



ASX & MEDIA RELEASE

23 NOVEMBER 2017

## UPDATED TGA RULES ASSIST MEDICAL PRACTITIONER ACCESS TO MEDLAB'S CANNABIS PRODUCTS

- Recent changes to the TGA's Special Access Scheme make Medlab's cannabis medicines available based on specific needs
- Medical practitioners can prescribe Medlab's NanaBis™ (Cannabis CBD/THC pain product) and NanaBidial™ (Cannabis CBD seizure product) under TGA guidelines
- Medlab's Australian manufactured cannabis product expected to be available in late February 2018.
- Medlab allowed to import significantly larger annual volumes of cannabis

**As medical life science company, Medlab Clinical Limited (ASX: MDC), prepares to commence its first clinical trial of a cannabis-based medicine shortly at the Royal North Shore Hospital, the Therapeutic Goods Administration (TGA) has announced changes to its Special Access Scheme to allow medical practitioners to use this type of cannabis medicine.**

The effect of changes to the TGA's Special Access Scheme<sup>2</sup> is to make it easier for medical practitioners to prescribe cannabis-based medicines for patients in need, under certain conditions (see attached TGA flow chart).

**This clinical trial of Medlab's cannabis-based medicine (NanaBis™) is understood to be the first of its kind in the world.**

The clinical trial will take place at Royal North Shore Hospital in Sydney, under the supervision of Professor Stephen Clarke OAM, a medical oncologist, palliative medicine specialist and Professor of Medicine at the University of Sydney. Patients in the trial will be seriously ill oncology patients and would be administered NanaBis™ to assist pain management and in place of opioids.

### Commentary

According to Medlab CEO, Sean Hall, continued support from the medical community and Therapeutic Goods Administration for cannabis-based medicine was pleasing.

"In pursuing a clinical trial route, we are seeking to make our medicines distinctive, giving medical practitioners, Government and industry stakeholders such as the Australian Medical Association (AMA) confidence in prescribing for our products," Sean Hall said.

AMA President, Dr Michael Gannon in March this year was quoted as saying "Show us the scientific evidence and doctors will prescribe it [cannabis]..."<sup>1</sup>

"The effect of the TGA changes<sup>2</sup> enable Medlab a faster route to commercialisation of our research," Sean Hall said.

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<sup>1</sup> <https://ama.com.au/ausmed/green-light-medicinal-cannabis-ama-says-proceed-caution>

<sup>2</sup> <https://www.tga.gov.au/sites/default/files/access-medicinal-cannabis-products-steps-using-access-schemes.pdf>

Medlab has successfully renewed its Federal annual licences for continued importation of cannabis, allowing for significant increases in the amounts of cannabis allowed to be imported.

Medlab management estimates the annual finished product commercial value of its allowable importation of cannabis material to be approximately \$30M AUD of what is an estimated Australian market of \$250M.

According to Medlab CEO, Sean Hall the new licence was a significant step forward in Medlab's cannabis programme.

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**ABOUT MEDLAB – [www.medlab.co](http://www.medlab.co)**

Medlab Clinical is an Australian based medical life science company, developing therapeutic pathways for diagnosed chronic diseases. It is advanced in developing therapies for pain management, depression and obesity as well as earning revenue from sale of nutritional products in Australia and the United States. In pain management Medlab is developing cannabis-based medicines. The Medlab developed nano-particle medicine delivery system, Nanocelle™, is being applied to its medicines, nutritional products and off-patent drugs like statins. Medlab has a growing patent portfolio.

# Access to medicinal cannabis products in Australia

## Resource for doctors

### Step 1

#### Doctor has consultation with patient

##### Prescribing considerations

- Is a medicinal cannabis product appropriate for my patient?
- Do I have the appropriate expertise/qualifications? Should I consider specialist involvement?
- Review evidence for potential products in the context of the patient's condition.
- Use this information to guide specific product selection.

*Depending on the circumstances, you may need to seek approval/authorisation from the TGA, your state/territory health department and/or the ODC before you can prescribe, access or arrange importation of medicinal cannabis products.*

##### Seeking approval/authorisation for a specific medicinal cannabis product

- a) Gather product details – trade name, formulation, dosage form, route of administration, dose and product specifications.
- b) Follow steps 2A and 2B then:
  - 1) if imported stock is already in Australia or Australian manufactured stock is available, follow Step 3A.
  - 2) if stock must be imported into Australia, follow Step 3B. \*\*\*

For further information, see the TGA's Access to medicinal cannabis products webpage.

For assistance call 1800 220 007 (or 02 6232 8866) or email [medicinal.cannabis@health.gov.au](mailto:medicinal.cannabis@health.gov.au)

### Step 2A

#### TGA access schemes

##### For individual patients:

[Special Access Scheme Category A or B \(SAS A or SAS B\)](#)

Submit [notification/application](#) (for SAS B include supporting evidence, product details).

*Timeframe: 2-3 working days for SAS B\**

##### For a class of patients:

[Authorised Prescriber \(AP\)](#)

Submit application – [Agreement to Treatment Directions form, treatment protocol](#) (include supporting evidence, product details), HREC/College endorsement.

*Timeframe: Max. 10 working days\**

\* Timing dependent on applications containing all necessary information.

### Step 2B

#### Check your state/territory requirements

Rules relating to medicinal cannabis products may vary between states and territories.

[Contact your state/territory health department](#) to confirm requirements.

Obtain prescribing approval if required (may not be required if schedule 4, for example cannabidiol)

*Timeframe: Dependent on state, but usually less than 20 working days*



#### Import licence and permit (from the ODC)

\*\*\* If accessing through SAS A or intending to import product from overseas (Step 3B):

- Check import licence status of importer:
  - If no licence is held, importer must apply for a [licence from the ODC](#). (Max. 30 working days)
- Import permit is issued on a case by case basis.

### Step 3A

#### If stock available in Australia

##### SAS B or AP only

##### Pharmacist or medical practitioner:

- Contact supplier.
- Provide supplier SAS B approval or AP authorisation and state/territory approval if required.
- Supplier releases product.

### Step 3B

#### If product must be imported

##### Pharmacist or medical practitioner:

- Determine importer.
  - Importer must hold an [ODC licence](#). \*\*\*
- Send SAS A notification/SAS B approval/AP authorisation and state/territory approval to importer.

##### Importer:

- Apply to ODC for an import permit (per shipment).  
*For SAS A notifications ODC give priority one working day assessment time\**
- Liaise with overseas supplier.
- Exporter supplies product.
- Importation of product.
- Supply of product.

\* Timing dependent on evidence of state/territory approval and quality of product.

**PATIENT ACCESS**