@dhhs.tas.gov.au'; 'Margot.Johnson@dhhs.vic.gov.au'; 'Doug.young@dhhs.vic.gov.au'; 'Katherine.Ong@dhhs.vic.gov.au'; neil.keen@health.wa.gov.au; jane.carpenter@health.wa.gov.au; 'hugh.heggie@nt.gov.au'; 'Sandra.Schmidt@nt.gov.au'; 'ChiefHealthOfficer.DoH@nt.gov.au'; 'mreye@doh.health.nsw.gov.au'; 'suzanne.pierce@chiefscientist.nsw.gov.au'; Tanya Bain; anna.gelavis@health.wa.gov.au; michael.fitzsimons@act.gov.au; 'cireland@epilepsy.org.au'; 'Anne.Tonkin@adelaide.edu.au'; 'cecelia.gore@nt.gov.au'; [Redacted]

Subject: RE: Medicinal Cannabis - Online application portal - Application form requirements [SEC=UNCLASSIFIED]
Importance: High

Good Morning All

Thank you [Redacted] for sending the below and making the introduction.

By way of background, last year the Australian Government responded to a number of recommendations made as a result of the Review of Medicines and Medical Devices Regulation (MMDR). Subsequently, the TGA is currently building an externally facing IT system that will enable health practitioners to create, submit and manage applications/notifications under the Special Access Scheme (SAS) (rather than using the current paper forms). Given the recent discussions relating to the streamlining of Commonwealth and state/territory processes associated with accessing medicinal cannabis in Australia, I would like to schedule time with each of you to discuss the following proposed approach:

- When a medicinal cannabis product is selected in the system, the user will be presented with the fields that are currently included within the respective state/territory application forms for prescribing medicinal cannabis (as well as the fields required by the TGA).
- Upon submitting the SAS application/notification through the system, both the TGA and the relevant state/territory health department will receive the information required to process the application/notification.

The above proposal provides a single entry point for prescribers of medicinal cannabis to submit the relevant data requirements to the TGA and the state/territory simultaneously.

To ensure a prototype of the above can be provided ahead of the teleconference scheduled for 9 March, I kindly request that each state/territory propose a time to talk through the above at your earliest convenience.

Please do not hesitate to contact me if you have any questions. I look forward to hearing from you.

Kind regards

[Redacted]

[Redacted]

Experimental Products Section
Pharmacovigilance and Special Access Branch
<image001.png>
Therapeutic Goods Administration
Health Products Regulation Group
Australian Government Department of Health
T: [Redacted] | E: [Redacted]
Location: Symonston GD-47

PO Box 100, Woden ACT 2606, Australia

This response is general information given to you without prejudice; it is not binding on the TGA and you should get your own independent legal advice to ensure that all of the legislative requirements are met.

From: [Redacted] **On Behalf Of** Medicinal Cannabis
Sent: Friday, 23 February 2018 9:52 AM
Subject: Medicinal Cannabis - Online application portal - Application form requirements
[SEC=UNCLASSIFIED]

Dear all,

In the lead up to the scheduled meetings in March (the teleconference on the 9th and the Access Working Group Meeting on the 20th), I am pleased to advise that we have begun developing a solution to consolidate the state and territory requirements (as well as those required by the TGA) relating to accessing medical cannabis in Australia into a single form to be submitted online. This will allow prescribers of medical cannabis to provide information to meet state/territory and commonwealth requirements through a single portal. As you are aware, we have a teleconference scheduled for Friday, 9 March to discuss this matter in further detail to which we will distribute a draft prototype of the solution to all attendees for consideration and comment.

As part of this work, we will need to gather all the individual state and territory requirements that form part of the jurisdictional applications. Our project team will need a definitive list of requirements to begin development. At present we are utilising your application forms to make our preliminary developments. To expedite this development process, I kindly ask you to review the individual requirements contained within your

respective application forms and provide a definitive list of these requirements by **COB, Wednesday 28 February 2018**. If no response is received, we will take that to mean the requirements contained within your current application forms are correct and to be included within this scope of work.

I would like to take this opportunity to introduce my colleague, [redacted], who will be taking the lead on the development of this work. Should you have any questions please do not hesitate to contact him at [redacted] or on [redacted]

Kind regards,

[redacted]

[redacted]

Medicine Shortages Section
Pharmacovigilance and Special Access Branch
Phone: [redacted]
Email: medicinal.cannabis@health.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606
www.tga.gov.au

I acknowledge the traditional custodians of the lands and waters where we live and work, and pay my respects to elders past, present and future.

This response is general information given to you without prejudice; it is not binding on the TGA and you should get your own independent legal advice to ensure that all of the legislative requirements are met.

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RTI REQUEST

Gregory Perry

From: Gelavis, Anna <Anna.Gelavis@health.wa.gov.au>
Sent: Thursday, 15 February 2018 1:37 PM
To: Susan Ballantyne; Medicinal Cannabis; Gregory Perry;
jmack@doh.health.nsw.gov.au; peter.gilfedder@doh.health.nsw.gov.au;
'jfizz@doh.health.nsw.gov.au'; 'rvink@doh.health.nsw.gov.au';
Andrew.Pengilley@act.gov.au; vivien.bevan@act.gov.au;
'Kirsty.Whybrow@act.gov.au'; 'chris.kelly@act.gov.au'; Anglea AF. Fitzhenry;
'Liam.Golding@sa.gov.au'; 'Bernard.Laidlaw@sa.gov.au';
'Martyn.England@sa.gov.au'; peter.boyles@dhhs.tas.gov.au;
'sam.halliday@dhhs.tas.gov.au'; 'Margot.Johnson@dhhs.vic.gov.au';
'Doug.young@dhhs.vic.gov.au'; 'Katherine.Ong@dhhs.vic.gov.au'; Keen, Neil;
Carpenter, Jane; 'hugh.heggie@nt.gov.au'; 'Sandra.Schmidt@nt.gov.au';
'ChiefHealthOfficer.DoH@nt.gov.au'; 'mreye@doh.health.nsw.gov.au';
'suzanne.pierce@chiefscientist.nsw.gov.au'; Tanya Bain;
michael.fitzsimons@act.gov.au; 'cireland@epilepsy.org.au';
'Anne.Tonkin@adelaide.edu.au'; 'cecelia.gore@nt.gov.au'; [REDACTED]
[REDACTED]

Subject: RE: Medicinal Cannabis Access Working Group - proposed meeting dates in March 2018 [SEC=UNCLASSIFIED]

Hi [REDACTED]

The 20th suits me as well.

Regards

Anna Gelavis
Manager | Drugs of Dependence Unit

Medicines and Poisons Regulation Branch
Office of Chief Health Officer
Public and Aboriginal Health Division
Department of Health
T: 08 9222 2049 F:08 9222 2463
anna.gelavis@health.wa.gov.au
www.health.wa.gov.au/S8

Delivering a Healthy WA

From: Susan Ballantyne [mailto:Susan.Ballantyne@health.qld.gov.au]
Sent: Thursday, 15 February 2018 05:42
To: Medicinal Cannabis; Gregory Perry; jmack@doh.health.nsw.gov.au; peter.gilfedder@doh.health.nsw.gov.au;
'jfizz@doh.health.nsw.gov.au'; 'rvink@doh.health.nsw.gov.au'; Andrew.Pengilley@act.gov.au;
vivien.bevan@act.gov.au; 'Kirsty.Whybrow@act.gov.au'; 'chris.kelly@act.gov.au'; Anglea AF. Fitzhenry;
'Liam.Golding@sa.gov.au'; 'Bernard.Laidlaw@sa.gov.au'; 'Martyn.England@sa.gov.au'; peter.boyles@dhhs.tas.gov.au;
'sam.halliday@dhhs.tas.gov.au'; 'Margot.Johnson@dhhs.vic.gov.au'; 'Doug.young@dhhs.vic.gov.au';
'Katherine.Ong@dhhs.vic.gov.au'; Keen, Neil; Carpenter, Jane; 'hugh.heggie@nt.gov.au';
'Sandra.Schmidt@nt.gov.au'; 'ChiefHealthOfficer.DoH@nt.gov.au'; 'mreye@doh.health.nsw.gov.au';
'suzanne.pierce@chiefscientist.nsw.gov.au'; Tanya Bain; Gelavis, Anna; michael.fitzsimons@act.gov.au;
'cireland@epilepsy.org.au'; 'Anne.Tonkin@adelaide.edu.au'; 'cecelia.gore@nt.gov.au'; [REDACTED]
[REDACTED]

Subject: RE: Medicinal Cannabis Access Working Group - proposed meeting dates in March 2018 [SEC=UNCLASSIFIED]

Hi [redacted] – 20th March would be most suitable for me
Sue

From: [redacted] **On Behalf Of** Medicinal Cannabis

Sent: Tuesday, 13 February 2018 4:47 PM

To: Gregory Perry; Susan Ballantyne; jmack@doh.health.nsw.gov.au; peter.gilfedder@doh.health.nsw.gov.au; jfizz@doh.health.nsw.gov.au; rvink@doh.health.nsw.gov.au; Andrew.Pengilley@act.gov.au; vivien.bevan@act.gov.au; Kirsty.Whybrow@act.gov.au; chris.kelly@act.gov.au; Anglea AF. Fitzhenry; Liam.Golding@sa.gov.au; Bernard.Laidlaw@sa.gov.au; Martyn.England@sa.gov.au; peter.boyles@dhhs.tas.gov.au; sam.halliday@dhhs.tas.gov.au; Margot.Johnson@dhhs.vic.gov.au; Doug.young@dhhs.vic.gov.au; Katherine.Ong@dhhs.vic.gov.au; neil.keen@health.wa.gov.au; jane.carpenter@health.wa.gov.au; hugh.heggie@nt.gov.au; Sandra.Schmidt@nt.gov.au; ChiefHealthOfficer.DoH@nt.gov.au; mreye@doh.health.nsw.gov.au; suzanne.pierce@chiefscientist.nsw.gov.au; Tanya Bain; anna.gelavis@health.wa.gov.au; michael.fitzsimons@act.gov.au; cireland@epilepsy.org.au; Anne.Tonkin@adelaide.edu.au; cecelia.gore@nt.gov.au; [redacted]

[redacted] Medicinal Cannabis

Subject: Medicinal Cannabis Access Working Group - proposed meeting dates in March 2018 [SEC=UNCLASSIFIED]

Dear all,

As you may be aware [redacted] has just started 3 weeks leave. In his absence he has tasked me with finding a suitable date for the next Cannabis Access Working Group Meeting which is due to be held in Canberra sometime in March.

I currently have 2 proposed dates for the meeting

- 1) 7th of March 2018 or
- 2) 20th of March 2018

Please advise by **COB Thursday 15th of February** if you are able to attend on a particular date, or if both of these dates are possible for you. I apologise for the tight timeframe for response, it is difficult to secure conference rooms in Canberra and March is fast approaching so I would like to have a firm date to everyone by early next week.

Ideally it would be wonderful if everyone could attend in person but we will be able to teleconference anyone unable to come to Canberra, please just let me know so I can make the arrangements.

Once I have a firm date I will let you all know and I will also ask for suggestions for agenda items. I will then forward an agenda closer to the day, but in general this meeting will be an opportunity to discuss core responsibilities at the state/territory and federal levels, decision making considerations and opportunity for streamlining processes. It will also be a good general catch up between the states and territories and the Commonwealth where we can discuss recent developments in the patient access to medicinal cannabis space.

I look forward to receiving your responses.

If you have any other medicinal cannabis matters for discussion with the TGA while [redacted] is away please don't hesitate to contact me instead.

Thanks and kind regards,

[redacted]

[redacted]
Medicine Shortages Section
Pharmacovigilance and Special Access Branch
Phone: [redacted]
Email: medicinal.cannabis@health.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606
www.tga.gov.au

I acknowledge the traditional custodians of the lands and waters where we live and work, and pay my respects to elders past, present and future.

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RTI REQUEST

Gregory Perry

From: [redacted]
Sent: Tuesday, 13 March 2018 10:52 AM
To: Gregory Perry
Subject: RE: Medicinal cannabis teleconference meeting minutes for comment - 9/03/2018 [SEC=UNCLASSIFIED]

Hi Greg,

Thanks, [redacted] and I are here all day today so please feel free to give us a call when you're available.

Kind regards,

[redacted]

[redacted]

Medicine Shortages Section
Pharmacovigilance and Special Access Branch
Phone: [redacted]
Email: medicinal.cannabis@health.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606
www.tga.gov.au

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From: Gregory Perry [<mailto:Gregory.Perry@health.qld.gov.au>]
Sent: Monday, 12 March 2018 1:20 PM
To: [redacted]
Subject: RE: Medicinal cannabis teleconference meeting minutes for comment - 9/03/2018 [SEC=UNCLASSIFIED]

Hi [redacted] thanks for those – I don't believe we have had a situation where we have disagreed with the TGA approval. And think we have significant overlap – tried to cal – but holiday there so will call tomorrow

Thanks greg

From: [redacted]
Sent: Monday, 12 March 2018 10:28 AM
To: 'judith.MACKSON@moh.health.nsw.gov.au'; Gregory Perry; 'Doug.young@dhhs.vic.gov.au'; Anglea AF. Fitzhenry; neil.keen@health.wa.gov.au; 'cecelia.gore@nt.gov.au'; peter.boyles@dhhs.tas.gov.au; michael.fitzsimons@act.gov.au
Subject: Medicinal cannabis teleconference meeting minutes for comment - 9/03/2018 [SEC=UNCLASSIFIED]

Dear all,

Thank you for participating in the teleconference on Friday.

Please find the minutes from the meeting attached, including a summary table at the end of the document. Please disseminate to your appropriate colleagues.

I apologise if we have not included a full name or have misspelt any names on the list of attendees. If these could be corrected that would be appreciated.

We kindly request that all states and territories could provide comment on the minutes by **COB Tuesday 13/03/2018.**

Please note that it is a public holiday in Canberra today so most of the TGA and ODC are out of office but will return tomorrow.

Kind regards,

[Redacted]

[Redacted]

Medicine Shortages Section
Pharmacovigilance and Special Access Branch
Phone: [Redacted]
Email: medicine.shortages@health.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606
www.tga.gov.au

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