OCEANIA REGULATORY REPORT 2024

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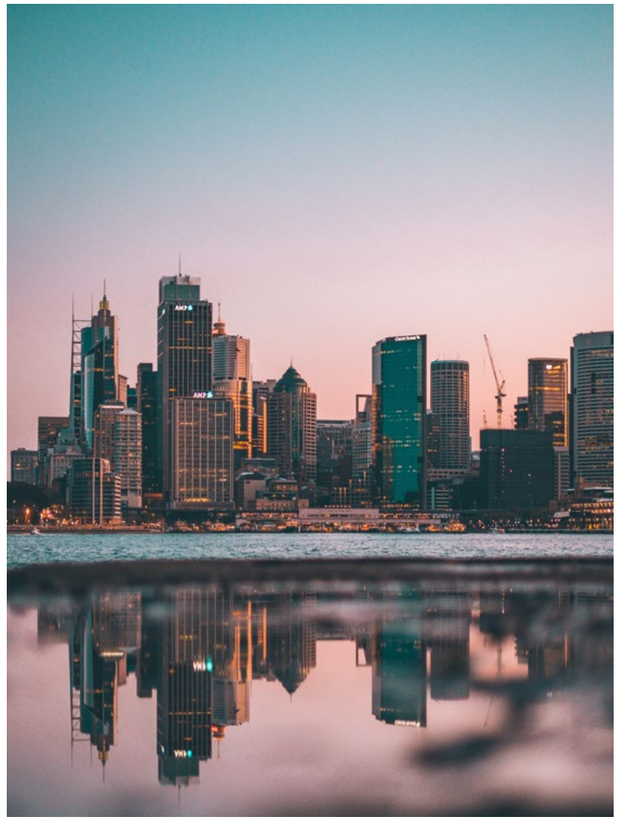
Introduction



Oceania Regulatory Report 2024 | INTRODUCTION

The regulatory frameworks that Australia and New Zealand have developed for their respective legal cannabis industries share some top-level similarities; however, there are key differences, which could become more pronounced in the medium term as the two systems evolve. On the question of adult-use, New Zealand opted for an all-or-nothing popular referendum for full-scale legalisation in 2020, which, upon rejection, has rendered the development of an adult-use regulatory framework unlikely for the foreseeable future. Australia meanwhile has seen a groundswell in public opinion on the issue, manifesting into legislative steps taken by representatives at the regional and federal levels, and is likely to see an adult-use market develop incrementally in the coming years. On CBD, in contrast to most countries with significant medical cannabis access, both have taken the approach that the cannabinoid should be accessed via medical channels only, though both have recently passed legislation to make CBD products containing a low dose of THC more easily accessible than other higher-THC cannabinoid products. The two countries are undertaking reforms to their medical cannabis regulations that are the inverse of each other – New Zealand to lower the product quality standards required of domestic producers in order to export from the country, and Australia to raise the product quality standards required of international producers in order to import into the country. Both of these efforts at reform are taken with the same goal, to level the playing field between domestic and international producers of medical cannabis. These reforms could result in Australian and New Zealand producers becoming more competitive in the context of the global cannabis industry, and are significant for any company involved in either country.

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Lead Sponsor

Glenn E. Martin's involvement with cannabis has evolved over several decades, from bootleg business to multinational corporation. Now CEO of WEED, Inc., pivotal nuances have shaped his path. Like many, he began smoking cannabis in his backyard in 1969. He was 15, and his yard happened to be in Hidden Valley Estates, a suburb of Tucson, Az. Living just 50 miles north of Mexico, "South of the Border" friends would supply him with cannabis, and he became a cannabis connoisseur, as he diversified his sources and market.

While producing rock concerts for groups ranging from the Rolling Stones, Foreigner, The Who, Waylon Jennings and Jackson Browne to local aspiring minstrels, he brought in cannabis from equatorial zones such as South America, where ultraviolet light resulted in plant chemistry that differed from cannabis grown in Alaska which bloomed under infrared light.

As the possibility emerged that cannabis could alleviate PTSD and anxiety for veterans, cancer pain and some women's health issues, Martin wanted to know how cannabis chemistry could be genetically engineered for medical effectiveness. Seeing potential, in 2006, he launched WEED, Inc., now publicly traded on OTCQB as BUDZ and formally known as United Mines.

Built from scratch, never a shell or RTO, WEED, Inc. is a global cannabis and hemp bioresearch company based in the US, focused on the development and application of cannabis-derived compounds for the treatment of human and animal diseases. Focus has also been on expansion of research, intellectual property and branding, along with enhancement of stock market appeal. International subsidiaries, product development plans and scientists at different universities have been components of the strategy.

For research, the company partnered with scientists at the University of Texas, at Galveston, and at Hebrew University, in Israel, where cannabis research had been afoot since the 1960s, and where cannabis was medically legalised in 2017. WEED, Inc.'s Pilot DNA Study tested 30 proprietary strains of cannabis that Martin anticipates will soon be tested in human trials.

WEED, Inc. subsidiaries were launched in Israel, followed by Hong Kong and Australia, the "Gateways to Asia" to facilitate research and product development. The company expects to be able to sell medicinal cannabis at a price point that would undercut the black market, unlike expensive medical cannabis now available.

Meanwhile, WEED, Inc. subsidiaries are maturing.

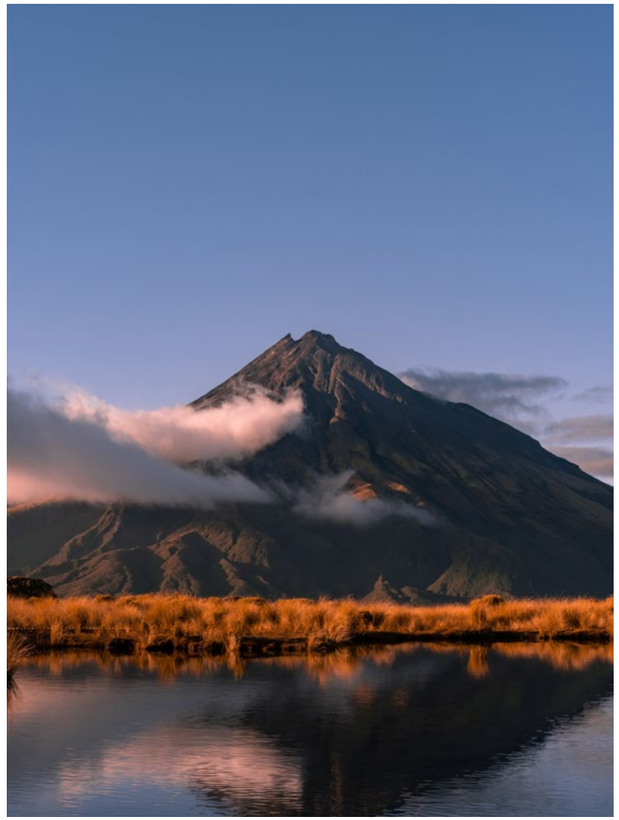
WEED Australia Ltd., a public company reporting under Australian Securities and Investment Commission (ASIC) rules and founded in 2017, has completed five years of audited financials. Now readying a formal public offering, WEED Australia Ltd. was one of the first public cannabis companies in Australia. WEED Inc announced the launch of a new $40M financing round under Regulation A+, Tier 2, as qualified by the Securities and Exchange Commission in 2022.

The company is also expanding its operations with carefully strategised acquisitions, such as the purchase of Arizona-based hemp grower and research entity Hemperical Genetics LLC in May 2022, through a subsidiary.

The acquisition comes with a HEMP growers licence and over 250+ strains/seeds. 15 being kept F-1 pure Landrace strains from the 70s. WEEDs world class genetics group is pursu- ing a number of federal applications for its WEED®, PANAMA RED™ and ACAPULCO GOLD™ trademarks to cover such products as rolling papers, grinders, tobacco pipes, and nutritional supplements for pets for joint mobility.

Foreword

By Glenn E. Martin, WEED, Inc.



When WEED Australia Ltd. first started out in 2017, there were a little over 20,000 medical cannabis patients. Fast forward almost seven years and that number is now somewhere close to 600,000 patients, according to reputable research and sources. This is significant progress for the market in Australia and, more importantly, for its current and potential patient population.

However, there are likely many, many more people who are self-medicating with cannabis obtained from the illicit market for two main reasons; the first being the difficulty in obtaining a medical cannabis prescription from an authorised doctor, while the second being the high cost of legal, medical cannabis prescriptions (therefore rendering it out of reach for many patients). These two challenges alone form the foundations of WEED Australia Ltd.

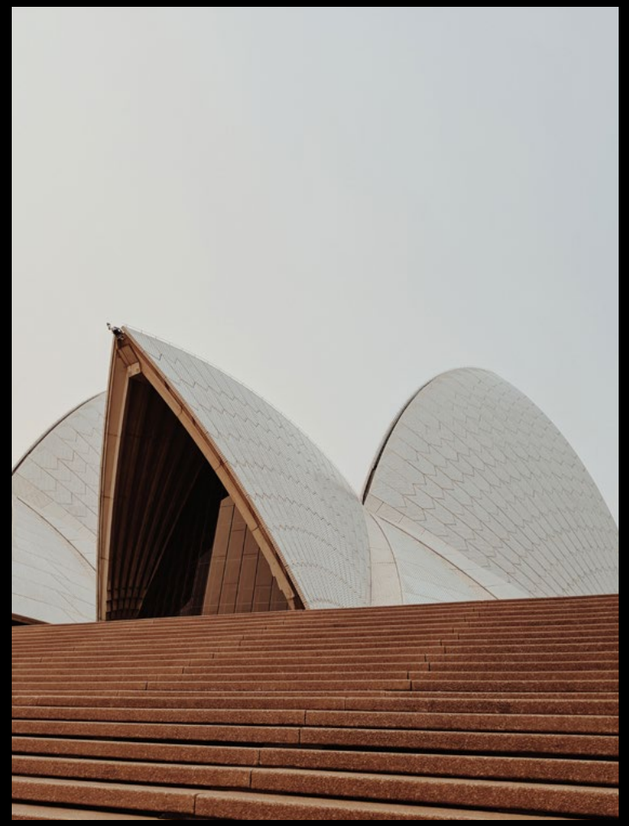
Since our inception, we have been advocating for thorough and ongoing educational programmes for doctors and other healthcare professionals, so that they are properly informed about cannabis as a medicine and its many benefits. We continue to advocate for this education today.

Our vision is to produce Australian-grown medical cannabis for Australians. Grown and sold domestically. We are aiming for twice the quality and half the price, to make our medical cannabis products available to all patients - not just a select few that can afford it.

While progress has been steady since policy reform and rescheduling of high-THC cannabis in 2016, there is still a long way to go for the market in Australia. However, from climate to culture, Australia is perfectly positioned to succeed in developing thriving medical and adult-use cannabis markets over the coming years.

After over 50 years of advocating for a legal cannabis industry in the United States, it has been and will continue to be an honour to build out the 'American Dream' on a global basis in countries like Australia, Israel and Hong Kong.

Australia



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Regulation

Adult-Use

Adult-use cannabis is federally illegal in Australia, with a few exceptions based on state/territory-level laws that contradict federal law. In a few States and Territories, small possession quantities have been decriminalised, as for example in the Australian Capital Territory, the possession (50g dried and 150g fresh) and home cultivation (max. 4 plants per household) of cannabis was decriminalised in January 2020. However, there have been recent developments regionally and federally in the form of proposals and bills by lawmakers to establish a legal framework in the country. This has primarily been driven by the growing public sentiment in favour of legalising cannabis – a survey conducted by Essential Report in August 2023, highlighted that 50% of approximately 1,150 respondents currently are in favour of regulating and taxing cannabis to a certain extent in the country, and another survey conducted by 'The 2019 National Drug Strategy Household Survey' showed that 78% of Australians aged 14 and over do not support the criminalisation of cannabis possession.

Regional/Territorial Legalisation

Regionally, significant progress has been made by the Legalise Cannabis Party, as, following state elections, the party currently holds Upper House seats in Western Australia (WA), Victoria and New South Wales (NSW) – highlighting growing public support for the legalisation of cannabis in Australia. In June 2023, the Legalise Cannabis Party simultaneously introduced their 'Regulation of Personal Adult Use of Cannabis Bill 2023' in the upper houses of the three states of WA, NSW and Victoria.

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The bill is the first stage of the party's three-stage legalisation plan, which includes:

Stage One – Home Grow and Possession
(Regulation of Personal Adult Use of Cannabis Bill 2023)

- Legalisation of cannabis possession for personal use
- Legalisation of home cultivation of up to six plants per household
- Legalisation of the access to cannabis seeds
- Legalisation of gifting up to 50 grams of cannabis
- Establishment of measures for the safety of minors and youth

Stage Two – Social Clubs

- Establishment of growers' co-operative where consumers can assign their growing rights
- Provision of a framework for licensed non-profit social clubs regulating production, safety, transport, storage and distribution
- Expungement of historical criminal records regarding personal-use cannabis

Stage Three – Commercial Distribution

- Establishment of licences and permits for cultivators, producers and retailers
- Establishment of assessment procedures regarding labelling, product safety and cannabinoid profile by state regulators
- Placement of controls on market participants (favouring smaller operators)
- Prohibition of adult-use sales near schools

Through these three stages, the single-issue party aims to legalise cannabis gradually. This shares similarities with Germany's 'Two Pillar Model', whereby personal use of cannabis and non-profit social clubs would be legalised in the first stage before a regulated commercial market is created. Although support for cannabis legalisation is growing in Australia, the bills must receive the support of major parties to pass into law, which may prove difficult as MPs in both the Australian Labor Party and the Liberal/National Coalition hold conservative and restrictive stances regarding adult-use cannabis.

Federal Legalisation

Federally, the Australian Greens party is currently pushing for adult-use legalisation, as on 10 August 2023, the Greens Senator David Shoebridge introduced 'The Greens Legalising Cannabis Bill 2023' to the Senate. This is the first time a cannabis legalisation bill has been introduced to Australia's Federal Parliament, and if approved by both the Senate and House, it would legalise cannabis nationally.

The bill seeks to establish a regulated adult-use cannabis framework in the country covering the entire supply chain, including the registration of cannabis strains, while establishing a national cannabis agency (the Cannabis Australia National Agency – CANA), which will oversee the licensing and regulations of the national cannabis market. It should be noted that the bill will make no changes to the medicinal cannabis scheme in the country.

The Greens Legalising Cannabis Bill 2023 – Key Points:

- Establishment of the Cannabis Australia National Agency (CANA)
  - Regulation of cannabis activities including the overseeing, issuing and authorisation of licences for regulated activities
  - Creation of a cannabis-strain register
  - Establishment of regular testing procedures of cannabis products for strength and contamination
  - Data collection of national cannabis activities
  - Establishment of a register of approved responsible cannabis training providers
  - Establishment of regulatory frameworks that have an interest in serving the broader public, maximising safety and reducing harm associated with cannabis activities
- Regulating Cannabis for Individuals/Consumers
  - Legalisation of home cultivation of up to six plants
  - Legalisation of the sale or trade of small amounts of cannabis amounting to less than A$50
  - Legalisation of the possession of cannabis by adults 18+
  - Legalisation of cannabis product manufacturing such as brownies or other cannabis products for personal consumption
- Regulating Cannabis for Businesses
  - Authorisation of the commercial supply chain of adult-use cannabis will be overseen and regulated by CANA
  - Business activities at each point of the supply chain will only be permitted with a valid licence – this includes licences for cultivation, manufacturing, retail, imports and exports
  - Establishment of licensing fees for companies, except for First Nations people or a body corporate controlled by one or more indigenous peoples
  - Prohibition of licence holders who sell or make cannabis products available to minors
  - Requirement of complying with labelling requirements, and must be in compliance with Responsible Service of Cannabis training
  - Legalisation of licensed Cannabis Cafés to sell registered cannabis products and to allow consumers to consume products on the premises (outdoors)
  - Prohibition of electronic and public advertisements relating to cannabis products outside of licensed facilities (licensed cannabis cafés are exempt)
  - Implementation of a 15% tax rate in addition to the Goods and Services Tax (GST)

Alongside the introduction of the bill, the Greens also published the 'Legalising Cannabis Bill 2023 Report', which covers a national survey and consultation results with regard to cannabis legalisation and the results have been used to make amendments to the introduced bill. Within the report, survey results display overwhelming support for legalisation, as over 92% of 8,900 respondents support adult-use cannabis legalisation in the country. The report also states that a taxed and regulated industry could generate 'A$28 billion in anticipated public revenue in the first 9 years of operation', thereby highlighting the potential economic benefits of adult-use legalisation.

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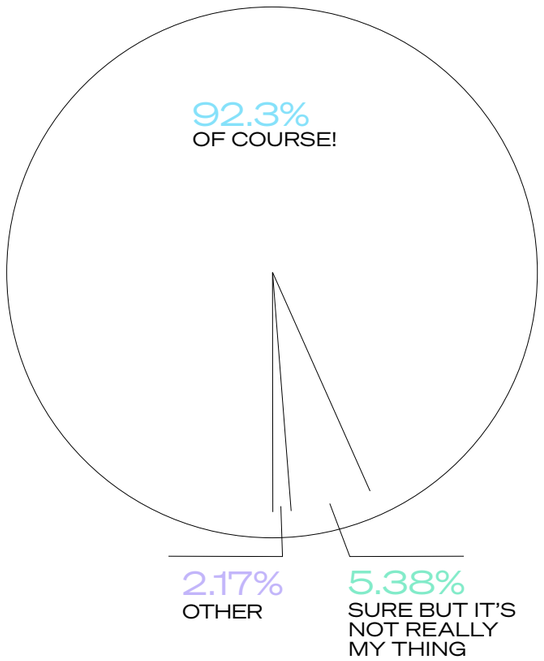
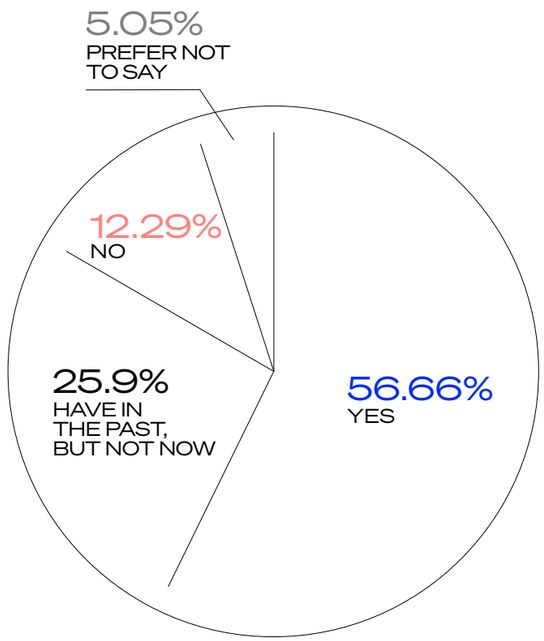
Should cannabis be legalised in Australia?



Participant no: 8,916 | Date: 6 April to 10 May 2023
Source: 'The Greens Legalising Cannabis Bill 2023 Report', Australian Greens, 2023

Do you use cannabis recreationally in Australia?



Participant nos: 8,916 | Date: 6 April to 10 May 2023
Source: 'The Greens Legalising Cannabis Bill 2023 Report', Australian Greens, 2023

The criminality of cannabis is another driving factor for adult-use cannabis legalisation in the country, as respondents stated that it does not have a strong enough effect to deter consumers from the illicit market and is heavy on public spending. This is apparent in the Greens' report, as only 17.68% of respondents agreed that criminalisation limited their access, whereas 82.29% of respondents mentioned that it was still easy or not difficult for them to access illicit cannabis products, highlighting the fact that despite the large amount of public funds invested into the justice system and policing for cannabis criminalisation, individuals are still able to purchase cannabis products easily.

Although the Greens' Legalising Cannabis Bill 2023 is a significant step forward for cannabis legalisation in Australia, the bill faces similar issues to the regional bills from the Legalise Cannabis Party, as for the bill to become an Act, it must be approved by both chambers in the government.

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Overview of Australian Commerical Hemp Regulations by State/Territory

Western Australia

Legislation: Industrial Hemp Act 2004
Regulations: Industrial Hemp Regulations 2004
Regulatory Body: Department of Primary Industries and Regional Development (PIRD)
THC at Planting: <0.5%
THC at Harvest: <1%
Licence Types:
- Cultivation
- Harvesting
- Processing

Licence Term: 3 years
Application Fee: A$328.00
Renewal Fee: A$131.00

Northern Territory

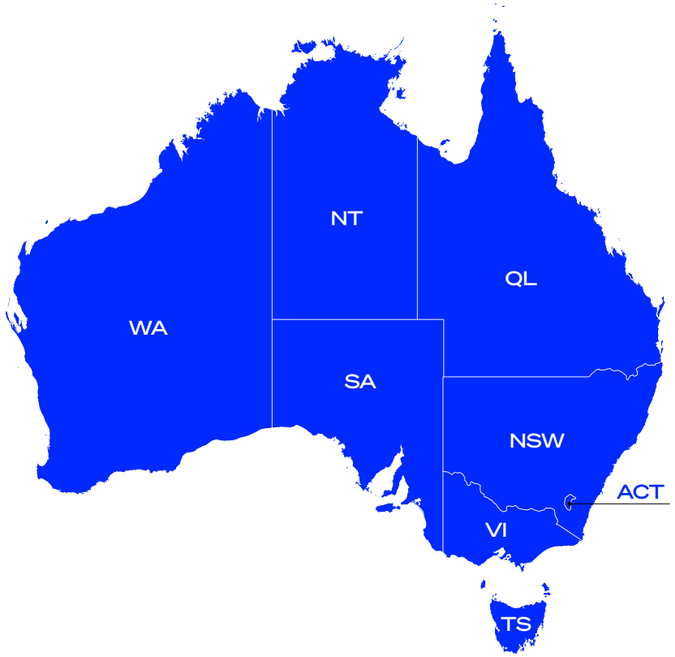
Legislation: Hemp Industry Act 2019
Regulations: Hemp Industry Regulations 2020
Regulatory Body: NT Government
THC at Planting: <0.5%
THC at Harvest: <1%
Licence Types:
- Commercial Licence (to possess, cultivate, process or supply low-THC hemp)
- Class A (research licence)
- Class B (research licence)

Licence Term: 5 years
Application Fee: A$1,311.00
Renewal Fee: Same as Application Fee

Queensland

Legislation: Drugs Misuse Act 1986
Regulations: Drugs Misuse Regulation 1987
Regulatory Body: Business Queensland
THC at Planting: <0.5%
THC at Harvest: <1%
Licence Types:
- Grower
- Researcher
- Seed Handler

Licence Term: 3 years
Application Fee (Grower): A$1,383.25
Renewal Fee (Grower): A$1,123.55



New South Wales

Legislation: Hemp Industry Act 2008
Regulations: Hemp Industry Regulation 2016
Regulatory Body: Department of Primary Industries (DPI)
THC at Planting: <0.5%
THC at Harvest: <1%
Licence Types:
- Cultivation and Supply for Commercial Production
- Cultivate and Supply for Manufacturing Process
- Scientific and Research

Licence Term: 5 years
Application Fee: A$572.00
Renewal Fee: A$418.00
Annual Fee: A$200.00

Australian Capital Territory

Legislation: Hemp Fibre Industry Facilitation Act 2004
Regulatory Body: Environment, Planning and Sustainable Development Directorate
THC at Planting: <0.5%
THC at Harvest: <1%
Licence Types:
- Category 1 Research Licence
- Category 2 Research Licence
- Grower Licences

Licence Term: 3 years

South Australia

Legislation: Industrial Hemp Act 2017
Regulations: Industrial Hemp Act Regulations 2017
Regulatory Body: Department of Primary Industries and Regions (PIRSA)
THC at Planting: <0.5%
THC at Harvest: <1%
Licence Types:
- Possession
- Cultivation
- Processing

Licence Term: 5 years
Application Fee: A$1,286.00
Renewal Fee: A$776.00

Tasmania

Legislation: Industrial Hemp Act 2015
Regulations: Industrial Hemp Regulations 2016
Regulatory Body: Department of Natural Resources and Environment Tasmania (DPIPWE)
THC at Planting: <0.5%
THC at Harvest: <1%
Licence Types:
- Supply
- Cultivate
- Manufacture
- Research
- Combination of above-mentioned licences

Licence Term: 5 years
Application Fees: None

Victoria

Legislation: Drugs, Poisons and Controlled Substances Act 1981 & Agriculture Legislation Amendment Bill 2022 (effective from 5 April 2023)
Regulations: Drugs, Poisons and Controlled Substances (Industrial Hemp) Regulations 2018
Regulatory Body: Agriculture Victoria
THC at Planting: <1% (from 5 April 2023)
THC at Harvest: <1%
Licence Types:
- Possess, Process, Sell or Supply
- Cultivate and Possess

Licence Term: 3 years
Application Fee (Cultivator): A$477.00
Renewal Fee (Cultivator): A$151.00

Source: Australian Hemp Council & State/Territory Government Websites, 2023

CBD

In terms of CBD regulations, Australia holds a rather restrictive stance compared with the rest of the world. The country still considers CBD as a medicine/narcotic and it must therefore be regulated under the framework of the Therapeutic Goods Administration (TGA). In December 2020, the TGA announced it would down-schedule low-dose CBD (CBD ≥ 98%, THC ≤1%), from Schedule 4 (Prescription Medicine) to Schedule 3 (Pharmacist Only Medicine). Thus, low-dose CBD products must be listed on the Australian Register of Therapeutic Goods (ARTG) and must be approved for a specific indication by the TGA. Additionally, products must be contained in child-resistant packaging and have a maximum daily dose of 150 milligrams. Only products that are ingested through the mouth sublingually are included in the down-scheduling. Thus, other low-dose CBD products such as vapes and topical creams are still classified as prescription-only medicines.

Although the down-scheduling came into effect on 1 February 2021, there are still no low-dose over-the-counter (OTC) CBD products available in Australian pharmacies, as the requirements for becoming an ARTG-listed product are very strict and costly for companies to undertake. Under the current regulation, companies need to prove that their low-dose CBD product is beneficial for the treatment of a certain medical condition, thereby requiring efficacy, safety and quality data studies of their product, which is time-consuming and expensive. Following product tests and trials, the company must submit a dossier with all of their product data and evidence of their production facility's Good Manufacturing Practice (GMP) certification. The submission is then assessed by the TGA to examine whether the product meets its criteria, which can take over 300 days. As the stringent requirements can be too onerous in terms of time and financial resources, only a few larger medicinal cannabis companies such as Little Green Pharma, Bod Science and Cann Group have the capabilities to undertake an ARTG-listing process.

However, in 2023, it was announced that clinical trials of CBD medicines to treat insomnia by both Bod Science and Cann Group have failed, whereas, there have been no further announcements regarding Little Green Pharma's clinical trial.

Industrial Hemp

In 2017, Australia permitted low-THC hemp seed to be sold as food; however, the leaves and flowering heads are still prohibited for human consumption. In regard to industrial hemp cultivation, each state has its own laws and regulations, which control the cultivation, processing, production and possession of industrial hemp. These regulations are governed by the state or territory government and differ in terms of permissible THC limits, licence types and application fees.

Medicinal

Overview

Since 2016, medicinal cannabis and its production for medical purposes have been federally legal in Australia, which has created a strong growth market in the country. The two federal authorities that regulate the medicinal cannabis market are the Therapeutic Goods Administration (TGA), which oversees the approval process of medical products and prescriptions, and the Office of Drug Control (ODC), which assesses and awards permits and licences to medicinal cannabis companies and their corresponding activities. However, it is under the individual state's discretion how these regulations are implemented thus laws regarding patient access and commercial activities differ (minimally) on a state-by-state basis.

Currently, the only approved cannabinoid medicines in the ARTG are Sativex™ and Epidyolex™. All other cannabis medicines are defined as unauthorised medicines. The supply and access to these medicines are regulated on a federal and territorial level. In most jurisdictions, in order to prescribe unauthorised medical cannabis products, doctors need to obtain approval from the TGA, and in some states, approval from health authorities of the given territory/state. In regards to medical cannabis standards, the **Therapeutic Goods (Standard for Medicinal Cannabis) (TGO 93) Order 2017**, by the TGA sets the minimum quality requirements for unapproved medicinal cannabis products that are imported into and supplied/manufactured in Australia.

Prescribers & Patient Access

Under the Special Access Scheme (SAS), medical practitioners can prescribe/import medical cannabis that is not listed in the ARTG, for a single patient on a case-by-case basis. The SAS has three pathways, which are categories A, B and C; however, in relation to medical cannabis prescriptions, only categories A and B are relevant. In category A, medical practitioners may submit a prescription notification for medical cannabis products to the TGA which are not already commercially imported or produced in Australia. This provides patients with access to medical cannabis, although products have to be individually imported by via the ODC. As the process requires doctors to facilitate the per-patient imports it is rarely used as it is more time-consuming and difficult to undertake compared to SAS-B. However, in category B (the most common pathway for access of unapproved medical cannabis products), health practitioners can apply for a TGA approval and must provide a clinical justification for the use of medical cannabis and as to why other products included in the ARTG are not suitable for the treatment of a specific patient.

Another pathway through which health practitioners may prescribe unapproved medical cannabis is in becoming an Authorised Prescriber (AP). As an AP, medical practitioners are able to prescribe a specified medicinal cannabis product for certain indications and to a certain class of patients. To become an AP, medical practitioners must obtain approval from the Human Research Ethics Committee (HREC) or endorsement from a specialist college. However, APs do not need HREC approval or specialist college endorsement if the selected medicine ingredient category, dosage form and indication are included in the TGA's list of medicinal cannabis medicines with an established history of use. These tend to be capsules, oils and oral sprays that are placed in medicinal cannabis categories 1 - 3 which are used to treat disorders including refractory chronic pain, sleep disorders, anxiety, autism spectrum disorder and cancer pain. Under this scheme, APs are able to prescribe medicinal cannabis products to their patients without needing to notify the TGA each time they prescribe within the approval period (max. five years). Additionally, APs must report the number of patients they treat every six months.

Since November 2021, SAS and AP submissions for unapproved medicinal cannabis products are now based on categories set by the active ingredient content (cannabinoid content) rather than brand names. This change was placed to reduce the administrative burden for prescribers and allow for the flexibility of brand substitution for patients, in the event where supply chain issues occur.

The medicinal cannabis categories are as follows:

- **Category 1** - CBD medicinal cannabis product (CBD ≥98%)
- **Category 2** - CBD dominant medicinal cannabis product (CBD ≥60% and <98%)
- **Category 3** - Balanced medicinal cannabis product (CBD <60% and ≥40%)
- **Category 4** - THC dominant medicinal cannabis product (THC 60-98%)
- **Category 5** - THC medicinal cannabis product (THC >98%)

Therapeutic Goods (Standard for Medicinal Cannabis) (TGO 93)

TGO 93 is the standard that specifies the minimum quality requirements for medical cannabis products in Australia. The TGO 93 applies to all medicinal cannabis companies that import and supply medicinal cannabis products (finished, ingredient, or starting material) in Australia. The TGO 93 covers requirements and guidelines associated with European Pharmacopoeia monographs, sourcing of active ingredients, decontamination, adulterations, testing, manufacturing quality, packaging, labelling and microbiological attributes.

In March 2022, the TGO 93 saw a significant update, which made it mandatory for medicinal cannabis imports to meet GMP requirements as of 1 July 2023. This could potentially have a profound impact on the Australian cannabis industry, as before 1 July 2023, imports were not required to meet GMP standards. Thus, in the years before this amendment, the domestic cannabis industry had to compete with international imports that did not need to meet the same GMP requirements domestic producers had to abide by. This created an unfair playing field for domestic producers as they had to compete with cheaper medicinal cannabis imports that potentially could be inferior in quality or dangerous for consumption. Through these new updates, the TGA creates an import market that is homogenised in standards, but also creates an even playing field for Australian medical cannabis producers.

The TGO 93 update specifically set applicable standards and required evidence for products produced in the following countries by importers/sponsors:

- **United Kingdom**
  - Products must be manufactured at a site that meets GMP standards
  - Evidence is a GMP certification from either a UK authority (MHRA) or a licensing authority of one of the EU member states
- **European Union Member State**
  - Products must be manufactured at a site that meets EU-GMP standards
  - Evidence is a GMP certification from a licensing authority of one of the EU member states
- **Canada (Three Options Available)**
  - Option 1
    - Products must be manufactured at a site that meets Canadian Good Manufacturing Practices
    - Evidence is a copy of the Drug Establishment Licence issued by Health Canada
  - Option 2
    - Products must be manufactured at a site that meets EU-GMP standards
    - Evidence is a GMP certification from a licensing authority of one of the EU member states and written confirmation from Health Canada that the manufacturing site operates in accordance with Part 5: Good Production Practices of the Cannabis Regulations SOR/2018-144 (Canada)

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- Option 3
  - Products must be manufactured at a site that is in accordance with the PIC/S Guide to GMP, but the importer cannot obtain the evidence referred to in options (1) or (2); the importer or sponsor can request that the TGA conduct an inspection of the manufacturing facility
  - Evidence is a written confirmation from the TGA that the manufacturing site operates in accordance with the PIC/S Guide to GMP and a written confirmation from Health Canada that the manufacturing site operates in accordance with Part 5: Good Production Practices of the Cannabis Regulations SOR/2018-144 (Canada)

- **South Africa**
  - Products must be manufactured at a site that meets the South African Guide to GMP standards
  - Evidence is a written confirmation from the South African Health Products Regulatory Authority that the manufacturing site operates in accordance with the South African Guide to GMP

- **Israel**
  - Products must be manufactured at a site that meets EU-GMP standards
  - Evidence is a Certificate of Good Manufacturing Practice issued to the manufacturer of the product by the Israeli Ministry of Health

Licensing & Permits

In Australia, medicinal cannabis cultivation, production, manufacturing and import/export regulations are governed by the Commonwealth Office of Drug Control (ODC). Under the current framework, a medicinal cannabis licence and permit for activities is mandatory for medicinal cannabis companies.

Applicable Licences for Medicinal Cannabis Companies
(depending on territory/state, additional approvals from relevant authorities may be needed):

- **Medicinal Cannabis Licence** (A$13,220 new, A$27,520 annual)
  - Authorises cultivation (the growing of cannabis plants) or production (the separation of cannabis and cannabis resin), or both
  - May also authorise manufacturing activities
  - Activities may be authorised either separately or all under the one licence

- **Medicinal Cannabis Permit – Cultivation & Production**
  (A$11,910 new, A$9,070 subsequent)
  - Applicable for a specific premises/facility
  - Cultivation includes sowing of seed, planting, growing, tending, nurturing, harvesting, grafting, dividing, or transplanting a cannabis plant
  - Production includes the separation of cannabis and cannabis resin from the plant

- **Medicinal Cannabis Permit - Manufacturing**
  (A$7,860 new, A$5,980 subsequent)
  - Applicable for a specific premises/facility
  - GMP licence required from the TGA
  - Manufacturing includes production, processing, assembling, packaging, labelling, storage, sterilising, testing and release for supply of medicinal cannabis products

- **Import Licence and Permit**
  - Medicinal cannabis imports require a licence and permit from the ODC before importation
  - Products must conform with TGO 93
  - Licence is valid for 12 months
  - A permit is required for each shipment
  - Relevant exporter needs to holds appropriate licences and approvals from their own and the Australian government

- **Export Licence and Permit**
  - Medicinal cannabis exports require a licence and permit from the ODC before exportation
  - Companies must demonstrate they can ensure an adequate supply of medicinal products for the Australian market before exportation
  - Products must be registered or listed in the ARTG

EXPERT INTERVIEW

Glenn E. Martin

Chairman, President & CEO
WEED, Inc.
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Tell us a little bit about WEED, Inc., and in particular your activities in Australia with WEED Australia Ltd.?

I started the company as United Mines back in 2005 and we changed our name to WEED, Inc. in September 2014. As we built up we were a full reporting SEC (U.S. Securities and Exchange Commission) company. Then in 2016, the Australian government came out with national cannabis 'schemes' and within six months of these schemes going national, I set up WEED Australia Ltd., as well as the Cannabis Institute of Australia underneath WEED Australia Ltd. as our non-profit. I didn't - and still don't - want to grow cannabis for 'stoners'. We're only interested in the medical aspect, R&D and medical product development.

Through WEED, Inc. in the United States, we have these very rare strains that have been developed over 50+ years, like Panama Red and Acapulco Gold. These give us the genetics we need. We're one of the very few companies to have these very pure genetics, which is why we want to do studies at the University of Queensland and the University of Sydney.

I wanted to build an Australian cannabis company for Australians, and that's what I concentrated on. We started WEED Australia Ltd. in March of 2017 as a public company and now we have seven full years of fully-audited financials under the Australian Securities and Investment Commission. WEED Australia Ltd.'s strategy is to use our proprietary research, medical patents and clinical trials to create unique medical products and services for the treatment of human and animal diseases. We've assembled a highly qualified team of well respected PhDs, scientists, researchers and business experts to reach our goal of establishing a strong domestic distribution market.

We were ready to do an IPO in 2019, but then, of course, COVID came around and derailed our plans. Now that everything is a little more settled post-COVID, we plan to go ahead with an IPO in the next 18 months.

Last year, we appointed the fantastic Amanda Brunskill-Scott to take the reins as managing director of WEED Australia Ltd. Amanda is also our in-house counsel for both WEED Australia Ltd. and the Cannabis Institute of Australia.

What medical cannabis treatments are you focused on in Australia currently, either in an R&D or commercial capacity?

In Australia we have concentrated on bringing our highly-concentrated CBD to the market; super-concentrated CBD that's up to 5000 milligrams per ounce bottle. We also do some CBG. The feedback we've received from doctors has been fantastic and they love it.

Right now, until we can build our own facility and grow flower in Australia, we're importing our super-concentrated CBD into the country.

I was in Australia last summer and, for 28% to 30% THC medical cannabis, it was AU$180 to $240 for a 10-gram package of flower - so AU$18-24 per gram. That's too expensive. And it's pricing a lot of patients out of getting the medicine they need. So our main goal is to provide medical cannabis to Australian patients that is twice the quality and half the price.

We need to get it to the people who need it the most at a cost that they can afford. Realistically, we need to be aiming to sell our flower at AU$10 per gram. We want to bring our naturally-grown Panama Red and Acapulco Gold strains to the market and to patients; strains which have been developed over 50+ years.

Once we have our own facility post-IPO, we can grow our flagship, naturally-grown strains in Australia.

Oceania Regulatory Report 2024 | EXPERT INTERVIEW

What challenges do WEED Australia Ltd., and other cannabis businesses, face in the region?

The manufacture, sale and supply of medical cannabis in Australia is, of course, highly regulated through the Controlled Substances Act. There are regulations from the Office of Drug Control (ODC) and Therapeutic Goods Administration (TGA) too. So navigating the regulations and the different controlling bodies is a challenge in itself - but I enjoy a challenge.

In 2016 when the national medical cannabis scheme was announced, CBD was moved to a Schedule 4 'prescription medicine' drug. Cannabis was reclassified as a Schedule 8 - a 'Controlled Drug' - from Schedule 9 ('Prohibited Substance') in November of the same year. So while that was certainly progression, especially for patients, and the national medical cannabis scheme was also positive, Schedule 8 still makes it extremely difficult for businesses like ours. It's going to be a continued challenge to get cannabis rescheduled again, but it needs to happen.

Generally speaking, one of the biggest challenges that companies like WEED Australia Ltd. face in the region is the lack of education that doctors and other healthcare professionals have on cannabis. This is a challenge for the entire market in Australia,and other markets around the world. Like other regions, opioid-based medicines are still the go-to treatments for conditions like chronic pain in Australia. The education is just not there.

In 2019, we were at a conference that was put on by the Pharmaceutical Guild of Australia and it was basically all opioid manufacturers. Out of the 600-odd companies that were in attendance, we were the only medical cannabis company. There are reportedly up to about 1700 doctors now in Australia who are authorised to issue prescriptions for medical cannabis. But the market doesn't seem to be growing so well, and from what I've seen there are still a hell of a lot of patients who are not able to get access to the plant to treat a variety of ailments and conditions.

For me, there needs to be a programme of education for doctors and other healthcare professionals. There's no point in doing the odd one-hour session here or there, to try and educate them about the benefits, potential side effects etc. We're talking about 12-14 week education programmes that put medical cannabis and its benefits at the forefront of their thinking when prescribing.

I think the other key challenge for the Australian market is that many cannabis companies there have focused on - or are currently still focusing on - the export market, before the domestic market has even developed. No one seems to be really focusing on growing Australian cannabis and hemp for Australians. Instead, what we see is a lot of people just trying to make money because of their high prices and export-focused business models, growing purely to sell product into Europe and other regions.

Do you see a regulated, adult-use cannabis market developing in Australia in the near future?

I think adult-use cannabis has to be legalised and has to be regulated in Australia. When I first went over to Australia just a few years ago, there were roughly 25,000 medical cannabis patients. Now we're looking at anywhere between 400,000-600,000 patients, according to estimates from sources like the University of Sydney.

Like we saw in many states in the U.S., there'll be a significant amount of these patients, I would say, that are receiving a prescription - but they actually just want it for recreational use. And like the majority of countries around the world, there are potentially millions of other recreational users in Australia who go out and buy their cannabis on the illicit market because they can't currently buy it legally. They're buying it already, they're smoking it already, so isn't it best to legalise and regulate it? Personally, I don't see any issue with somebody wanting to enjoy the effects of high-THC cannabis recreationally.

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I do believe in the next couple of years we'll see adult-use legalisation and an adult-use market develop in Australia, or at least some strong progress towards adult-use policy reform, as the regulatory bodies in Australia watch and learn from what's happening elsewhere in the world with adult-use regulation.

What lessons should Australian cannabis businesses learn from other markets around the world?

Some are already learning the hard way by putting tens, if not hundreds of millions, of Australian dollars into facilities that are extremely expensive to build, and the Australian market is still so small. Many have already gone out of business. And this is obviously something we've seen in Canada and the US. These companies get major investment, build huge expensive facilities, overproduce - and never make a dime, before going out of business.

For me, the focus has to be on producing a high quality product at the lowest possible price. Then it's mutually beneficial. As a business you can still make decent money, but patients can also access the plant at a price they can afford to pay. That's the mistake a lot of these companies make; they produce their product and try to sell it at a high price - but they can't sell enough of it at this higher price.

Out of the first public and private cannabis companies in Australia, very few remain. Most of them have gone out of business already.

How does your business strategy position WEED Australia Ltd. as a key player in the industry in Australia and Oceania in the coming years?

As I've mentioned, the majority of companies don't even grow cannabis in Australia, because that's not their business model. They're importing from Canada or countries in Europe, or if they are growing in Australia, they're growing product for export. We're different. Our plan has always been to focus on the domestic market and grow domestically in Australia. We want to bring the plant and its medical benefits to Australian patients.

COVID scuppered our IPO plans in Australia, but now we're getting everything back on track. From that, we'll look to raise AU$30-50 million. We have land and facilities picked out, so off the back of the IPO we'll be ready to build our own facility and concentrate 100% on growing for the domestic market in Australia. We won't be looking to export anywhere initially,thereby taking care of the Australian market and Australian patients first and foremost.

We've also hired Australian law firm Mills Oakley to assist us with our IPO. One of the partners there, Dr. Teresa Nicoletti, is the country's leading lawyer for the regulation of medical cannabis on both a federal and state level. For 25 years she's been helping the TGA write legislation and also wrote some of the rules for the ODC. Before COVID hit, we were also working with KPMG.

We are fully committed to the domestic market here in Australia. Once we're properly funded through our IPO, we'll proceed with our plans and look to accelerate everything across the board.

Oceania Regulatory Report 2024 | EXPERT INTERVIEW

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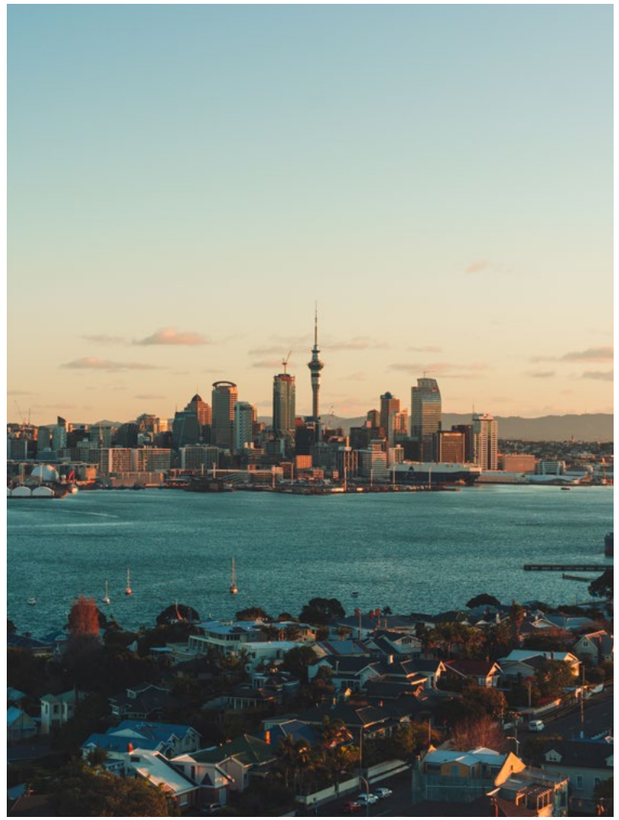
New Zealand



Oceania Regulatory Report 2024 | NEW ZEALAND

Regulation

Adult-Use

In 2020, New Zealand held a referendum on legalisation of the personal use of cannabis. The outcome of the vote was a narrow majority against legalisation, meaning that possession of cannabis without medical grounds remains illegal. There is no indication of upcoming legislation that would change the current regulation on adult-use cannabis.

CBD

With the Misuse of Drugs (Medicinal Cannabis) Amendment Act 2018, CBD was reclassified as a prescription medicine in New Zealand. Prior to this, it was treated as a controlled drug, meaning access was even more restricted.

CBD products in New Zealand are intended for medicinal use. They are not approved for use in general consumer products, such as cosmetics or food supplements.

In October 2023 authorities reclassified CBD from a prescription-only medicine to a restricted (pharmacist-only) medicine. The reclassification will allow supply of approved low-dose CBD medicines, by registered pharmacists, without prescription for patients aged 18 years and older under certain conditions. This harmonises regulations with Australia, where a similar measure regarding low-dose CBD products was adopted in 2020.

Hemp cultivation (<0.3% THC) is distinct from medicinal cannabis cultivation, but still requires a licence from the Ministry of Health. Additionally, flowers and leaves are prohibited for human consumption.

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Medicinal

Overview

In 2008, New Zealand's health authorities approved Sativex™ for the treatment of symptoms of multiple sclerosis. This represented the first time that a cannabis product was available for medical use in the country.

In 2016, access to imported non-pharmaceutical cannabis products was opened up. Doctors required ministerial approval for prescriptions of these products on a patient-by-patient basis, however, which restricted their use for treatment.

In 2020, New Zealand implemented the new Medicinal Cannabis Scheme, a significant piece of legislation that has shaped the industry in the country. The key features and components of the scheme include:

1. **Quality Standards:** A minimum quality standard was developed, which includes variations for different categories of product.
2. **Licensing:** The scheme provides a framework for the domestic cultivation, production and distribution of medicinal cannabis products.
3. **Easier Prescription:** Under the scheme, doctors can prescribe medicinal cannabis products without needing to seek approval from the Ministry of Health, as had previously been the case.
4. **Establishment of Medicinal Cannabis Agency:** The Medicinal Cannabis Agency was established to oversee the scheme. The agency's role includes setting and maintaining product quality standards, issuing licences, and monitoring compliance.

Product Definitions

New Zealand defines a number of different categories for medicinal cannabis, with different regulatory implications in each case (for example, regarding quality control and authorisation to handle products).

Categories:

Starting material is fresh or dried cannabis that is intended to be used in or for a medicinal cannabis product.

A **cannabis-based ingredient** is extracted from cannabis and intended to be used in or for a dosage product.

A **medicinal cannabis product** is the finished product intended for therapeutic use. This includes material intended for compounding. It must not contain any prescription medicine or controlled drug other than cannabis or cannabis-based ingredients.

A **dosage product** refers to a finished product in a form that can be directly administered to a patient in a measured amount to achieve the desired therapeutic effect.

A **CBD product** is a dosage product or a cannabis-based ingredient that contains cannabidiol and only trace elements of Tetrahydrocannabinol (THC), if any. (THCs and specified substances within the product must not exceed 2% of the total CBD, THC and other specified substances.)

Minimum Quality Standard

As part of the Medicinal Cannabis Scheme, a minimum quality standard was developed for quality control in production and manufacturing. The standard sets lists of contaminants to be tested for, maximum permissible limits of those contaminants, quality standards for analysis and packaging, and more.

The scope of standards which apply to a given product can vary depending on the intended category, purpose, format, or the stage of manufacture of the product.

The minimum quality standard is established and maintained by the Medicinal Cannabis Agency, and is informed by international standards – in particular those set out in the European Pharmacopoeia (10th edition).

As part of broader regulatory change (see changes to the regulations on page 19), some updates will be made to the minimum quality standard. These will involve incorporating by reference the European Pharmacopoeia 11th edition (in its entirety), as well as

elements from the US and UK pharmacopoeias. These changes are expected to come in during 2024.

All suppliers of cannabis-based ingredients, starting material for export and medicinal cannabis products (including CBD products) must provide evidence to the Medicinal Cannabis Agency that their products meet the minimum standard before they can be supplied.

The contents of the minimum quality standard regulations are as follows:

Overall requirements

- Minimum quality standard imposed
- Requirements for testing with maximum limits
- Other requirements
- Testing and validation of testing method

Details of other requirements

- Shelf life and storage conditions
- Identification of cannabis
- Identification of active ingredients
- Assay limits for active ingredients
- No adulteration
- Container material
- Sources of active ingredients and cannabinoids
- Restrictions on decontamination
- Pesticides
- Labelling
- Form and dosage form
- Excipients and other ingredients

Table 1 sets out which items are required to meet the minimum quality standard.

TABLE 1

Requirements of medicinal cannabis product in New Zealand to meet the minimum quality standard (by product category)

Type	Import	For domestic supply	For export
Starting material	Not required	Not required	Required*
Cannabis-based ingredients (including CBD products)	Required	Required	Required**
Medicinal cannabis products (including CBD products)	Required	Required	Required**

*May no longer be required, subject to upcoming changes (see changes to the regulations, page 19)
**May no longer be required in the cases of products intended for the purposes of testing, analysis or research (see changes to the regulations, page 19)

Changes to the Regulations

A set of changes to the regulatory framework for medicinal cannabis in New Zealand are being worked on by the authorities. While the precise details of the new regulations are not yet fixed, the government has specified what their intended goals are with the changes. These regulations are expected to be finished in early 2024, and will come into effect sometime in 2024. The main consequence of the changes will be to facilitate easier export of products, something that domestic producers have consistently highlighted as an issue. With the new regulations, producers will theoretically be able to achieve better economies of scale for their products, thereby lowering the price of treatment for patients in New Zealand.

The key changes are aimed at:

- Broadening the types of cannabis plant forms that can be considered 'starting material' and 'cannabis-based ingredient'
- Enabling the export of cannabis seed under the Medicinal Cannabis Scheme
- Enabling the export of starting material, cannabis-based ingredients and medicinal cannabis products (without needing to meet the minimum quality standard) for the purposes of testing, analysis or research
- Enabling the import of cannabis-based ingredients and medicinal cannabis products (without needing to meet the minimum quality standard) for the purposes of testing, analysis or research
- Removing the requirement for consignments of starting material to meet the minimum quality standard before export
- Removing the requirement for cannabis-based ingredients and medicinal cannabis products to meet the minimum quality standard before export if they are manufactured to GMP and meet the quality requirements of the importing country
- Allowing a licence to possess controlled drugs (issued under the Misuse of Drugs Regulations 1977) to authorise non-therapeutic research activities using medicinal cannabis or industrial hemp.

Licensing

Under the Medicinal Cannabis Scheme, companies involved in the medicinal cannabis industry in New Zealand require a licence. The licence specifies the types of 'activity' that can be carried out by the licence holder and the people working under their authority. A licence holder may need more than one activity specified on their licence to cover the full scope of their business operations.

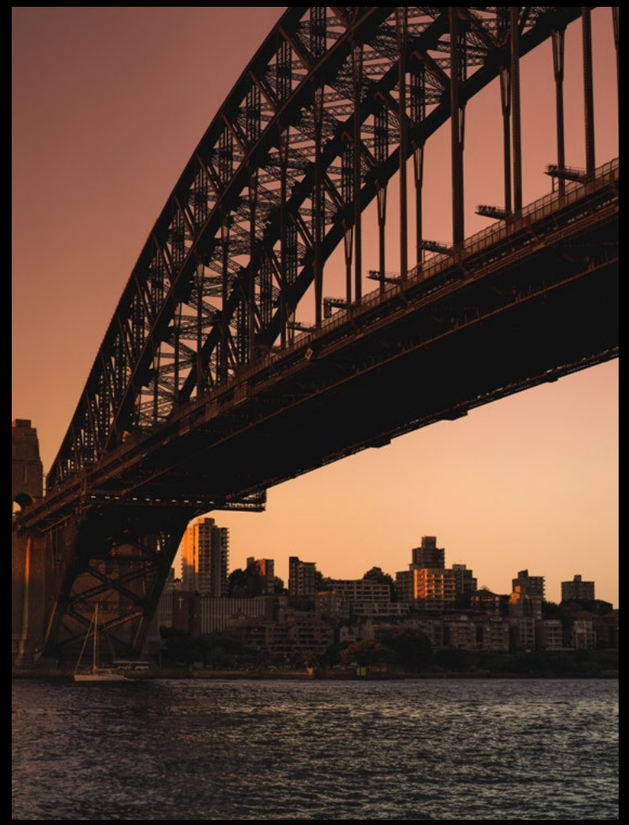
There is a fee associated with each activity on initial application for the licence, as well as for each renewal of it. The maximum period for which a licence can be granted is five years.

Five types of 'activity' are specified (fees in brackets):

- Cultivation (NZ$5,462.50 new, NZ$3,392.50 renewal))
  - Cultivation of cannabis for use in a medicinal cannabis product
  - Cultivation and supply of seeds/plants to another cultivator or appropriate medicinal cannabis licence holder
  - Cultivation of starting material for export by a licensed supplier, or
  - Undertaking of research involving cultivation (for example, research into breeding cultivars with specific characteristics).
- Nursery (NZ$747.50 new, NZ$747.50 renewal)
  - Import of seeds under an import licence
  - Purchase of cannabis seeds from a licensed cultivator
  - Supply of seeds to a medicinal cannabis licence holder with the 'cultivation' activity specified.
- Research (no fee)
  - Supply or administering of a medicinal cannabis product that is not a CBD product to a person who is a research subject in a clinical trial.
- Manufacturing (NZ$3,105 new, NZ$2,645 renewal)
  - Processing of dried cannabis
  - Extraction of a cannabis-based ingredient
  - Manufacture of a medicinal cannabis product
  - Developing of test methods
  - Performing laboratory testing
  - Engaging in product development of medicinal cannabis products.
- Supply (NZ$6,382.50 new, NZ$5,922.50 renewal)
  - Supply or export of starting material, cannabis-based ingredients, or medicinal cannabis products
  - A medicinal cannabis licence is not necessary to supply CBD products; however, a licence under the Medicines Act 1981 is required.

In order to export medicinal cannabis products, a unique permit is required for every consignment of products for export, which is available via application to the Medicinal Cannabis Agency. The processing time for such a permit can be up to 30 working days, and the application fee is NZ$194.22. An import licence from the importing country is required in order for an export permit to be issued.

Conclusion



Oceania Regulatory Report 2024 | CONCLUSION

The regulatory systems for legal cannabis in both Australia and New Zealand are undergoing changes, and in each case those changes are intended to broaden the opportunities for domestic companies to succeed, and to facilitate easier access to cheaper products for patients. Australia is making progress towards developing a system for adult-use cannabis, with a clear majority of the public in favour of reform on this front. Depending on the success of the Australian system, as well as other such systems evolving in Europe, the adult-use question may once again become a discussion in New Zealand. Despite the current differences in regulation, the two systems continue to evolve, and ultimately the industries of each are likely to become integrated. This is already the case to some degree, as New Zealand depends on Australian products in part to treat its patients. If both countries continue their efforts to broaden patient access and facilitate trade, there is potential for companies to participate in the markets of both countries and reap the benefits of each. For now, a significant separation remains, and companies looking to participate in their legal cannabis industries still need to bear in mind the key differences between each system in order to succeed.

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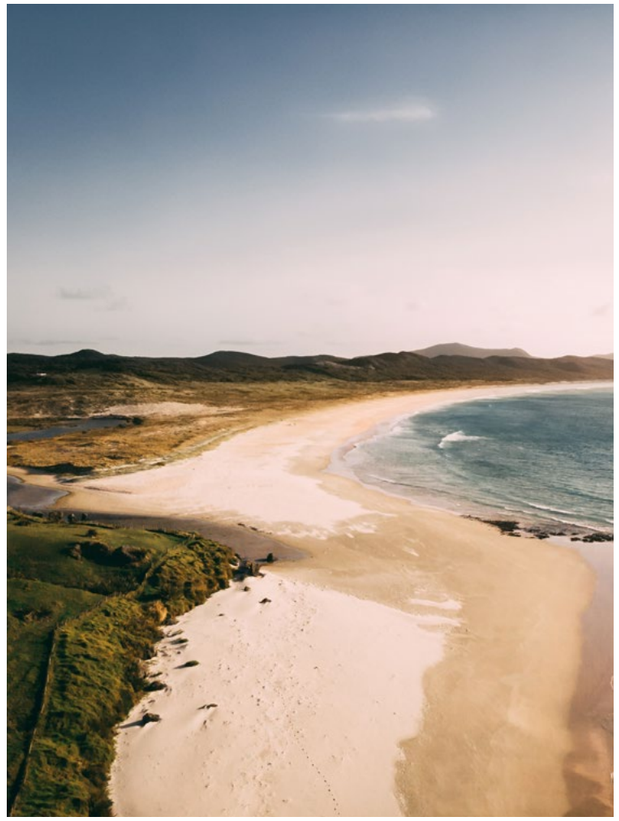
Acronyms



Oceania Regulatory Report 2024 | ACRONYMS

AP	Authorised Prescriber
ARTG	Australian Register of Therapeutic Goods
CANA	Cannabis Australia National Agency
GMP	Good Manufacturing Practice
GST	Goods and Services Tax
HREC	Human Research Ethics Committee
MHRA	Medicines and Healthcare products Regulatory Agency
NSW	New South Wales
NT	Northern Territory
ODC	Office of Drug Control
OTC	Over-the-counter
PIC/S	The Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme
SAS	Special Access Scheme
TGA	Therapeutic Goods Administration
WA	Western Australia

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