Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Ms Shannan Opia
Greenhouse Medical
1 Lake Orr Drive
Varsity lakes QLD 4227
Email: support@hellomello.com.au
Ref: MB24-1239631

Notice of decision to grant an approval
under paragraph 19(1)(a) of the *Therapeutic Goods Act 1989*
(Special Access Scheme – Category B)

I refer to the application made on 23 Jul 2024 seeking approval by the Secretary of the Department of Health and Aged Care to a health practitioner for the importation into, the exportation from, or the supply in Australia of specified therapeutic goods (namely, a specified medicine) that are not registered goods, listed goods or exempt goods for use in the treatment of another person in accordance with paragraph 19(1)(a) of the *Therapeutic Goods Act 1989* (**the Act**).

This is a notice of decision given to you in accordance with subsection 19(4) of the Act.

Decision
I am a delegate of the Secretary of the Department of Health and Aged Care for the purposes of section 19(1) of the Act. I have decided to grant approval to Ms Shannan Opia (NMW0001455874) (the **approval holder**) identified in column 1 of Schedule 1 to this notice to import into, export from, or supply in Australia the specified medicine identified in column 2 of Schedule 1 for use in the treatment of the patient identified in column 3.

Reasons for decision
I have decided to grant this approval having considered the application made on 23 Jul 2024 and the information provided with that application.

In making this decision, I am satisfied that:

(a) the specified medicine is not included in the Australian Register of Therapeutic Goods (**Register**) or otherwise exempt from the requirement to include the specified medicine in the Register;

(b) the importation into, the exportation from, or the supply in Australia of the specified medicine is for use in the treatment of another person; and

(c) the approval holder is a health practitioner within the meaning of the Act.

Conditions

This approval is granted subject to the following conditions imposed by me in accordance with subsection 19(1) of the Act:

1. the approval holder must only import into, export from, or supply in Australia the specified medicine for use in the treatment of the patient in the manner described in the application;
2. the approval holder, and the patient (or the person with the legal authority to consent to the treatment on behalf of the patient) must accept responsibility for the outcome of the use of the specified medicine;
3. the approval holder must obtain and record informed consent from each patient (or the person with the legal authority to consent to the treatment on behalf of the patient) in relation to the proposed use of the product, in accordance with professional practice standards and the AHPRA Code of Conduct;
4. the approval holder must report adverse events or defects associated with the use of the specified medicine to the TGA within 15 calendar days after the approval holder becomes aware of the adverse event. The preferred reporting route is via the online portal https://aems.tga.gov.au;
5. the approval holder must adhere to all standards of professional practice and conduct, as governed by the relevant professional regulatory authority.

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.

Information is limited on the use of medicinal cannabis products in children and young adults. As extra care is needed, it is expected that paediatric specialists or relevant medical specialists are involved in the management of paediatric patients, in particular products containing THC (category 2- 5).

This product is authorised for inhalation via vaporisation only. If vaporized cannabis is to be used, it is recommended that the device selected has been studied in a research setting and found to be safe and effective

Please note that it is the responsibility of the approval holder to arrange for the importation into, exportation from, or the supply in Australia of the specified medicine and to provide evidence of this approval to the person or persons with whom the importation into, the exportation from, or the supply in Australia is arranged.

Additional restrictions may be placed on the importation of therapeutic goods as outlined below. You will need to check with the relevant agencies to obtain permission if required.

- *Customs (Prohibited Imports) Regulations 1956* - import permits and licences are required for substances controlled under these Regulations. Contact the Office of Drug Control at NCS@health.gov.au for further information.

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- *Biosecurity Act 2015* - permission may be required prior to importing any material of biological origin (human, animal, plant or microbial). Contact the Department of Agriculture, Water and the Environment at imports@agriculture.gov.au for information.
- *Environment Protection and Biodiversity Conservation Act 1999* - permission may be required prior to importing endangered species. Contact the Department of Agriculture, Water and the Environment at wps@awe.gov.au for information.
- *Gene Technology Act 2000* – permission may be required prior to importing genetically modified organisms. Email the Office of the Gene Technology Regulator (OGTR) at ogtr@health.gov.au for information.
- State and territory requirements - contact the relevant state/territory health department for further information.

Period of approval

This approval has effect for a period of 24 Month(s) commencing on the date of this notice, unless the Secretary (or a delegate) decides to revoke the approval.

Dated 24 Jul 2024

Renu BHUTKAR
Delegate of the Secretary
Therapeutic Goods Administration

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Schedule 1

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Column 1 Approval holder	Column 2 Specified medicine	Column 3 Patient	Column 4 Conditions
Ms Shannan Opia (NMW0001455874) Greenhouse Medical 1 Lake Orr Drive Varsity lakes QLD 4227	*Medicine:* Category 5-THC Medicinal Cannabis Product (THC greater than 98%) *Product description:* Herb, dried (for vaporisation)	*Patient initials:* AS *Patient gender:* Female *Patient DOB:* 25 Jul 1989	*Purpose:* Anxiety *Dosage:* As per prescription

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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/resources/resource/guidance/guidance-requesting-reconsideration-initial-decision> 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"

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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.

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