



Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Miss Jenni McCluskey
Jenni McCluskey
174 Corio Street Shepparton
3 Hindmarsh court
Shepparton VIC 3630
Email: jenni.mccluskey@hotmail.com
Ref: MB23-0886195

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 02 Mar 2023 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 Miss Jenni McCluskey (NMW0001044335) (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 02 Mar 2023 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 informed consent in writing from the 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 specified medicine;
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 become aware of the adverse event. The preferred reporting route is via the online portal <https://aems.tga.gov.au>;

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

You should note that the above product is included in Schedule 8 of the Standard for Uniform Scheduling of Medicines and Poisons (SUSMP) and therefore it will be necessary to comply with any relevant State or Territory legislation.

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.

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 02 Mar 2023

Nasis ELLIS
Delegate of the Secretary
Therapeutic Goods Administration

Schedule 1

Reference: MB23-0886195

Column 1 Approval holder	Column 2 Specified medicine	Column 3 Patient	Column 4 Conditions
Miss Jenni McCluskey (NMW0001044335)	<i>Medicine:</i> Category 3-Balanced medicinal cannabis product (CBD less than 60% and ≥40%)	<i>Patient initials:</i> MT <i>Patient gender:</i> Male <i>Patient DOB:</i> 09 Oct 1969	<i>Purpose:</i> chronic pain <i>Dosage:</i> As per prescription
Jenni McCluskey 174 Corio Street Shepparton 3 Hindmarsh court Shepparton VIC 3630	<i>Product description:</i> Oral Liquid		