Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Dr John Tsingos

Our Reference: MAP22-0043395

Dear Dr Tsingos,

Notice of decision to grant an authority under subsection 19(5) of the *Therapeutic Goods Act 1989* (Authorised Prescriber Scheme) in relation to:

Product: Category 1-CBD medicinal cannabis product (CBD≥98%) - - Capsule

I refer to your application dated 13 Dec 2022 seeking an authority to supply specified therapeutic goods for use in the treatment of humans, to a specified class of recipients under subsection 19(5) of the *Therapeutic Goods Act 1989* (**the Act**).

Decision

As a delegate of the Secretary of the Department of Health and Aged Care under subsection 19(5) of the Act I have decided to grant an authority:

- to the specified medical practitioner identified in column 1 of **Schedule 1** to this notice ('the Authorised Prescriber');
- to supply the specified therapeutic goods, or class of goods, identified in column 2 of **Schedule 1** for the indication(s) identified in column 3;
- for supply to a class of recipients (patients) suffering from a life-threatening, or otherwise serious illness or condition.

When supplying the goods, you must comply with:

- the treatment directions (if any) identified in column 4 of **Schedule 1** (subsection 19(7) of the Act and subregulation 12B(3) of the *Therapeutic Goods Regulations 1990* (**the Regulations**) refer); and
- the conditions referred to below.

Reasons

I grant this authority having considered the information in the application including evidence of approval of an ethics committee or endorsement from a specialist college.
I am satisfied that each of the following requirements is met:

- **Class of medical practioners**
  The Authorised Prescriber is included in the class of medical practitioners being medical practitioners engaged in clinical practice in or outside a hospital (paragraph 19(6)(a) of the Act and subregulation 12B(1) of the Regulations refer);

- **Approval of ethics committee/endorsement from specialist college**
  The Authorised Prescriber has the approval of National Institute of Integrative Medicine (NIIM) Human Research Ethics Committee (HREC) to supply the specified therapeutic goods, or class of goods (paragraph 19(6)(aa) of the Act refers);
- **Class of recipients**
  The class of recipients (patients) consists of persons each of whom is suffering from a life-threatening, or otherwise serious, illness or condition (paragraph 19(6)(b) of the Act and subregulation 12B(2) refers).

Conditions

This authority is granted subject to the following conditions (if any) imposed by me in accordance with subsection 19(5A) of the Act:

The Authorised Prescriber ('you') must only prescribe the specified therapeutic goods or class of goods ('the product') for patients under your immediate care.

If your registration as a medical practitioner is suspended or cancelled, you must notify the TGA within 5 business days of you receiving notification of the suspension or cancellation.

You must obtain informed consent in writing from each patient (or guardian) in relation to the proposed use of the product. Before obtaining consent, you must inform the patient that the product is not in the Australian Register of Therapeutic Goods and has not been evaluated for quality, safety and efficacy in the Australian context.

You must instruct the patient (or guardian) to return any unused product to you or to a pharmacy for destruction.

You must report any suspected adverse reaction to the product to the TGA within 15 calendar days after becoming aware of the reaction.

You must report any fatal or life-threatening adverse reaction to the product to the TGA within 7 calendar days after becoming aware of the reaction. You must follow up with a complete report (if not provided within the 7 calendar day period) within 8 additional calendar days.

You must also report any suspected adverse reaction to the product to the ethics committee or specialist college which provided approval or endorsement.

You must continue to have the approval of the ethics committee or the endorsement of the specialist college to supply the product.

If the ethics committee or specialist college suspends, withdraws or revokes the approval or endorsement, you must notify the TGA within 7 calendar days after becoming aware of this.

You must prescribe the product only for use in adult patients (over 18 years) except where the HREC or specialist college has provided explicit endorsement for use in the paediatric population.

You must ensure that other medical practitioners involved in the treatment of a patient's conditions are kept informed of the use of the product and progress to ensure good medicine practice.

Other information

This product is included in Schedule 4 of the Customs (Prohibited Imports) Regulations 1956. The Drug Control Section (DCS) of the Department of Health is responsible for issuing import permits and licences for substances controlled under Schedule 4 of these Regulations. The contact email address for DCS is DCS@health.gov.au

Patients should not drive or operate machinery while being treated with medicinal cannabis. In addition, measurable concentrations of THC (tetrahydrocannabinol – the main psychoactive substance in cannabis) can be detected in urine many days after the last dose. It may take up to five days for 80 to 90 per cent of the dose to be excreted. Drug-driving is a criminal offence, and patients should discuss the implications for safe and legal driving with their doctor

Reporting requirements

Under regulation 47B of the Regulations, you are required to report details of the supply of the therapeutic good to the Secretary on a six monthly basis. The reporting periods are for 1 January to 30 June, and 1 July to 31 December, respectively. Reports must be provided within one calendar month of the reporting period ending. It is preferred the report is provided using the SAS & AP Online System, available at https://compliance.health.gov.au/sas/ however a paper form is available from the Authorised Prescriber webpage for exceptional circumstances.

Review rights

Your review rights in relation to this decision are outlined at **Schedule 2** to this notice.
Please contact the Authorised Prescriber team by phone on 02 6289 4632 or email to authorised.prescribers@health.gov.au for further queries regarding this matter.

Period authority is in effect

This authority has effect for the period commencing on the date of this notice until 11 Feb 2025, unless the Secretary (or a delegate) decides to revoke the authority sooner.
Dated 13 Dec 2022

Dean APOLLONI
Delegate of the Secretary
Therapeutic Goods Administration

Schedule 1:

Details of authority granted under subsection 19(5) of the *Therapeutic Goods Act 1989*

Reference (MAP22-0043395)

Column 1 Authorised Prescriber	Column 2 Specified therapeutic goods (or class of goods)	Column 3 Indication(s)	Column 4 Treatment directions (if any)
Dr John Tsingos (MED0001332063) South Juniors Medical Centre 558A Anzac Pde Kingsford NSW 2032	Category 1-CBD medicinal cannabis product (CBD≥98%) - - Capsule	For the following indication(s): 1. Alzheimer's Disease 2. Anorexia 3. Anxiety 4. Attention Deficit Disorder with Hyperactivity (ADHD) 5. Autism Spectrum Disorder (ASD) 6. Cachexia 7. Cancer symptom management 8. Cancer-related pain 9. Chemotherapy-Induced Nausea and Vomiting (CINV) 10. Chronic non-cancer pain 11. Crohn's Disease 12. Dementia 13. Depression 14. Endometriosis 15. Epilepsy 16. Inflammatory Bowel Disease (IBD) 17. Insomnia 18. Irritable Bowel Syndrome (IBS) 19. Mood Disorder 20. Multiple Sclerosis 21. Neuropathic Pain 22. Osteoarthritis 23. Palliative Care 24. Parkinson's Disease 25. Post-Traumatic Stress Disorder (PTSD) 26. Seizure Management 27. Sleep Disorder 28. Spasticity 29. Spasticity-associated Pain	

Schedule 2:

Request for reconsideration of an initial decision

This decision is a reviewable initial decision under section 60 of the Act. Under section 60, a person whose interests are affected by a 'reviewable' initial decision, can seek reconsideration of the initial decision.

As this document constitutes written notice of the making of an initial decision being given by the Secretary, a request for reconsideration of this initial decision must be given to the Minister in writing within 90 (calendar) days after the initial decision notice is given and be accompanied by any information that you wish to have considered by the Minister. A request for reconsideration given to the Minister outside the statutory 90 day reconsideration period cannot be accepted.

The Minister may either personally undertake a request for reconsideration of an initial decision or delegate this function to an officer of the Department with the appropriate delegation.

Under section 60(3A) of the Act, the Minister (or the Minister's delegate) is not able to consider any information provided after the making of a request for reconsideration of an initial decision unless the information is provided in response to a request from the Minister (or the Minister's delegate), or it is information that indicates that the quality, safety or efficacy of the relevant therapeutic goods is unacceptable.

Guidelines for requesting reconsideration of an initial decision

Prior to requesting reconsideration of an initial decision, persons affected by an initial decision are advised to refer to the TGA website https://www.tga.gov.au/reconsideration-reviewable-initial-decisions for specific information and detailed guidance for making a request for reconsideration. A request for reconsideration should then be made in writing, signed and dated by the person requesting reconsideration and should include the following:

- a copy of the initial decision notification letter, i.e. this letter (or other evidence of notification);
- identify, and describe with as much specificity as possible, which component(s) of the initial decision should be reconsidered and set out the reasons why reconsideration is requested;
- any information/documentation in support of the request, clearly labelled to correspond with (any or each of) the reasons why reconsideration is requested; and
- an email address nominated for the purposes of receiving correspondence in relation to the request for reconsideration.

All requests for reconsideration should be given to the Minister by email:
Email: **'decision.review@health.gov.au'**
Subject: **"<insert name of person/company making request>** - Request for Reconsideration Under Section 60 of the Therapeutic Goods Act 1989"

Requests for reconsideration that include material which cannot be attached to a single email, may be submitted under multiple, sequentially numbered emails (e.g. "… - Email 1 of 3", "… - Email 2 of 3" etc). All sequentially numbered emails must be given to the Minister on the same date.

Under section 60 of the Act, the decision upon reconsideration by the Minister (or the Minister's delegate) must be to either 'confirm', 'revoke' or 'revoke and substitute' the initial decision. The Minister (or the Minister's delegate) must give notice in writing of the outcome of the decision upon reconsideration to the person whose interests are affected, within 60 (calendar) days after making a

request for reconsideration. If the Minister (or the Minister's delegate) fails to give such notice within 60 days, the Minister (or the Minister's delegate) is deemed to have confirmed the initial decision.

Subject to the Administrative Appeals Tribunal Act 1975 (AAT Act), if you are dissatisfied with the decision upon reconsideration by the Minister (or the Minister's delegate), you can apply to the Administrative Appeals Tribunal (AAT) for a review of that decision upon reconsideration.

NOTE: This initial decision remains in effect unless and until it is revoked or revoked and substituted by the Minister (or the Minister's delegate) as a result of a request for reconsideration under section 60 of the Act OR is set aside, varied or remitted by the AAT or is otherwise overturned or stayed.