

The Canadian market is surging forward as the world leader in the capitalisation of cannabis related business opportunities, but the Australian market is also gearing up for the race.

Statistics from earlier this year indicate that 4.9 million Canadians use cannabis, spending a total \$5.6 billion on the product per annum. In Canada, the total cannabis market (including medical consumption, legal recreational products & illegal counterfeit products) is expected to generate up to **US\$7.17 billion in total sales in 2019.**

The estimated total cannabis market size in Australia is estimated to be US\$3.89 billion, including legal and illicit consumer spending. The Australian legal medicinal cannabis market alone, which is currently valued at US\$17.7 million has the potential to balloon to **US\$3 billion by 2028** according to NewFrontier data as stated in 'The Oceania Cannabis Report – 2018 Industry Outlook' published in October 2018.

While the framework for the legitimate access to cannabis in Australia has historically been highly restrictive and complex, recent **regulatory reforms are expected to improve access** to medicinal cannabis with the patient population expected to reach 330,000 by 2025. Additionally, the industrial applications of cannabis and hemp present compelling opportunities including agricultural use and the production of hemp rope and other fabrics.

The cannabis cultivation and manufacturing industries in Australia are in their infancy. The sourcing of legitimate imported cannabis products can be a complex process, the expense of which is passed onto the consumer. Accordingly, there is considerable impetus for the development of the Australian cannabis market.

Internationally, Australia's burgeoning cannabis industry is gaining recognition with Canadian companies such as Canopy Growth, Aphria, Cronos Group and Aurora investing into Australia's medical cannabis programs. In the public markets space, 6 of the top 10 cannabis related ASX companies have market caps greater than \$50 million. Althea Group's IPO on 21 September 2018, backed by Aphria, raised \$19.6 million and is already the fourth-largest listed cannabis-related company on the ASX.

Regulatory and legislative developments are boosting Australia's ambitious cannabis industry and Australia is emerging as a leader in the Oceania region, emulating Canada's position as a leader in the North American cannabis market.



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Cannabis products in Australia: The regulatory climate

Cannabis

Overview of product and opportunity

Medicinal cannabis products include either plant-derived cannabinoids or cannabinoid molecules that are synthetically produced.

Plant derived products include:

- raw cannabis plant material;
- liquids (oils and tinctures); and
- concentrated plant extracts (often made into capsules).

Where tetrahydrocannabinol (THC) is the cannabinoid responsible for the psychoactive effects of cannabis, cannabinol (CBD) has proven useful in the management of seizures, pain and may have anxiolytic and antipsychotic effects.

Global supplies of cannabis for medicinal purposes are relatively scarce and expensive, which gives rise to opportunities for the supply of locally cultivated cannabis for medicinal and scientific purposes in Australia.

General prohibition

All Australian States and Territories prohibit (with criminal penalties) the supplying of cannabis and the possession of large (including trafficable) quantities of cannabis.

While the possession and use of small amounts of cannabis (presumptively for personal use) is illegal it has however been decriminalised in certain States and Territories.

Permitted use

Pursuant to Commonwealth legislative amendments, the use of cannabis for medical or scientific purposes is permitted so long as a license and permit have been granted by the Commonwealth Office of Drug Control (**ODC**).

The ODC, in conjunction with the Therapeutic Goods Administration (**TGA**), oversees the application review process and monitoring of permits and licences necessary for the importation, cultivation, manufacture and exportation of cannabis for medical or scientific purposes.

Access to medicinal cannabis

In most States and Territories in Australia, approval or permission is required by a medical practitioner in order to prescribe medicinal cannabis products to patients.

Cannabis medicines may be registered on the Australian Register of Therapeutic Goods (**ARTG**) if they are assessed and approved by the TGA. At present, the only cannabis product registered as a medicine and marketed in Australia is the nabiximols oromucosal spray (Sativex).

Importation

Currently, there is not a significant supply of medicinal cannabis products available for import (resulting in a supply shortage for patients), which is in part why the Government has legalised the domestic cultivation of cannabis for medicinal use.

Medicinal cannabis products are currently only available to patients via importation whilst the Australian domestic cultivation scheme is being established.

Importation is only permitted by the following parties under the relevant licence for that party:

- a prescriber (ie medical practitioner) or pharmacist with a licence and permit to import issued by the ODC; and
- an importer (also known as a sponsor) holding a licence from the NSW Ministry of Health (or equivalent State/Territory authority if applicable) and a licence & permit to import issued by the ODC.

Cultivation and production

Cultivation includes all steps up to, but not including, harvest. Production consists of harvest and placing in a container for the purposes of research or manufacture.

The Commonwealth Government controls all regulatory aspects of the cultivation and production of cannabis for medicinal purposes through a national licensing and monitoring scheme administered by the ODC and the TGA.

The cultivation of cannabis in Australia for medical and related scientific purposes has been permitted since October 2016.

An ODC licence is required in order to legally cultivate and/or produce cannabis for medicinal or research purposes and such a licence must be accompanied by an associated permit. There is no limit to the number of medicinal cannabis licences or permits that can exist.

In order to be granted an ODC licence, a cultivator and/or producer must supply to a manufacturer who holds an ODC medicinal cannabis manufacturing licence or to a researcher with the appropriate authorisation.

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Manufacture

The Commonwealth Government, together with the States and Territories is responsible for the manufacture of, and patient access to, medicinal cannabis.

Manufacturers must be licensed by the TGA, the ODC and the equivalent authority in their home Australian State or Territory in order to manufacture a medicinal cannabis product.

As at 8 October 2018, there are 22 manufacturers listed on the ODC website as being licensed to manufacture medicinal cannabis products. However, it should be noted that names and contact details on the website are published with the manufacturer's consent, and therefore not all persons licenced to manufacture have been included in the list.

People licensed to manufacture are able to enter into contractual arrangements with permit-holding cultivators to produce cannabis.

Exportation

As of February 2018, certain medicinal cannabis products may be exported under a licence and permit to export.

To ensure licensees are not exporting medicinal cannabis to the detriment of Australian patients, the ODC will condition licences to ensure domestic supply.

Goods that can be exported include:

- medicinal cannabis products manufactured in Australia under a GMP licence;
- medicinal cannabis products listed as export-only, or registered, on the ARTG; and
- extracts of cannabis (or extracts of cannabis resin) manufactured under a licence and permit that are not in the final dosage form.

Goods that cannot be exported are cannabis (eg flowers, leaves) and cannabis resin.

Hemp

Overview of products

Hemp is a product produced from cannabis plants with a typically low THC content (and therefore provides no psychotropic effect from its consumption) but high CBD.

Hemp products include:

- hemp fibre (which can be made into rope, clothing etc);
- hemp seed products (consumable): and
- skin products (including skincare oil and sunscreen).

It is noted that low THC hemp is not the same as medicinal cannabis.

Low THC hemp has been around for many years and has a variety of uses (eg textiles, rope, paper, fuel, stockfeed and oil).

Permitted use

- A number of hemp products are permitted to be imported to Australia without any licence or permit.
- Farmers can grow low-THC hemp crops for fibre, seed and oil production if they have authority.
- Since November 2017, low-THC hemp products (namely hemp seed and hemp seed oil) have been permitted for human consumption provided they are compliant with the Australian code of Goods Manufacturing Practice. Other parts of a low THC hemp plant, its leaves and flowering heads must not be sold as food or for human consumption.

Importation

The following substances may be imported without import permission:

- hemp fibre;
- hulled hemp seeds;
- hemp seed meal:
- hemp seed oil (provided the total cannabidiol content of the hemp seed oil is 75mg/kg or less and the total THC content is 50mg/kg or less); and
- products that contain hulled hemp seeds, derived from hemps and/or hemp seed oil provided that the total cannabidiol content of the hemp seed oil is 75mg/kg or less and the total THC content is 50mg/kg or less.

Cultivation

Industrial hemp can only be grown in Australia under a licence issued by the relevant State or Territory government.

Manufacture

The manufacture of hemp products is regulated by States and Territories.

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Key players in the Australian market

Company	Activities	Market Cap (\$A)
CANN GROUP LIMITED	Cultivation of cannabis for medicinal and research purposes and manufacturing of medicinal cannabis products.	268
EXL	Operates in the industrial hemp, dietary supplements and emerging medical cannabis sectors. EXL's businesses include: Elixinol US, Elixinol AUS and Hemp Foods Australia.	148
Althea Health and Wellbeing	Althea Group Holdings is an Australian producer, supplier and exporter of pharmaceutical grade medicinal cannabis. AGH also offers a range of education, access and management services to support eligible patients and healthcare professionals in navigating medicinal cannabis treatment pathways.	132
AusCann Australasian Medicinal Canadas	AusCann Group Holdings Ltd (AC8, formerly TW Holdings) is a Perth-based company with the aim of producing and providing quality, economical and clinically validated cannabis medicines. AusCann provides education to medical practitioners on the therapeutic benefits of medical cannabis and the range of conditions and symptoms it can relieve.	116
medlab	Medlab, which produces a proprietary spray delivery system to alleviate intense pain suffered by cancer patients, has teamed up with Canadian group Pharmascience. The two are engaged in R&D on Medlab's flagship product, NanaBis, which received licenses to sell in Australia back in January 2018.	101
CRESO	Creso Pharma develops, registers, and commercialises pharmaceutical-grade cannabis and hemp-based nutraceutical products and treatments for human and animal health in Europe, the Middle East, and the Asia Pacific.	60
THC Global Group	THC is focused on the manufacturing and distribution of hydroponics equipment, materials and nutrients; large-scale hydroponic greenhouse design and construction; and the development and delivery of medicinal cannabis.	60
≥ MMJ	MMJ Group Holdings is a cannabis investment company. MMJ owns a portfolio of minority investments and aims to invest across the emerging cannabis-related sectors including healthcare, technology, infrastructure, logistics, processing, cultivation, equipment and retail.	57

Company	Activities	Market Cap (\$A)
impression healthcare	Impression Healthcare announced that it has executed a Memorandum of Understanding with an established and reputable Canadian producer of cannabis oils.	51
7	Zelda Therapeutics is an Australian-based bio- pharmaceutical company that is focused on developing a range of cannabinoid-based formulations for the treatment of a variety of medical conditions.	51
mgc pharma	MGC Pharmaceuticals is a medical and cosmetic cannabis Company with global operations to supply the legalised markets with cannabis products including the development of non-psychoactive cannabidiol (CBD) cosmetic products.	49
bod australia	In the past year it has gained Special Access Scheme approval for its MediCabilis cannabis oil and teamed up with Chemist Warehouse to dispense the product, obtained a cannabis export licence and entered a collaboration with Biologics Research Institute Australia.	43
RHINOMED	The ASX listed company specialising in nasal respiratory products, Rhinomed is seeking opportunities to harness cannabinoid-based medicines with its patented systems.	40
idt authaberhed	IDT's processing of raw cannabis flower from Cann's Mildura site is expected to start in the second half of 2020.	33
ROTOGRO MILITARISMAL IMPRO	Roto-Gro International is an Australian-based company with licensed, proprietary, patented, and patents-pending technology in the stackable rotary hydroponic garden space. RotoGro holds worldwide exclusive licenses for lawful medicinal and recreational cannabis markets and holds worldwide nonexclusive licences for all other purposes including pharmaceuticals, nutraceuticals and perishable foods.	20
SUDA PHARMACEUTICALS LTD	SUDA Pharmaceuticals claims its OroMist oral spray increases absorption rates by up to 95% when compared to standard tablets. Suda recently engaged 2 international specialty consultancies as part of a plan to expand its business development footprint in the USA, Europe, Russia and China.	14
eve investments	Eve Investments acquired tea tree and honey farmer Jonbrook's product pipeline, which includes different types of melaleuca and medical cannabis-based honey.	10

Note: Market capitalisation as at August 2019

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