Gregory Perry

From: Gregory Perry
Sent: Monday, 12 March 2018 12:13 PM
To: Dorothy Vicenzino
Cc: Tanya Bain
Subject: FW: Medicinal cannabis teleconference meeting minutes for comment - 9/03/2018 [SEC=UNCLASSIFIED]
Attachments: Minutes.docx

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]

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

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

"Important: This transmission is intended only for the use of the addressee and may contain confidential or legally privileged information. If you are not the intended recipient, you are notified that any use or dissemination of this communication is strictly prohibited. If you receive this transmission in error please notify the author immediately and delete all copies of this transmission."

Draft Agenda: State/Territory meeting on medicinal cannabis access – 6 February 2018

1. Welcome and problem definition

   Perception that access to medicinal cannabis products is too bureaucratic, lack of understanding of need for state/territory approvals and Commonwealth approvals, risks of different decisions at jurisdictional levels receiving adverse media attention.

2. Core responsibilities

   a. States and territories – good medical practice
   b. TGA – supply of medicines
   c. Are there overlaps? How to handle.

3. Single Smartform – issues for consideration

   a. Can one form suit all jurisdictions?
   b. Eight forms?
   c. Privacy issues

4. Decision making processes – options

   a. Delegation of SAS Cat B to states/territories

Issues: Lack of consistency, no appetite from Commonwealth

   b. TGA makes decision first, then states/territories

Issues: Risks remain of perception of different decisions

   c. States/territories make decisions first, then TGA

Issues: Political risks rests with the states/territories

   d. Parallel decision making processes

Issues: essentially status quo, doesn't address issues

5. Use of Committees

6. Other options for consideration
   a. Better communications on the need for controls
   b. ?

DRAFT Media statement – **Queensland government streamlines access to Sativex (Nabiximol)**

The Palaszczuk Government is committed to ensuring Queenslanders have access to the optimal range of cannabis-based medicines to promote better health outcomes.

In November 2017, Sativex (nabiximol) became available in Australia. Sativex is the only nationally-registered Schedule 8 medicinal cannabis product on the Australian Register of Therapeutic Goods. All other medicinal cannabis products are unapproved goods that require both a Therapeutic Goods Administration (TGA) and state approval to be prescribed.

The Minister for Health and Ambulance Services Dr Stephen Miles said "these amendments will further open up patient access to Sativex. Until now in Queensland it was only available to certain specialist doctors for the treatment of multiple sclerosis."

"These amendments will mean that additional specialists and GPs can now be approved to use Sativex on a case-by-case basis."

Changes to the Health (Drugs and Poisons) Regulations 1996 allow more streamlined access to this registered medicine for patients where a medical practitioner considers there may be a clinical benefit.

The legislative controls remain on the prescribing of schedule 8 controlled drugs for the protection of patients, health professionals and the wider community from the known harms and risks of these.

Pages 31 through 33 redacted for the following reasons:
- -
Sch3(7) - Legal Professional Privilege

Gregory Perry

From: Gregory Perry
Sent: Friday, 16 February 2018 4:26 PM
To: [redacted]
Subject: RE: Furthering collaboration and streamlining medicinal cannabis access [SEC=UNCLASSIFIED]

Thanks [redacted] all the best hope all goes well and your back on the wicket asap!!

greg

From: [redacted]
Sent: Friday, 16 February 2018 3:46 PM
To: 'Judith.MACKSON@moh.health.nsw.gov.au'; 'jfizz@doh.health.nsw.gov.au'; 'suzanne.pierce@chiefscientist.nsw.gov.au'; Gregory Perry; [redacted] Susan Ballantyne; 'Margot.Johnson@dhhs.vic.gov.au'; Doug.Young@dhhs.vic.gov.au; Jessica.Reiseger@dhhs.vic.gov.au; Anna.Peatt@dhhs.vic.gov.au; Katherine.Ong@dhhs.vic.gov.au; kecha@doh.health.nsw.gov.au
Cc: [redacted]
Subject: Furthering collaboration and streamlining medicinal cannabis access [SEC=UNCLASSIFIED]

All,

A quick note from me before I take off for two weeks [redacted] on the meeting last week. I apologise that I wanted to put something out earlier but there have been some other ongoing discussions that have delayed this.

I want to thank everyone for very fruitful, forthright and open discussions and I think that we made good progress in addressing a difficult area. The next step is to socialise with the rest of our colleagues and hopefully find a landing spot.

Firstly, I should note that the TGA's position on the use of specialist endorsement is, and will remain, that they will use them on a case by case basis. To the extent that states will see a need for and require specialist endorsement, that can remain and the form will be developed to accommodate that.

The big progress is on the agreement for a form that will submit simultaneously to both jurisdictions. Work on this has begun and [redacted] from the TGA may contact you on pushing this forward. We are hoping to have a prototype in time for the Patient Access Working Group meeting, which at this stage looks like being in 20 March.

I note that there was some agreement on the principles going forward and these included:

- The treating doctor should be the usual treating doctor, not a third party doctor.
- Palliative care should not require specialist endorsement.
- We should be moving away from specialist endorsement where there is agreed guidance and the doctor is complying with that.
- We should consult on difficult cases (unusual indications, things for which there are no guidances, cases where there is history from the doctor or the patient around addiction) before issuing decisions.

If there is anything else I haven't added, please let us know.

My colleague, [redacted] will be driving this forward from here.

Thanks again for the useful discussions. I should be back on deck on 5 March.

Best regards,

[redacted]
Assistant Secretary, Health Products Regulation Group

Health Diversity Champion

Phone: [redacted]
Email: [redacted]

Australian Government Department of Health
PO Box 100
Woden ACT 2606

www.odc.gov.au

Gregory Perry

From: Mark Zgrajewski
Sent: Monday, 15 January 2018 11:02 AM
To: Julie Stokes; Gregory Perry
Cc: Mark Zgrajewski; Isobel Cruise
Subject: Health (Drugs and Poisons) (Cannabis and Other Matters) Amendment Regulation 2018

Hi Julie and Greg,

As I discussed with earlier today, Kirsten has requested the media statement prepared by PD/Comms be updated to lead with the Nabiximols amendments, and that Dorothy approve this approach.

The media should act as a pre-emptive response to Minister Hunt's call for state streamlining of MC access, along the line of:

- The amendments will open up patient access to nabiximols, also known as Sativex. This is a nationally-registered medicinal cannabis drug, but in Queensland it is only available to certain specialist doctors for the treatment of multiple sclerosis. The *Public Health (Medicinal Cannabis) Act 2016* allows a variety of specialists to prescribe medicinal cannabis products for a broad range of conditions. The amendments will allow these specialists to also prescribe nabiximols as part of their patient's overall treatment plan. In addition, the amendments will give the chief executive of Queensland Health the power to approve other specialists and GPs to use nabiximols on a case-by-case basis.

The proposed GiC date is 15 March, but we may get this through quicker, depending on how long it takes the DDG, DG and Minister to approve the Executive Council package.

If you could get Dorothy to agree this new media ASAP, we will get the package to Kathleen this week. We can develop the actual media wording while the package is going up the line.

Please let me know if I may assist further.

Regards,

Queensland Government

Mark Zgrajewski
Manager
Legislative Policy | Strategic Policy and Legislation Branch
Department of Health
p: 07 3708 5582
a: 33 Charlotte Street, Brisbane Q 4001
w: Queensland Health | e: mark.zgrajewski@health.qld.gov.au

Gregory Perry

Subject:	Internal Mtg - SMART form and medicinal cannabis access portal - Teleconference [SEC=UNCLASSIFIED]
Location:	TGA Executive Boardroom
Start:	Fri 9/03/2018 1:00 PM
End:	Fri 9/03/2018 2:30 PM
Show Time As:	Tentative
Recurrence:	(none)
Organizer:	

Update 9/03/18

In preparation for this afternoon's teleconference, please find attached an agenda and mock designs which depict the current workflow in the externally facing Special Access Scheme (SAS) IT system as some of you would have discussed with over the last week. As an example, the attached solicits the required information for both the TGA and the NSW Health department throughout a single workflow (noting that the information required by NSW Health relates to the details of the prescriber and the patient). Upon submission of this via the online system, both the TGA and NSW Health department will be provided with the required information to process their respective applications. This is based on the assumption that the user of the system is seeking access to a medicinal cannabis product and is prescribing in NSW.

Dial-In Numbers:
Toll Free Dial-In Number(s):
Australia

Participant Passcode:

The Minister for Health, Greg Hunt wrote to the Health Ministers for each of the states and territories last month. In this letter he talked about a number of issues for access to medicinal cannabis in Australia. In particular, he mentioned the need to develop a SMART form and medicinal cannabis access portal which would allow doctors to fill in a single form containing all the required information and to submit it to TGA and states/territories simultaneously.

The TGA would now like to bring all of the states and territories together to discuss the development of the SMART form, the portal, and your requirements.

For this meeting to be productive, it is imperative that all stakeholders attend. Please confirm your attendance at this teleconference by acknowledging this invitation

Please note that this teleconference is separate to the Medicinal Cannabis Access Working Group meeting to be held in Canberra later in March.


AGENDA - Teleconference ...


NSW Requirements - ...

Australian Government
Department of Health
Therapeutic Goods Administration

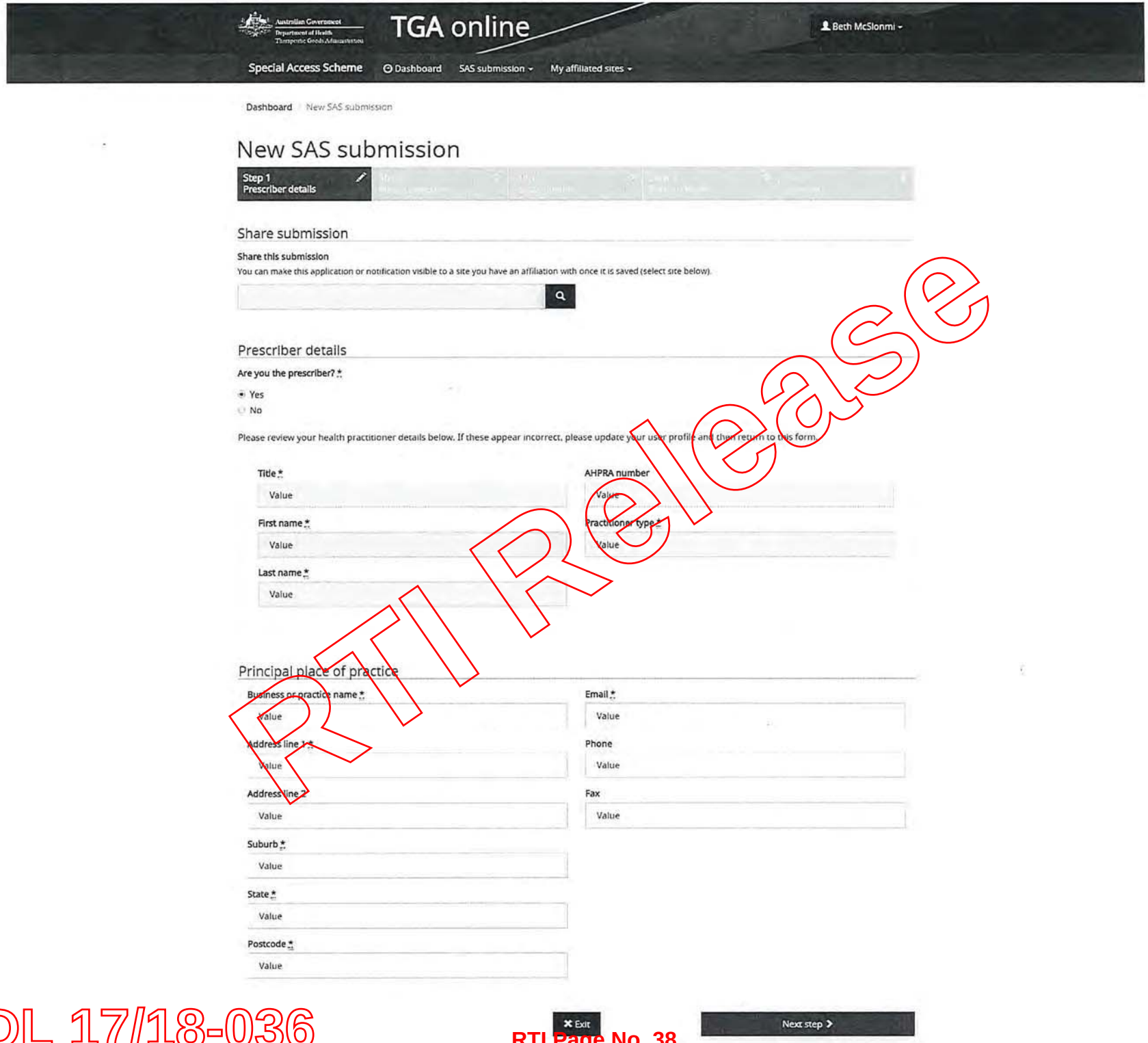
Agenda

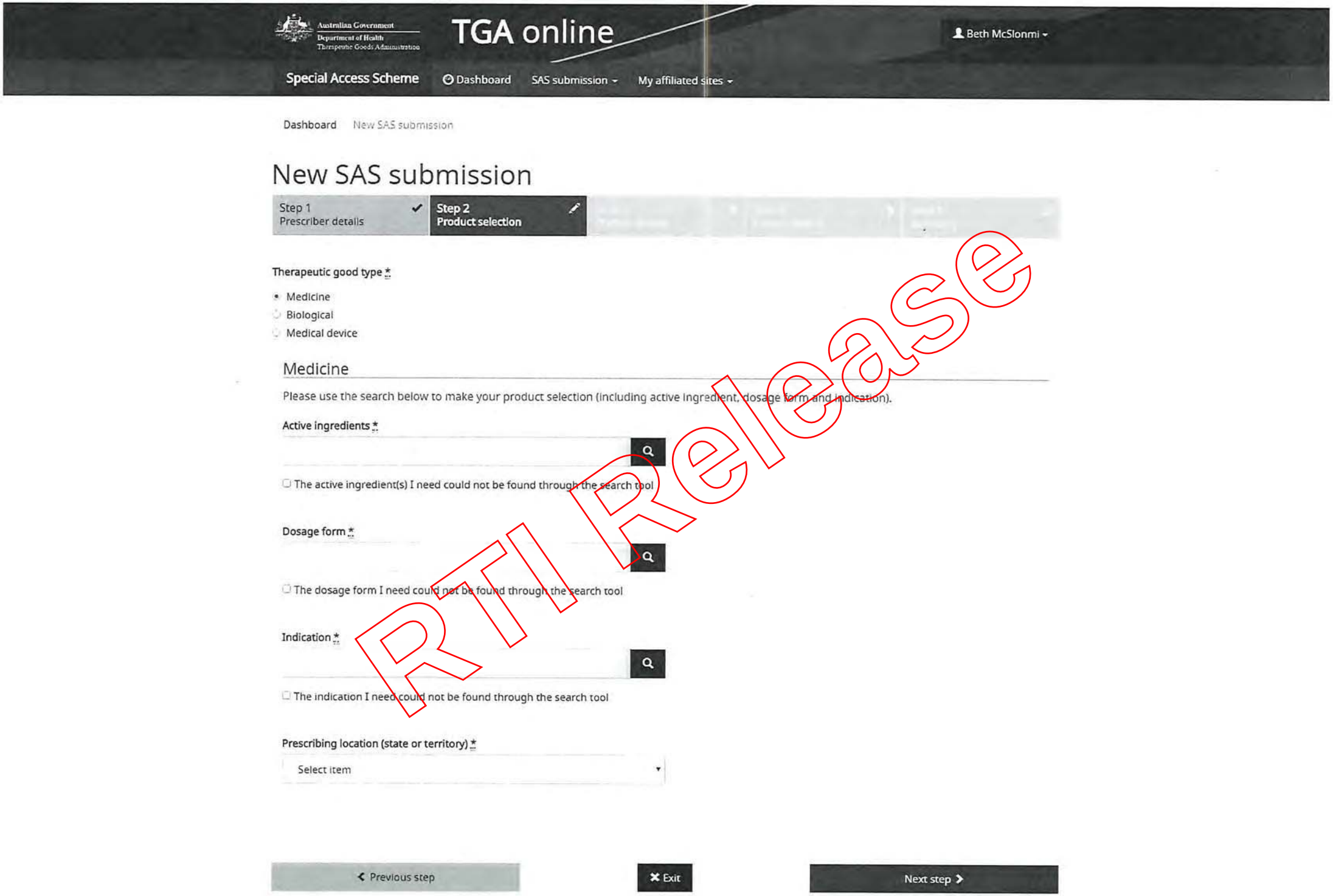
SAS Online System Development and TGA/NSW interim solution– Medicinal Cannabis

9th of March 2018
2-3.30pm

1. **Introductions**
2. **Purpose**
3. **Background**
4. **Progress**
5. **Discussion of online system**
6. **Interim solution between NSW and TGA**
7. **Actions/outcomes**
8. **Close**

PO Box 100 Woden ACT 2606 ABN 40 939 406 804
Phone: 02 6232 8444 Fax: 02 6203 1605 Email: info@tga.gov.au
https://www.tga.gov.au


Australian Government
Department of Health
Therapeutic Goods Administration
TGA online
Beth McSlonmi
Special Access Scheme
Dashboard
SAS submission
My affiliated sites
Dashboard
New SAS submission
New SAS submission
Step 1
Prescriber details
Share submission
Share this submission
You can make this application or notification visible to a site you have an affiliation with once it is saved (select site below).
Prescriber details
Are you the prescriber? *
Yes
No
Please review your health practitioner details below. If these appear incorrect, please update your user profile and then return to this form.
Title *
Value
First name *
Value
Last name *
Value
AHPRA number
Value
Practitioner type *
Value
Principal place of practice
Business or practice name *
Value
Address line 1 *
Value
Address line 2
Value
Suburb *
Value
State *
Value
Postcode *
Value
Email *
Value
Phone
Value
Fax
Value
Exit
Next step


Australian Government
Department of Health
Therapeutic Goods Administration
TGA online
Beth McSlonmi
Special Access Scheme
Dashboard
SAS submission
My affiliated sites
Dashboard
New SAS submission
New SAS submission
Step 1
Prescriber details
Step 2
Product selection
Therapeutic good type *
Medicine
Biological
Medical device
Medicine
Please use the search below to make your product selection (including active ingredient, dosage form and indication).
Active ingredients *
The active ingredient(s) I need could not be found through the search tool
Dosage form *
The dosage form I need could not be found through the search tool
Indication *
The indication I need could not be found through the search tool
Prescribing location (state or territory) *
Select item
Previous step
Exit
Next step

Dashboard / New SAS submission

New SAS submission

Step 1 Prescriber details ✓ | Step 2 Product selection ✓ | Step 3 Product details

Submission pathway

Based on your selection in the previous steps, the pathway for this submission has been determined as **Category B**. Click here to learn about the available SAS pathways.

Product details (Medicine)

Active ingredient(s)

Value

Dosage form

Value

Strength *

Value

Strength unit *

Value

Route of administration *

Value

Dosage and frequency (e.g., 1 tds) *

Expected duration of treatment *

Duration unit *

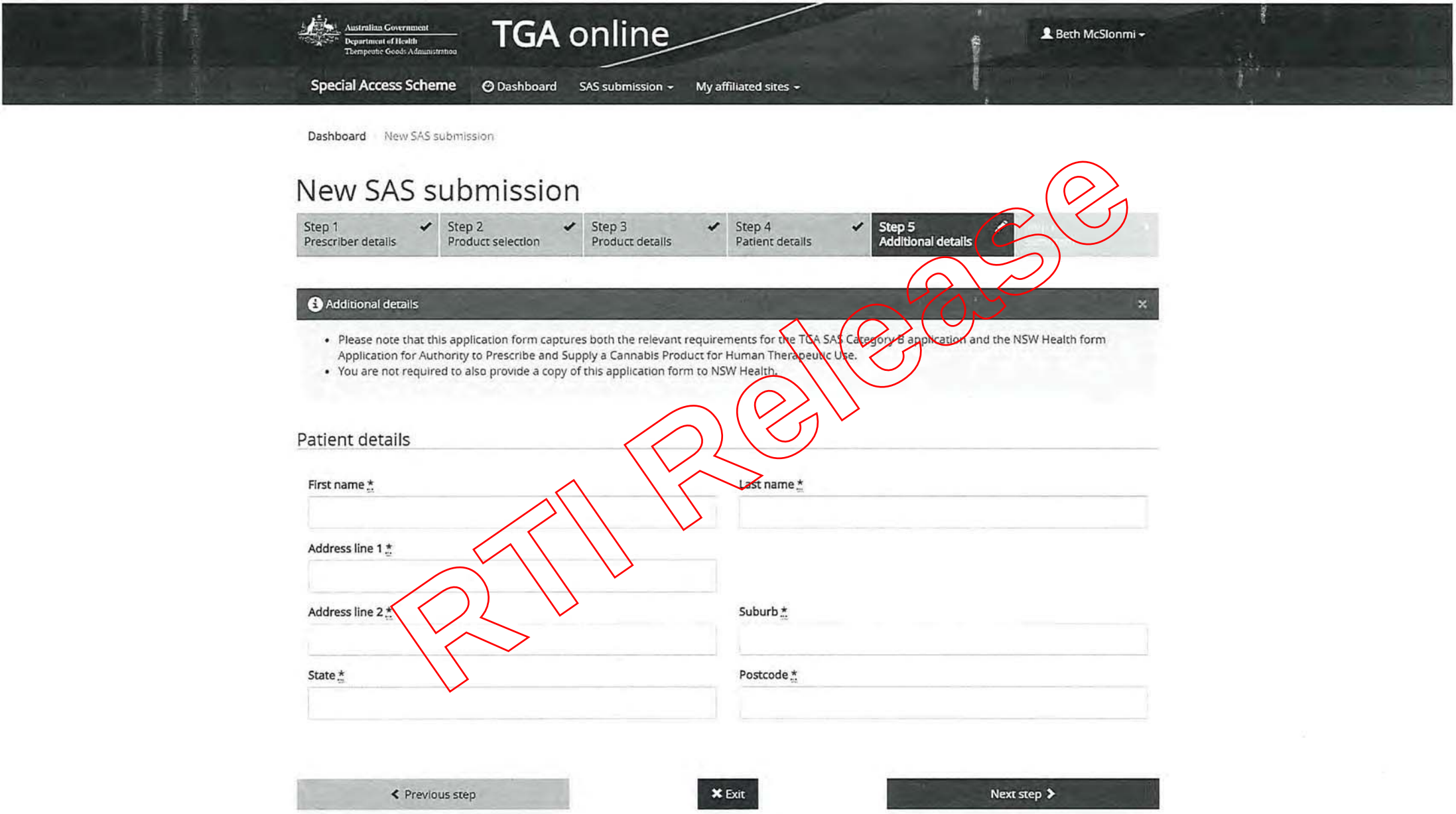
Trade name *

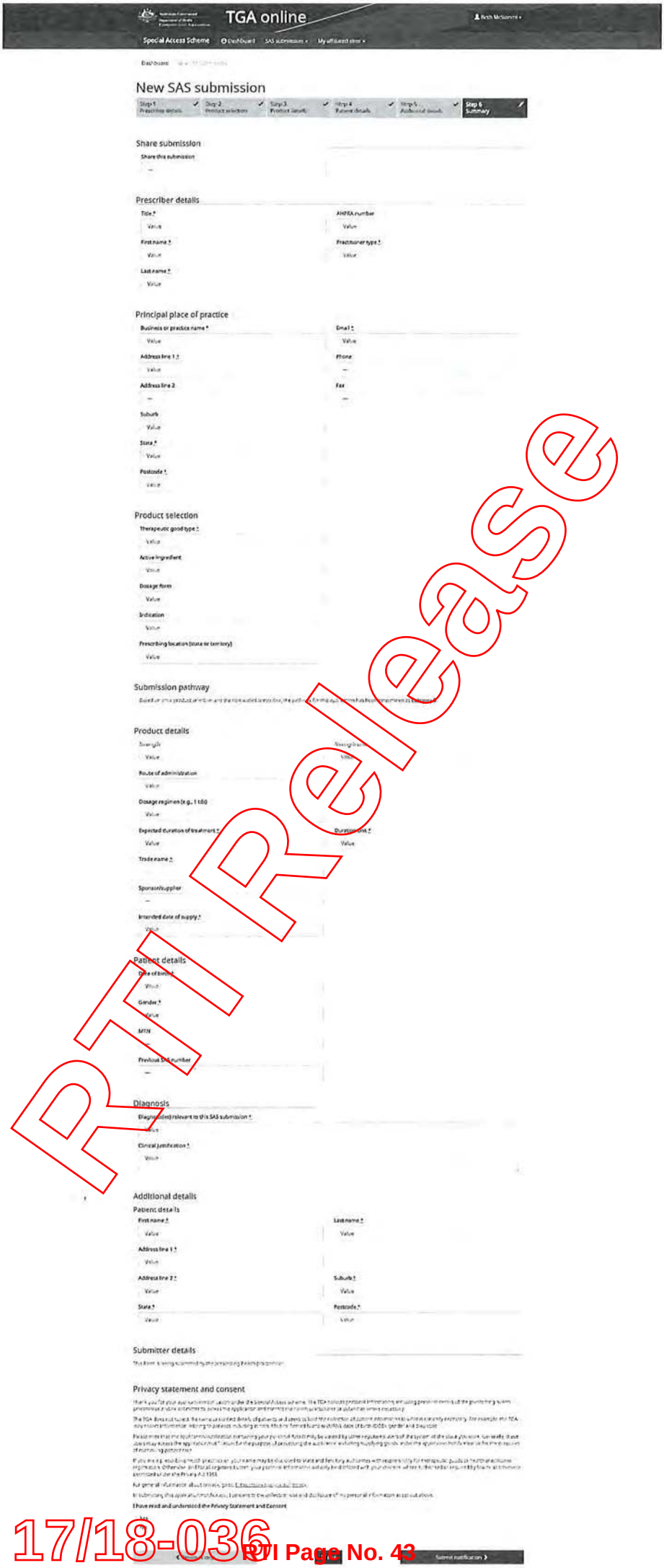
Sponsor/supplier

Intended date of supply *

< Previous step | ✖ Exit | Next step >


Australian Government
Department of Health
Therapeutic Goods Administration
TGA online
Beth McSlonmi
Special Access Scheme
Dashboard
SAS submission
My affiliated sites
Dashboard
New SAS submission
New SAS submission
Step 1
Prescriber details
Step 2
Product selection
Step 3
Product details
Step 4
Patient details
Patient details
Date of birth *
Gender *
Male
Female
Intersex/indeterminate/unspecified
MRN
Previous SAS number
Diagnosis
Diagnosis(es) relevant to this SAS submission *
Clinical justification *
Previous step
Exit
Next step


Australian Government
Department of Health
Therapeutic Goods Administration
TGA online
Beth McSlonmi
Special Access Scheme
Dashboard
SAS submission
My affiliated sites
Dashboard
New SAS submission
New SAS submission
Step 1
Prescriber details
Step 2
Product selection
Step 3
Product details
Step 4
Patient details
Step 5
Additional details
Additional details
Please note that this application form captures both the relevant requirements for the TGA SAS Category B application and the NSW Health form Application for Authority to Prescribe and Supply a Cannabis Product for Human Therapeutic Use.
You are not required to also provide a copy of this application form to NSW Health.
Patient details
First name *
Last name *
Address line 1 *
Address line 2 *
Suburb *
State *
Postcode *
Previous step
Exit
Next step



SharePoint Ref No: 13290

Registration No.: C-ECTF-

RESPONSE:

☑ Minister

- o 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: Steph

Name: Hon Greg Hunt MP - Federal Minister for Health

Issue: Coag Health Council to further Streamline the approval pathways for medicinal cannabis products

☐ **BRIEFING NOTE REQUIRED**

- o Background Information only

☐ **URGENT**

Previous Dept Ref #:

INSTRUCTIONS:

Reviewed by: Steph Date: 06/06/17

Sent to ESU by: M Date: 6/6

ESU ONLY

Doc Type:

Brief Template:

Letter Template:

Action Officer: Due Date:

Opening Paragraph:

6 JUN 2017

The Hon Greg Hunt MP
Minister for Health
Minister for Sport

Ref No: MC17-009506

The Hon Cameron Dick MP
Minister for Health
Minister for Ambulance Services
PO Box 48
BRISBANE QLD 4001

30 MAY 2017

Dear Minister Cameron

I am writing to you to seek your assistance to find a path through the Council of Australian Governments (CoAG) Health Council to further streamline the approval pathways for medicinal cannabis products. As you will recall, at the meeting of the Council on 24 March we collectively considered the need for further cooperation and work on medicinal cannabis issues.

I thank you for the co-operation of your Department to date. Much work has been done and all jurisdictions have made considerable progress towards simplifying access arrangements for patients. However, there remains considerable public perception that the processes at the Commonwealth and state level are duplicative and administratively burdensome.

I acknowledge that there are good, constitutional reasons why there are two levels of control on the prescribing of these products and I do not propose that we change that. State health departments have responsibility for, and experience with, medical practice, while the Commonwealth, through the Therapeutic Goods Administration (TGA), is responsible for approving supply of products and seeking information on the intended use (indications) for medicinal cannabis products.

In working together, it is essential that we do not create gaps in the regulatory chain, but also that we do not overlap what we are doing. The approval processes at state and Commonwealth level should be streamlined, seamless and minimise the regulatory burden on medical practitioners and pharmacists.

In improving patient access times, there are opportunities to streamline our processes. The TGA approves supply of the unapproved product and requests supporting information to justify why the unapproved product is being used rather than approved products. The jurisdictions, through their drugs and poisons regulation, oversee the prescribing of medicinal cannabis products to appropriate patients. At the current time, there can be duplication and differences in what information is required by the TGA and the jurisdictions. It be would be more efficient if there were one set of information provided by the prescriber which can satisfy both TGA and the jurisdictional requirements.

I note that Queensland uses a clinical advisory committee in certain circumstances and I would encourage you to consider that your specialist clinical advisory committee only reviews unusual indications rather than more common ones to also reduce duplication with TGA in the approval process.

Parliament House, Canberra ACT 2600 Telephone (02) 6277 7220

Queensland is one of the few jurisdictions which have specially legislated for medicinal cannabis product access; while the other jurisdictions have largely elected to work through pre-existing Schedule 8 processes, though some have overlaid an expert committee. While these processes are not perfect, they do have the advantage of being, in the main, the same process that works for other unregistered narcotic drugs.

I think that this is the ideal solution and I would be eager to work with you through the CoAG processes to help ensure that Queensland's processes *in practice* work as effectively as existing Schedule 8 processes.

I am informed that the greatest concern arising from the Queensland process is the legislated maximum 90 day timeframe for approvals. Patient advocates have seized on this to correctly point out that terminally ill patients, one of the groups that might benefit from unregistered medicinal cannabis products, may not be able to wait up to 90 days for an approval. I understand that in practice, approvals from Queensland Health are given much quicker and it would be good if these timeframes could be better communicated.

Further, I wonder if the separate approval process for pharmacies is also required. My understanding is that these pharmacies would already need an approval to handle and dispense other Schedule 8 medicines and so the separate approval for medicinal cannabis products can leave the system open to criticism of being duplicative.

A final area of concern that has been raised directly with my Office and the Australian Government Department of Health is the need for an approval under Queensland legislation for cannabidiol (CBD), which is a Schedule 4 substance, and I wonder whether this could be reviewed. CBD, while still a prescription only substance, does not have the issues of addiction and abuse more traditionally associated with tetra-hydrocannibinol. Are there any other situations in Queensland legislation where Schedule 4 substances require an additional approval process?

I am pleased to advise that in July senior officials from my Department (the TGA and the Office of Drug Control) will be visiting Brisbane to further assist with doctor communication and education, meet with state officials and address any regulatory questions from industry.

I thank you in advance for your consideration of these matters. I think that it is very important for all Australian governments to work together and to ensure that, collectively, we are not seen as a barrier for access to these medicines. I look forward to discussing it further with you at the next meeting of the CoAG Health Council.

Yours sincerely,

Greg Hunt

17 JUL 2017

RM folder reference No:	C-ECTF-17/3094
Division:	Prevention
File Ref No:	

Brief for Ministerial Correspondence

SUBJECT: Overview of issues raised by the disallowance of amendments to Therapeutic Goods Regulations 1990

Key Issues

1. On 30 May 2017, the Honourable Greg Hunt MP, Commonwealth Minister for Health and Minister for Sport, wrote to the Honourable Cameron Dick MP, Queensland Minister for Health and Minister for Ambulance Services, seeking assistance to find a way for the COAG Health Council to further streamline the approval pathways for medicinal cannabis products.
2. Note the disallowance of a range of amendments to the Therapeutic Goods Regulations 1990 (Cwlth) by the Australian Senate will have significant implications for the access and authorisation of medicinal cannabis products in Queensland.
3. Minister Hunt provides a number of suggestions for how Queensland could contribute to a more streamlined and seamless system.
4. On 13 June 2017, the Australian Senate voted to disallow amendments to the Therapeutic Goods Regulations 1990 (Cwlth). Specifically, medicinal cannabis products can now be accessed under the *Therapeutic Goods Act 1989* (Cwlth) via:
   - 4.1 the Special Access Scheme Category A (SASA) for terminally ill patients;
   - 4.2 traveller's exemption for travellers under treatment of a medical practitioner who may travel to Australia with medicinal cannabis products for their own personal use;
   - 4.3 personal importation for a patient or their immediate family to import medicinal products (that is by person) with no requirement for any other Therapeutic Goods Administration (TGA) approval as they are already exempt; and
   - 4.4 extemporaneous compounding has been expanded from the public hospital system to include private companies that can be accessed by the public.
5. An overview of how these changes will impact the Queensland regulatory framework is provided in Attachments 2, 3 and 4.
6. A number of issues raised in the letter from Minister Hunt will be affected by the disallowance, particularly the TGA's ability to ensure the quality of the medicinal cannabis product provided to patients through some access pathways. The response letter (Attachment 1) highlights the concerns that Queensland Health has about the framework.
7. Prescribers that use the SASA approval pathway will not be able to access bulk importation due to the way that program has been established. This will result in SASA applicants needing to organise importation on a case by case basis, resulting in patients waiting longer to receive product. The Queensland Department of Health is concerned about the TGA's ability to ensure the quality of the product to be used and can see benefits in patients having easier access to medicinal cannabis products as long as quality and safety can be addressed.
8. This new process following the disallowance will make it more difficult for the Queensland expert panel to approve SASA and personal importation applications because the panel may not know if the product meets TGA standards. The Queensland approval process comes before the Office of Drug Control (ODC) part of the process. More work will need to be undertaken with ODC to fully map and resolve these issues over coming weeks.

Results of Consultation

9. Preliminary discussions have been undertaken with the TGA and the ODC.

Resource Implications (including Financial)

10. This will be managed within existing resource allocation.

RM folder reference No:	C-ECTF-17/3094
Division:	Prevention
File Ref No:	

Background

11. On 11 May 2017, the disallowance, proposed by the Senator Di Natalie was defeated in the Senate only for a revote to be called for by Senator Jacqui Lambie due to her absence from the initial vote. The disallowance was upheld on the revote due to support from One Nation who had previously rejected the disallowance.
12. The TGA has allowed several companies to undertake bulk importation under changes made to the Therapeutic Goods Regulation in February 2017. Six companies have since been approved as wholesalers in Queensland.
13. A number of families with seriously ill children that are currently using illegal medicinal cannabis products are very actively engaged with the media and have continually stated the medicinal cannabis framework developed by the Commonwealth and Queensland Governments excessively burdensome and timely.
14. A number of medicinal cannabis advocates have raised the issue of affordability and are requesting amnesty to use unauthorised product in the interim period.

Attachments

15. Attachment 1: Letter of response to the Honourable Greg Hunt MP – C-ECTF-17/3094
    Attachment 2: Overview of the impact of the disallowance on the Queensland
    Attachment 3: Overview of current processes
    Attachment 4: Approvals Schema

Department Contact Officer

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

Minister for Health and
Minister for Ambulance Services
Member for Woodridge

Queensland Government

1 William Street Brisbane 4000
GPO Box 48 Brisbane
Queensland 4001 Australia
Telephone +617 3035 6100
Email health@ministerial.qld.gov.au
Website www.health.qld.gov.au

C-ECTF-17/3094

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

Dear Minister

Thank you for your letter seeking to utilise the COAG Health Council forum to examine opportunities for further cooperation in streamlining pathways for access to medicinal cannabis.

I appreciate you taking the time to write. I understand the disallowance motion passed in the Australian Senate on 13 June 2017 means that the checks and balances in the system have been recalibrated and the level of scrutiny that Queensland applies to applications for medicinal cannabis is increasingly important. There are considerable concerns that the application of checks on product quality afforded by the Therapeutic Goods Administration (TGA) through ensuring compliance with quality standards such as TGO93 will be more difficult, particularly for Special Access Scheme Category A applications and personal importation. Due to this, Queensland will continue to require applicants to provide evidence regarding product quality and safety.

Queensland works closely with the Commonwealth TGA and the Office of Drug Control to minimise any duplication of administrative procedures including prescribing, wholesaling and manufacturing of medicinal cannabis products.

Where medical practitioners have applied to the TGA for access to a medicinal cannabis product, the Queensland Department of Health considers the information supplied and accepted by the TGA under Special Access Scheme Category B or Authorised Prescriber as meeting the necessary Queensland standard for the recommended product. The Department advises prospective applicants to include the same information provided to the TGA in any Queensland application. The intent here is to minimise the need for separate information to be sourced by the applicant.

Queensland's *Public Health (Medicinal Cannabis) Act 2016* and subordinate legislation mirrors much of the existing administrative procedures required to regulate other unregistered narcotic drugs. Any additional controls for medicinal cannabis are in place where the Queensland Government believes the risk for diversion and misappropriation of a novel schedule 8 controlled drug is likely to be a considerable issue.

In practice, areas such as dispensing and wholesaling where quantities of medicinal cannabis are likely to be stored have thus been identified. The scrutiny applied to applications in Queensland aims to minimise risks to the community.

Criteria for referral to the Queensland Medicinal Cannabis Expert Panel are being developed to ensure only complex conditions, not covered by the existing Queensland Clinical Guidance and proposed national guidance, will be considered by the Expert Panel. Queensland processes ensure that patients with terminal conditions are expedited through the system. The Department has worked closely with the TGA in these situations. Previously, the delays in supply had been caused by the time to process export permits from Canada (30 days) and individual transport issues. The bulk importation by sponsors will considerably reduce these delays.

The cost of imported medicinal cannabis products continues to remain a significant barrier that needs to be addressed, a national funding model that ensures approved medicinal cannabis products are affordable to all Australians may be one area for discussion. I understand the stocks of product held by sponsors around Australia will not be available to patients using Special Access Scheme Category A. As long as this stock meets TGA standards I would ask that the Commonwealth consider regulatory change to enable access to this stock through Special Access Scheme Category A to expedite supply for the terminally ill.

Cannabidiol is captured by the Queensland legislation. This policy decision was made so that the outcomes of treatment with this medicine could be measured to determine the benefits or otherwise of its use. The Queensland legislation offers an express pathway for paediatric neurologists to prescribe cannabidiol that requires only notification to the Department rather than an approval. This, in effect means that there is no delay in prescribing but affords a higher level of scrutiny and informs the Department and the broader treatment community of the effectiveness of this treatment

The Queensland Department of Health looks forward to continuing to work closely with the Commonwealth through the COAG Health Council forum, the TGA and the Office of Drug Control on this complex matter to optimise outcomes for patients in Queensland and more broadly across Australia.

Thank you again for bringing this matter to my

Yours sincerely

CAMERON DICK MP
Minister for Health
Minister for Ambulance Services

17/.3094

JULIES –

MIN CORRO Returned unsigned from MO.

CHO Requested "withdrawal" from MO in email on 11/12/17 @ 2.52pm

13/12/17
SDHO advised hold until further notice

22/12/17
NFA Close as per Div advice