Attachment 5: Approvals Schema

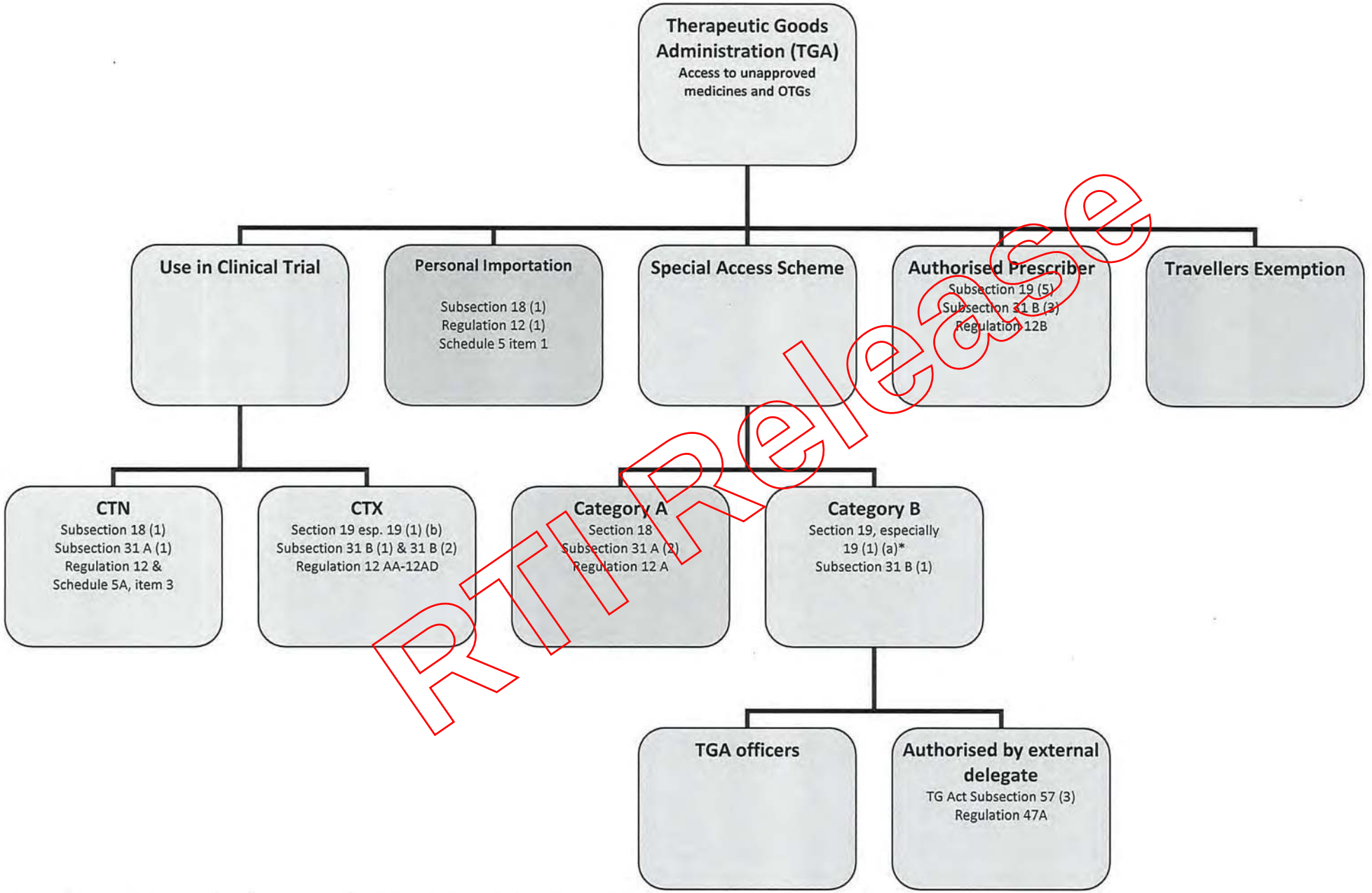

Figure 1: Access to unapproved medicines and Other Therapeutic Goods (OTGs)

Attachment 5: Approvals Schema

Personal Importation

TG Act Subsection 18 (1)
Regulation 12 (1)
Schedule 5 item 1

Personal importation occurs when:

- An individual arranges from within Australia for a therapeutic good to be sent to them from an overseas supplier or family/friend; and
- the goods are to be used by that individual or a member of his/her immediate family and are not sold or supplied to any other person.

https://www.tga.gov.au/personal-importation-scheme

You cannot import more than a **3 month supply** at the one time under the personal importation scheme. If you wish to bring **more than 3 months' supply** at the one time into Australia, an **Australian-registered** doctor will first need to apply to the TGA for Special Access Scheme approval.

The therapeutic good has to meet certain criteria including:

- not restricted under Australian Customs controls or quarantine rules and the goods do not contain a controlled substance; and
- if the goods are medicines in Schedule 4 or 8 of the Poisons Standard a prescription from an **Australian-registered** medical practitioner is held for the medicines.

To be able to import medicinal cannabis (Schedule 4 or Schedule 8 in Poisons Standard) under the TGA Personal importation scheme, the Patient/Carer - **MUST** have a Prescription from an **Australian-registered** medical practitioner

In Queensland, only a Patient-class prescriber or Single-Patient Prescriber who holds an Approval under the PHMC Act can write a prescription (s 92 Act Offences)

Attachment 5: Approvals Schema

Special Access Scheme - Category A*

TG Act - Section 18
Subsection 31 A (2)
TG Regulation 12 A

Step 1. Under Section 18 of the TG Act and Regulation 12A of the Regulations, medical practitioners can supply unapproved medicines to Category A patients but the TGA must be notified.

The medical practitioner completes the Category A form Special Access Scheme (TGA) certifying that:

- they have reached the conclusion that the patient is Category A; and
- they have obtained the **informed consent**** of the patient, or patient's guardian, to the product being given to the patient; and
- will prescribe the product in accordance with good medical practice.

https://www.tga.gov.au/sites/default/files/access-forms-sas-categorya-140901.pdf

Under section 31A(2) of Chapter 3 and section 41JD(2) of Chapter 4 of the TG Act, the TGA can require the treating medical practitioner of a Category A patient to provide to the TGA information or documents about the condition of the patient, and the supply and handling of a medicine or medical device in relation to that patient.

The TG Act allows information obtained under section 31A or section 41JD to be released to State or Territory bodies that have functions relating to therapeutic goods or that are responsible for the registration of medical practitioners or pharmacists.

Step 2.

- Medical practitioner sends signed Category A form to Australian Sponsor #

Step 3. Email to SAS@tga.gov.au or fax to 02 6232 8112 (Notification must be within 28 days. Failure to do so is an offence that carries a financial penalty under TG Act)

Queensland impacts

To be able to import medicinal cannabis under the TGA SAS Category A scheme, the Patient/Carer - **MUST** have a Prescription from a medical practitioner.

Queensland procedures remain intact

In Queensland, only a Patient-class prescriber or Single-Patient Prescriber who holds an Approval under the PHMC Act can write a prescription (s 92 Act Offences)

* Category A patients are defined in the legislation as "persons who are seriously ill with a condition from which death is reasonably likely to occur within a matter of months, or from which premature death is reasonably likely to occur in the absence of early treatment".

#Definition - A **sponsor** is a person or company who does one or more of the following:

- exports therapeutic goods from Australia
- imports therapeutic goods into Australia
- manufactures therapeutic goods for supply in Australia or elsewhere
- arranges for another party to import, export or manufacture therapeutic goods.

A full definition is provided in Chapter 1 Section 3 of the Therapeutic Goods Act 1989

† ***Public (Health Medicinal Cannabis) Act 2016***

Section 92 Offence to perform regulated activities for medicinal cannabis

(1) A person must not—

(a) perform, or attempt to perform, a regulated activity for medicinal cannabis; or

(b) agree to perform, or otherwise offer to perform, a regulated activity for medicinal cannabis.

Maximum penalty —750 penalty units (1 penalty unit = $ $121.90 - current from 1 July 2016)

****Informed Consent**

A patient should be specifically informed of the following:

- that the product is not approved in Australia;
- the possible benefits of treatment and any risks and side effects that are known;
- the possibility of unknown risks and late side effects; and
- any alternative treatments using approved products which are available.

Office of Drug Control

Travellers Exemption

A patient or a carer accompanying a patient may carry a medicinal cannabis product into Australia with no requirement for a TGA approval or notification.

The exemption only applies to medication in the persons accompanied baggage

The traveller is limited to 3 months' supply at the maximum dose recommended by the manufacturer.

1. Must obtain a prescription or letter from your doctor that outlines the name of your medication(s) and how much you are currently taking.
2. Must ensure the medication remains in its original packaging with the dispensing label intact. This will assist with identifying each substance at the border.
3. Must not bring more than a 3 month supply.
4. **Must declare all medication to Australian Border Force upon arrival.**

Queensland impacts

No person can possess a medicinal cannabis product that has not been lawfully prescribed in Queensland.

Should a person possess or use a medicinal cannabis product that has not been lawfully prescribed in Queensland, it may be an offence under s92 (1) of the *Public Health (Medicinal Cannabis) Act 2016* and *Drugs Misuse Act 1986*.

There are also likely to be offences under the *Commonwealth Customs Act 1901*

Importation would need to meet the requirements of the *Customs (Prohibited Imports)*

Attachment 5: Approvals Schema

Disallowance - items 1 and 4 of Schedule 1 of the Therapeutic Goods and Other Legislation Amendment (Narcotic Drugs) Regulation 2016 and made under the Crimes Act 1914 and the Therapeutic Goods Act 1989

Therapeutic Goods Act 1989

Section 18 Exempt goods

(1) The regulations may, subject to such conditions (if any) as are specified in the regulations, exempt:

(a) all therapeutic goods, except those included in a class of goods prescribed for the purposes of this paragraph; or
(b) specified therapeutic goods; or
(c) a specified class of therapeutic goods;

from the operation of this Part (except section 31A and sections 31C to 31F)

Attachment 4: Overview of current processes

Key Questions	Current State		Future State
Who can export?	Netherlands Canada		Israel (timeline unknown)
Who can import?	Patient Doctor Pharmacist Sponsor (other)		
How can you import MC products under each system?	Travellers exemption [3 months' supply at the maximum dose recommended by the manufacturer]	Only products that can be legally exported (No import licence and permit is required)	Should a person possess or use a medicinal cannabis product that has not been lawfully prescribed in Queensland, it may be an offence under *s92 (1) of the Public Health (Medicinal Cannabis) Act 2016* and *Drugs Misuse Act 1986.* There are also likely to be offences under the *Commonwealth Customs Act 1901* and that importation would need to meet the requirements of the Customs (Prohibited Imports) Regulation 1956.
	Personal Importation	Only products that can be legally exported and imported (ODC licence and permit required)	As Above
	SAS A	Only products that can be legally exported and imported ODC may seek declaration of evidence of compliance	As above
	SAS B	Only products that can be legally exported and imported;	As above

		and 'Bulk importation" sponsors Individual patient importation	
	Authorised prescribers	Only products that can be legally exported; and 'Bulk importation" sponsors Groups of patients (CTN and CTX importation)	As above
What regulatory instruments control quality of imported therapeutic goods?	• TGO 93 • TGO 77 • Australian Code of Good Manufacturing Practice • Australian Code of Good Wholesaling Practice for Medicines in Schedules 2, 3, 4 and 8. • Guidelines for Dispensing of Medicines published by the Pharmacy Board of Australia.		
Who regulates the quality of an imported product?	Travellers exemption	(Customs +/- State approval requirements)	
	Personal Importation	(Customs +/- State approval requirements)	
	SAS A	TGA	
	SAS B	TGA	
	Clinical Trials	TGA	
What is medicinal cannabis in Queensland?	**Meaning of *medicinal cannabis*** (1) ***Medicinal cannabis*** is a cannabis product that is— (a) not an approved good; and (b) used, or is intended by the manufacturer of the product to be used, for human therapeutic purposes. In this section— ***approved good*** means a registered good or a listed good under the *Therapeutic Goods Act 1989* (Cwlth).		
What is a cannabis product in Queensland?	**Meaning of *cannabis product*** A ***cannabis product*** is any product— (a) that is or was any part of a plant of the genus *Cannabis*, whether living or dead; or (b) otherwise derived, wholly or in part, from any part of a plant of the genus *Cannabis*, whether living or dead; or (c) that has, or is intended by the manufacturer of the product to have, a pharmacological effect that is substantially similar to the pharmacological effect of a product mentioned in paragraph (a) or (b).		

Who can obtain medicinal cannabis in Queensland?	Approval holders (Single-patient prescribers; pharmacists with a Dispensing approval and prescribers with a clinical trial approval) Patient-class prescribers		
Checks performed	• Suitability of person to hold approval (s10-Act)and (s9 –Reg) • Suitability of patient to undergo treatment with medicinal cannabis (s11 - Act) • Suitable Facility - Standard for Secure Storage and MCMP, +/-GMP,		
Who needs an approval in Queensland?	Single-patient prescribers (GP/Specialist)	Medicinal cannabis approval	
	Community Pharmacist	Dispensing approval	
	Private hospital pharmacist	Dispensing approval	
	Clinical trial prescriber	Clinical trial approval	
	Wholesaler	Wholesaling approval	
	Manufacturer	Manufacturing approval	
Who can prescribe medicinal cannabis in Queensland?	Single-patient prescribers (GP or specialist) who hold an approval		
	Patient-class prescribers (specialists under the Regulation) registered with Queensland Health for a class of patient with specified conditions. Must notify DG within 7 days.		
Term of Approvals	Medicinal Cannabis (SPP)	12 months	
	Dispensing Approval	12 months	
	Clinical Trial Approval	Duration of clinical trial	
	Patient-class Prescriber	Not specified	
	Wholesaling	2 years	
	Manufacturing	2 years	
Public Hospital pharmacy	Can dispense any medicinal cannabis product that has been lawfully prescribed in Queensland. Must have a MCMP Must notify the DG of MCMP		The Queensland legislation is silent on the issue of compounding. However, there is a capacity to make a Standard to guide the quality of compounding. **s34 PHMC Act -** Standard conditions for approvals (1) A regulation may prescribe the standard

			conditions that apply to an approval. (2) A regulation under subsection (1) may prescribe the standard conditions for an approval by reference to a code, guideline, protocol or standard relevant to the approval.
Private Hospital pharmacy (Qld)	Can dispense any medicinal cannabis product that has been lawfully prescribed in Queensland if they hold a Dispensing approval Must have a MCMP Must notify the DG of MCMP		
Community pharmacy	Can dispense any medicinal cannabis product that has been lawfully prescribed in Queensland if they hold a Dispensing approval Must have a MCMP Must notify the DG of MCMP		
Approved doctor - Dispensing	Can dispense any medicinal cannabis product that has been lawfully prescribed if they hold a Dispensing approval Must have a MCMP Must notify the DG of MCMP		

Attachment 3: Overview of impact of the disallowance

Interaction of the Therapeutic Goods Regulation 1990 and the regulation of medicinal cannabis in Queensland

On Tuesday 13th June 2017 the Senate voted to disallow amendments to the *Therapeutic Goods Regulations 1990* (Cth). Specifically, medicinal cannabis products can now be accessed under the *Therapeutic Goods Act 1989* (Cth) (TG Act) via:

- the Special Access Scheme Category A (SASA) for the seriously ill with a condition from which death is reasonably likely to occur within a matter of months, or from which premature death is reasonably likely to occur in the absence of early treatment.
- traveller's exemption (TE) for travellers under treatment of a medical practitioner may travel to Australia with medicinal cannabis products for their own personal use
- personal importation (PI) for a patient or their immediate family to import medicinal products (i.e. by person) with no requirement for any other TG approval as they are already exempt.

Section 6 of the *Public Health (Medicinal Cannabis) Act 2016* (Qld) (MC Act) defines 'medicinal cannabis' to mean:

Meaning of *medicinal cannabis*

(1) ***Medicinal cannabis*** is a cannabis product that is—

(a) not an approved good; and

(b) used, or is intended by the manufacturer of the product to be used, for human therapeutic purposes.

In this section—

approved good means a registered good or a listed good under the *Therapeutic Goods Act 1989* (Cwlth).

The table below looks at the interaction between Commonwealth (Cwth) legislation and medicinal cannabis approvals in Queensland under the *Public Health (Medicinal Cannabis) Act 2016* (Qld) (MC Act) and *Public Health (Medicinal Cannabis) Regulation 2017* (Qld) (MC Regulation).

Qld legislation	Intent	Cwth law	Intent	Issues	Options
Product					
MC Act s24(1)(i); (2)(c) s26(1)(c); (2)(b)	The chief executive may only grant an approval under the MC Act for a single–patient prescriber (SPP) or a clinical trial (CT) if the medicinal cannabis product to be used is manufactured or imported in accordance with the applicable law of the Commonwealth. This does not specifically require that the product must be accessed through any specific Commonwealth entity, including, for	TG Act, *Customs (Prohibited Imports) Regulations 1956* (Cth) (CPIR) and Therapeutic Goods Order 93 (standard for medicinal cannabis) (TGO93)	The importation of cannabis is administered by the Commonwealth Office of Drug Control (ODC). CPIR allows for the import of cannabis if the import is pursuant with the TG Act. TGO 93 is a standard to ensure the safety and efficacy of medicinal cannabis products, by ensuring that the products are manufactured uniformly, according to a quality standard. ODC can require TGO 93 as a requirement for an import approval.	For SASB and Authorised Prescriber (AP) applications only, the Therapeutic Goods Administration (TGA) will continue to check compliance with TGO 93 of any products requested and inform ODC. However, the SASA process allows use of a product before notification of the TGA compliance with TGO 93. Therefore, compliance with TGO 93 cannot be guaranteed.	As a part of the SASA and TE process, the TGA may disclose information to State and Territory authorities with responsibility for therapeutic goods or medical practitioner registration. Qld Health could require verification from the prescriber that the product to be used has been imported

Qld legislation	Intent	Cwth law	Intent	Issues	Options
	example, through the SASA or Special Access Scheme Category B (SASB). Likewise section 53 allows a patient-class prescriber (PCP) to prescribe a 'compliant' medicinal cannabis product that has the same requirements as above.				and manufactured in accordance with the applicable law and standards as criteria for granting an approval (i.e. TGO93).
Schedule 1: definition of 'compliant' medicinal cannabis' REQUIRES (through the word 'and') to be manufactured, imported, approved, or authorised to be supplied, in	***compliant***, for medicinal cannabis, means the medicinal cannabis has been— (a) prescribed, for the treatment of, or use by, a patient, in accordance with this Act; and (b) dispensed in accordance with this	TG Act, *Customs (Prohibited Imports) Regulations 1956* (Cth) (CPIR) and Therapeutic Goods Order 93 (standard for medicinal cannabis)	As above	The following are only allowed to obtain and possess compliant medicinal cannabis: - patient-class prescriber - eligible patient (PCP) - Carers - SPP - Patient (SPP) - Restricted access	As above. The impact of this is that anyone in possession of medicinal cannabis products that do not meet the definition of compliant is in contravention of the MC Act.

Qld legislation	Intent	Cwth law	Intent	Issues	Options
accordance with Cth laws, 53(2); 54(2); 55(1) 57(2); 59(2); 60(1); 61(1)(a);	Act, including any lawful direction under this Act; and (c) if the medicinal cannabis is the subject of a medicinal cannabis approval—prescribed and dispensed in accordance with the approval; and (d) manufactured or imported in accordance with the applicable law of the Commonwealth; and (e) approved, or authorised to be supplied, for the purpose of treating the patient, in accordance with the applicable law of the	(TGO93)		patient	

Qld legislation	Intent	Cwth law	Intent	Issues	Options
	Commonwealth.				
Qld legislation	Intent	Cwth law	Intent	Issues	Options
QH and TGA approvals					
MC Act s38(b)(vi) single-patient prescriber (SPP); s57(patient-class prescribers (PCP) and s66 clinical trials (CT)	Qld approvals for SPP and PCP and CT do not require having a TGA approval, however, make reference to the approval holder complying with the conditions of a TGA approval, if there is one.	TG Act	SASA: Access to unapproved therapeutic goods for the seriously ill with a condition from which death is reasonably likely to occur within a matter of months, or from which premature death is reasonably likely to occur in the absence of early treatment. https://www.tga.gov.au/form/special-access-scheme SASB: Access to unapproved therapeutic goods for all other patients that do not fit the Category A definition. https://www.tga.gov.au/form/special-access-scheme An AP (medical practitioner) may be granted authority by the TG to prescribe a specified unapproved therapeutic good (or class of unapproved therapeutic goods) to specific patients (or classes of recipients) with a particular medical condition. https://www.tga.gov.au/form/authorised-	SAS B and AP require TGA approval before prescribing a product. SASA does not require a TGA approval, and only requires a notification to the TGA 28 days after commencing treatment. Cannabis was previously only accessible through SASB and AP processes, which provided some scrutiny of the product. With the inclusion of SASA for access to medicinal cannabis - which does not require prior clinical support for the medicinal cannabis treatment – that people may access	All access to medicinal cannabis products in Queensland must be pursuant to an approval under the MC Act or MC Regulation. This is regardless of any **requirement** for a TGA approval. Should a person **unlawfully** obtain, possess or use a medicinal cannabis product in

Qld legislation	Intent	Cwth law	Intent	Issues	Options
			prescribers	cannabis via SASA without clinical evidence to support this as an appropriate treatment.	Queensland, it may be an offence under s92 MC Act, and under the *Drugs Misuse Act 1986* (Qld).

References to TGA & Cth in the MC Regulation	
• s.51(1)(d) – If there is a TGA approval in existence, for MC approvals under the MC Act – must comply with conditions of the TGA approval • s.52(1)(d) - If there is a TGA approval in existence, for dispensing approvals granted under the MC Reg – must comply with conditions of the TGA approval • s.57(2)(d) - If there is a TGA approval in existence, for PCP MC approvals granted under the MC Act – must comply with conditions of the TGA approval	The following provisions make reference to Commonwealth law but will not be impacted by changes brought about by the Senate disallowance: • s.7 • s.9(1)(c) • s.37 – relevant to s.92(2)(b) of the MC Act – manufacturing MC • s.80 – regarding packaging s.81 regarding labelling

ISSUES

1. **Product quality:** For SASB and AP applications, TGA will continue to check compliance with TGO 93 of any products requested. As SAS A notification does not need to be reported to TGA until up to 28 days after use, the TGA may not know of the use of the product until after its use. ODC are

considering how to seek a declaration or evidence of compliance with TGO 93 when a future importer applies for import permission for the product.

a. Noting an application for import permission would require evidence of State/Territory approval, where required, it is likely the prescriber would come to the State/Territory prior to requesting import permission. Hence the State/Territory would not know whether the product complies with TGO 93. Further, whether the product is a Schedule 4 restricted drug (S4) or a Schedule 8 controlled drug (S8) would not be known without a Certificate of Analysis (CoA). Therefore, the States/Territories may need to ask for a CoA of the product subject to State/Territory approval, at the application stage.

b. Queensland currently requests a copy of the CoA from the SPP but not the PCP and as a result Queensland has no ability to ensure the quality of medicinal cannabis product being supplied to a patient through PCP and SASA processes.

c. The MC Act and MC Regulation provides for the DG to request information through an 'Information Requirement Notice' to assist in determining an approval. If TGO 93 is deemed a critical requirement, a specific amendment could be included in the MC Act & MC Regulation as a requirement for consideration of any approval.

d. An important question is should QH be taking on this role of checking quality in any event? Should Qld approvals be issued with the same disclaimer as TGA SAS approvals – where the TGA also hasn't checked quality of the product – where it clearly states that QH bears no responsibility for quality etc. of the product which is not tested by QH and doctors prescribe, pharmacists dispense & patients use – at their own risk

2. **Qld approvals are independent of TGA:** even with changes to allow for access through the Commonwealth SASA, traveller's exemption and other personal importation processes, to prescribe a medicinal cannabis product in Queensland an approval under the MC Act or MC Reg (for manufacturing/ wholesaling) would still be required.

a. The TGA Traveller's Exemption allows a patient or a carer accompanying a patient (such as an immediate family member' of the person) to carry a medicinal cannabis product into Australia with no requirement for a TGA approval or notification. The traveller is limited to three (3) months' supply at the maximum dose recommended by the manufacturer. There is no requirement currently for import permission in these circumstances. https://www.tga.gov.au/entering-australia

b. Further changes to personal importation restrictions mean that a patient or their immediate family can import medicinal products (i.e. by post – provided the use of the postal service is not in breach of any laws, e.g. illicit drugs (incl. cannabis) is not able to be carried by Australia Post) with no requirement for any other TG approval as already exempt. It is limited to three (3) months' supply at maximum dose recommended by the manufacturer and requires a written authority issued by a medical practitioner registered under a law of the state or territory (this does not apply to traveller above). However, importation still requires an import licence and permit from the Office of Drug Control. https://www.tga.gov.au/personal-importation-scheme

c. Once entering Australia the state/territory medicinal cannabis regulation would come into play. In Queensland, there is no legal avenue for the possession and use a medicinal cannabis product that has been lawfully prescribed under the law of another country. The person would need to have a prescription pursuant to an approval under the MC Act. Should a person possess or use a medicinal cannabis product that has not been lawfully prescribed in Queensland, it may be an offence under s92 (1) of the MC Act, and may also be an offence under the *Drugs Misuse Act 1986*.

3. **Less oversight:** a PCP only needs to notify QH within 7 days of commencing treatment with a medicinal cannabis product. Further if the TGA approval is under SASA the doctor only needs to notify the TGA within 28 days of commencing treatment with a medicinal cannabis product. Therefore there will be a class of doctors, treating specific patients under the MC Act, which will not require any approval to prescribe MC.

4. **Importation delays:** Commonwealth changes to allow for bulk importation are restricted to SASB approvals so that all PI and SASA approvals will need to be imported directly from the overseas manufacturer. This may cause significant delays (up to 3 months) and increased costs associated with importing the products on a case by case basis. At this stage the Commonwealth has not discussed changing this requirement but it is likely to be identified as significant burden by stakeholders.

5. **Streamlining processes:** there may be pressure from stakeholders to streamline the Qld approval processes as this will be one of the few remaining rate limiters on a patient getting access to medicinal cannabis products.

Managing Conduct

SASA does not require an approval, and allows for any doctor treating a patient with a life threatening illness. It is important to note that the SASA does have notification requirements and the TGA has the ability to suspend, cancelled or impose conditions on the SASA.

Section 10(f) of the MC Act states that in deciding whether a person is a suitable person to hold, or to continue to hold, an approval, the chief executive may have regard to, and may make inquiries about:

> whether the person—
> (i) has held a similar instrument under a relevant law that was suspended, cancelled or had conditions imposed on it; or
> (ii) has been refused a similar instrument under a relevant law.

> ***relevant law*** means the following—
> (a) this Act;
> (b) the Health Act 1937
> (c) a corresponding law (includes the *Therapeutic Goods Act 1989* (Cwlth)).

As stated above the chief executive may have regard for any conditions imposed on a previous SASA while considering a treatment approval in Queensland.

Ministerial Brief for Approval

Department RecFind No:	
Division/HHS:	Prevention Division
File Ref No:	

SUBJECT: **Response to letter from Commonwealth Minister for Health, Greg Hunt, including an overview of issues raised by the disallowance of amendments to *Therapeutic Goods Regulations 1990.***

Recommendation/s

It is recommended the Minister:

1. **Note** the disallowance of a range of amendments to the Therapeutic Goods Regulations 1990 (Cth) by the Australian Senate, will have significant implications for the access and authorisation of medicinal cannabis products in Queensland.

   NOTED **PLEASE DISCUSS**

2. **Sign** the attached letter to the Commonwealth Minister for Health (Attachment 2) responding to issues raised about the streamlining approval pathways and the impact of the disallowance on Queensland.

   APPROVED / NOT APPROVED **PLEASE DISCUSS**

Cameron Dick MP **Date:** / /
Minister for Health and Minister for Ambulance Services

Issue/s

1. On 30 May 2017, the Commonwealth Minister for Health, Mr Greg Hunt, wrote a letter seeking the Queensland Minister for Health and Minister for Ambulance Services assistance to find a way for the Council of Australian Governments (CoAG) Health Council to further streamline the approval pathways for medicinal cannabis products. The letter is at Attachment 1.
2. In the letter Mr Hunt provides a number of suggestions for how Queensland could contribute to a more streamlined and seamless system.
3. On 13 June 2017, the Australian Senate voted to disallow amendments to the Therapeutic Goods Regulations 1990 (Cth). Specifically, medicinal cannabis products can now be accessed under the Therapeutic Goods Act 1989 (Cth) (TG Act) via:
   - 3.1 the Special Access Scheme Category A (SASA) for terminally ill patients;
   - 3.2 traveller's exemption for travellers under treatment of a medical practitioner may travel to Australia with medicinal cannabis products for their own personal use;
   - 3.3 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
   - 3.4 extemporaneous compounding has been expanded from the public hospital system to include private companies that can be accessed by the public.
4. An overview of how these changes will impact the Queensland regulatory framework is provided in Attachments 2, 3 and 4.

Michael Walsh
Director-General
/ /2017

Department RecFind No:	
Division/HHS:	
File Ref No:	

5. A number of issues raised in the letter from Mr 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 (provided in Attachment 5) highlights the concerns that Queensland Health (the Department) has about the framework.
6. 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 Department 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.
7. 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.

Vision

8. Enabling Safe, quality services: Continuously improve clinical governance systems and regulatory frameworks to ensure accountable and safe, high quality health services.

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.

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 call 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 have allowed several companies to undertake bulk importation under changes made to the TG Regulation in February 2017. Six companies have since been approved as wholesalers in Queensland.

Sensitivities

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 from Mr Greg Hunt, Commonwealth Minister for Health
    Attachment 2: Overview of the impact of the disallowance on the Queensland
    Attachment 3: Overview of current processes
    Attachment 4: Approvals Schema
    Attachment 5: Response letter to Mr Hunt

Department RecFind No:	
Division/HHS:	
File Ref No:	

Department Contact Officer

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

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[redacted]	[redacted]	[redacted]
20 June 2017	21 June 2017	XX June 2017

Ministerial Brief for Approval

Department RecFind No:	
Division/HHS:	Prevention Division
File Ref No:	

SUBJECT: **Response to letter from Commonwealth Minister for Health Greg Hunt, including overview of issues raised by the disallowance of amendments to *Therapeutic Goods Regulations 1990*.**

Recommendation/s

It is recommended the Minister:

1. **Note** the disallowance of a range of amendments to the *Therapeutic Goods Regulations 1990* (Cth) by the Australian Senate will have significant implications for how access to medicinal cannabis products will be authorised and will have a flow on effect to the Queensland regulatory framework.

   NOTED **PLEASE DISCUSS**

2. **Sign** the attached letter to the Commonwealth Minister for Health (Attachment 2) responding to issues raised about the streamlining approval pathways and the impact of the disallowance on Queensland.

   APPROVED / NOT APPROVED **PLEASE DISCUSS**

Cameron Dick MP
Minister for Health and Minister for Ambulance Services

Date: / /

Ministerial Office comments

Issue/s

1. On 30 May 2017, the Commonwealth Minister for Health, Mr Greg Hunt, wrote a letter seeking your assistance to find a way for the Council of Australian Governments (CoAG) Health Council to further streamline the approval pathways for medicinal cannabis products. The letter is provided in attachment 1.
2. In the letter Mr Hunt provides a number of suggestions for how Queensland could contribute to a more streamlined and seamless system including:
   - Reducing duplication of information requirement between TGA and Queensland Health;
   - Providing a fast-tracked process for terminally ill patients;
   - Regulating medicinal cannabis like other Schedule 8 medicines
   - Better communication around how long applications take to be processed in Queensland
   - Removing the need to have separate pharmacy approvals
   - Review the need to approve the use of cannabidiol (CBD) under the Public Health (Medicinal Cannabis) Act 2016.

Michael Walsh
Director-General
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3. On 13 June 2017, the Australian Senate voted to disallow amendments to the Therapeutic Goods Regulations 1990 (Cth). Specifically, medicinal cannabis products can now be accessed under the Therapeutic Goods Act 1989 (Cth) (TG Act) via:
   - the Special Access Scheme Category A (SASA) for the seriously ill with a condition from which death is reasonably likely to occur within a matter of months, or from which premature death is reasonably likely to occur in the absence of early treatment;
   - traveller's exemption for travellers under treatment of a medical practitioner may travel to Australia with medicinal cannabis products for their own personal use
   - personal importation for a patient or their immediate family to import medicinal products (i.e. by person) with no requirement for any other Therapeutic Goods Administration (TGA) approval as they are already exempt.
   - Extemporaneous compounding has been expanded from the public hospital system to include private companies that can be accessed by the public
4. An overview of how these changes will impact the Queensland regulatory framework is provided in attachment 2,3 and 4.
5. A number of issues raised in the letter from Mr Hunt will be affected by the disallowance; particularly the TGA's ability to ensure the quality of the medicinal cannabis product provided to patient through some access pathways. The response letter (provided in attachment 5) highlights the concerns that Queensland Health has about the framework and suggests ways to improve access to medicinal cannabis stocks for patients.
6. 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. Queensland Health is concerned about the TGA's ability to ensure the quality of the product to be used and can see benefits in patients have easier access to medicinal cannabis products as long as quality and safety can be addressed.
7. 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 ODC part of the process. More work will need to done with ODC to fully map and resolve these issues over coming weeks.

Vision

8. Enabling Safe, quality services: Continuously improve clinical governance systems and regulatory frameworks to ensure accountable and safe, high quality health services.

Results of Consultation

9. Preliminary discussions have been undertaken with the TGA and the Office of Drug Control (ODC)

Resource Implications (including Financial)

10. This will be managed within existing resource allocation.

Background

11. On 11 May 2017, the disallowance, proposed by the Senator De Natalie was defeated in the Senate only for a revote to be call for by Senator Jackie Lambie due to her absence from the

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initial vote. The disallowance was upheld on the revote due to support from One Nation who had previously rejected the disallowance.

12. The TGA have allowed several companies to undertake bulk importation under changes made to the TG Regulation in February 2017. Six companies have since been approved as wholesalers in Queensland.

Sensitivities

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 from Mr Greg Hunt, Commonwealth Minister for Health
    Attachment 2: Overview of the impact of the disallowance on the Queensland
    Attachment 3: Overview of current processes
    Attachment 4: Approvals Schema
    Attachment 5: Response letter to Mr Hunt

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