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The New Zealand and Global

Medicinal Cannabis Industry Update

JUNE 2021

Contents

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Contents

cannasouth

1 Introduction

Disclaimer

This information provided in this update is intended to assist investors with understanding the Medicinal Cannabis industry in New Zealand and the views expressed are those of Cannasouth Limited. The Information contained in this update does not constitute investment or financial advice, and nothing relating to the provision of the information herein shall be construed as creating a fiduciary, financial or other advisory relationship between Cannasouth and the reader or any other third party.

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You should also seek expert professional advice about this update in light of your particular current or future financial situation and particular investment needs. This update does not take into account your current financial or future financial situation or investment needs.

Executive Summary

This update is designed to provide insight into the emerging medicinal cannabis industry locally (i.e. New Zealand) and globally; the challenges, the opportunities, the New Zealand regulatory environment, and the barriers to entry.

There is much confusion and lack of understanding in what is a highly complex and regulated industry. Investors need to make informed decisions to avoid investing in opportunities that have little, or no chance of success in the current regulatory environment.

Cannasouth will shortly provide a market update focusing on creating genuine advances in the medicinal cannabis industry, and Cannasouth's growth strategy, timelines, and competitive advantage that make it a leader in the New Zealand market.

New Zealand's regulations only allow commercial production of pharmaceutical grade cannabis-based medicines which requires technical expertise in Research and Development (R&D), formulation, Good Manufacturing Practices (GMP), Quality Assurance (QA), pharmaceutical development, regulatory affairs and commercialisation of medicines. This is a significant barrier to entry which is not largely recognised by many investors and the public.

Drawing on Cannasouth's learnings in this fast-evolving industry, this update provides a detailed overview and looks to clarify some concepts and misconceptions in order to align expectations from different industry stakeholders including governments, patients, investors and potential customers.

Investors in this sector need to understand the capital required, timelines and lifecycle of establishing a business in this highly regulated, rapidly growing pharmaceutical medicinal cannabis industry.
Facility design, team establishment, development of Quality Management Systems (QMS), construction, commissioning, cultivation, validation, and product registration all take time to achieve and there are no shortcuts in producing compliant facilities and end products.

At the end of this process is a rapidly growing global demand for pharmaceutical quality ingredients and medicines as medicinal cannabis schemes continue to develop and patient access improves.

Key Takeaways

The New Zealand and global medicinal cannabis industry is complex and highly regulated and many companies in the sector here will likely not meet the required standards and will not survive.

To compete in the sector and produce compliant medicines, companies must have expertise in areas such as: Research and Development (R&D), formulation, Good Manufacturing Practices (GMP), Quality Assurance (QA), pharmaceutical development, regulatory affairs, and commercialisation of medicines. This is a significant barrier to entry.

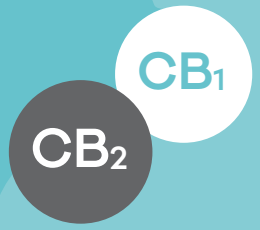
If investing in the sector take the time to understand the opportunities and complexities of the industry, the capital and timelines involved in establishing compliant operations and producing end products.

For New Zealand medicinal cannabis companies, the only option for manufacturing and developing products is in the "Pharmaceutical" category which requires complying with New Zealand Minimum Quality Standards (NZMQS) which aligns with GMP and is the gold standard for pharmaceutical manufacturing.

Key Takeaways

Consistency and reproducibility of any herbal medicine can only be assured if the plant material is defined in a rigorous manner. Commercial growers must establish crops which produce a high degree of consistency in composition.

New Zealand regulations do not allow the importation or manufacturing of supplements/ wellness products that contain cannabinoids. This is because, in New Zealand, any product containing more than trace levels of cannabinoids including THC and CBD are considered either prescription medicines or controlled drugs (and it is illegal to obtain them without a prescription).



With the discovery of cannabinoids effect on biological receptors in the Endo-Cannabinoid System (ECS) the potential exists for medicinal cannabis products to become a staple of modern medicine.

Drug development offers one of the greatest opportunities to improve and expand the pharmaceutical market and generate new technology, formulations, combinations, devices, clinical protocols & data, all potentially leading to the generation of Intellectual Property (IP).

Key Takeaways

The global CBD market is expected to reach

$13.4B

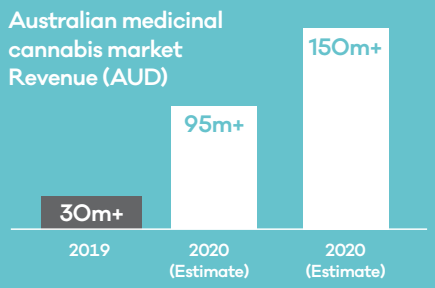
(USD) by 2028

The market is expected to expand at a CAGR of

21.2%

from 2021 to 2028

International markets, particularly Australia and Germany, are growing rapidly and offer big opportunities for New Zealand companies that can produce products to international pharmaceutical quality specifications.



There is substantial global demand for medicinal cannabis flower, cannabis-based ingredients and medicines that meet the necessary regulatory and quality requirements.

With purpose-built facilities and more than 220 years of combined international GMP pharmaceutical experience, Cannasouth is well positioned to be a market leader in the medicinal cannabis industry in New Zealand and compete globally.

More than

220 years

of combined GMP pharmaceutical experience

Who Is Cannasouth?

Company Structure

Cannasouth Limited is the parent company and 100% owner of subsidiary company Cannasouth Bioscience Limited, a biopharmaceutical company that researches, develops and supplies medicinal cannabis products.
In addition, the Group has investments in two joint ventures: Cannasouth Cultivation Ltd (for flower production) and Midwest Pharmaceutics (NZ) Ltd. (for medicines grade production and cannabinoid oil extraction services).

Cannasouth Limited (CSL)
Parent Company / Issuing Entity
Company no.: 6987773
NZBN: 9429046975331

100%

Cannasouth Bioscience Limited (CBL)
Company no.: 6284148
NZBN: 9429046132307

50%

Cannasouth Cultivation Limited[1] (CCL)
Company no.: 7629656
NZBN: 9429047591004

60%

Midwest Pharmaceutics (NZ) Limited[2] (MW)
Company no.: 2171366
NZBN: 9429032567427

1 50% Tokamaru Horticulture Industries Ltd

2 40% Mark Balchin & Greenmeadows Health Ltd

Cannasouth is a biopharmaceutical company, which has a vertically integrated business model. This business strategy enables it to control the quality of medicinal cannabis products throughout multiple stages of the production and supply chain.

Cannasouth was one of the first companies to operate in the New Zealand sector. The founders have a long history of involvement with industrial hemp dating back to 1995 and obtained one of the first Licences to cultivate industrial hemp in 2002.

Who Is Cannasouth?

Cannasouth's vision is to develop the next-generation cannabinoid therapeutics to improve the quality of life of New Zealanders and people around the world.

Cannasouth was New Zealand's first medicinal cannabis company to list on the New Zealand Stock Exchange (NZX:CBD) in June 2019.

Cannasouth's people are its key assets. The company has established a highly skilled team covering all areas of the business including governance, finance, R&D, quality, project management, cultivation, regulatory and formulation with over 220 years of combined GMP and pharmaceutical experience.

The company believes science and innovation should underpin everything it does. Cannasouth has established an advanced R&D department with industry leading cannabinoid isolation capabilities, including multiple Government funded research programs underway designed to produce the next generation of cannabinoid medicines and technologies.

Who Is Cannasouth?

Cannasouth is in the final stages of completing its industry leading Controlled Environment Agriculture (CEA) Sealed Greenhouse facility and is progressing the development of a pharmaceutical manufacturing facility designed to meet the highest global GMP pharmaceutical standards.

Initially, Cannasouth will be selling imported medicinal cannabis products until its own medicines, developed and manufactured in-house, are produced using cannabinoid extracts from high-quality, medical-grade cannabis biomass.

These medicines will be manufactured to meet current international pharmaceutical standards, including the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) and GMP, using environmentally friendly methods. Cannasouth believes patients have the right to innovative medicines made of pure therapeutic compounds of the highest quality.

Cannasouth has other revenue generating opportunities which are described in Section 2. These include export sales of biomass and Active Pharmaceutical Ingredient (API) or Cannabis-Based Ingredient (CBI) extraction and other toll services.

A Quick Look at Key Terms Used in This Update

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API

Active Pharmaceutical Ingredient

The biologically active component of a drug product.

CBI

Cannabis-Based Ingredient

An ingredient that is extracted from cannabis and is intended to be used for a dosage product.

FDF

Finished Dosage Form

The pharmaceutical drug products in the form in which they are marketed for use, with a specific mixture of active ingredients and inactive components (excipients), in a particular configuration (such as a capsule shell, for example), and apportioned into a particular dose.

GACP

Good Agricultural and Collection Practice

The GACP is a set of guidelines covering the quality of medicinal plant materials for processes such as cultivation (from seeds and propagation material), collection, harvest, primary processing, and bulk packaging.

GAP

Good Agricultural Practice

GAP is a set of guidelines that address environmental, economic and social sustainability for on-farm processes, and result in safe, quality food and non-food agricultural products.

GMP

Good Manufacturing Practice

The GMP guidelines describe a system for ensuring that products are consistently manufactured and controlled according to suitable quality standards. These guidelines are designed to minimise risks, ensure products are safe for use, and that they meet the release specifications, including the content label claim.

ICH

The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use

International body that discusses scientific and technical aspects of pharmaceuticals in order to ensure that safe, effective and high-quality medicines are developed, registered and maintained in the most efficient manner.

MCA

Medicinal Cannabis Agency

The government agency (division of New Zealand's Ministry of Health) responsible for overseeing the domestic production of medicinal cannabis and setting up and monitoring the regulatory and quality standards for medicinal cannabis products.

MCS

Medicinal Cannabis Scheme

The MCS in New Zealand enables the commercial cultivation of cannabis for medicinal use only and the manufacture and supply of medicinal cannabis starting material, ingredients, and medicines.

NZMQS

New Zealand Minimum Quality Standard

The standard implemented by the MCA to assess the quality of the medicinal cannabis products. This includes analytical testing, validation of analytical methods, manufacturing processes and stability data.

QMS

Quality Management System

Systems supporting the development and manufacture of pharmaceuticals through the product lifecycle. For pharmaceuticals, the gold standard quality system is GMP.

What to consider when investing in the New Zealand medicinal cannabis sector

? What is the strategy of the company? Does it align with the regulatory environment in New Zealand?

? What area of the value chain are they entering? Cultivation, manufacture, research and development or other?

? What is the organisational structure of the company? Who are the people, and do they have the required level of pharmaceutical GMP and regulatory experience?

? If the company is cultivating or manufacturing, does it have the required facilities to supply a pharmaceutical GMP medicinal cannabis industry?

? Beware of large offtake agreements and profit projections before facilities are even built.

? If starting now, how long will it take to begin production, recognising the multi-year development phase of pharmaceutical operations?

What to consider when investing in the New Zealand medicinal cannabis sector

Numerous companies have entered the New Zealand medicinal cannabis industry but unless regulations change, many will fail to meet complex pharmaceutical quality and regulatory barriers of entry.

Take the time before investing to understand the company's strategy and match that with a deep understanding of the complexities of the industry.

Understand which area of the value chain the company is entering, and which of the associated barriers to entry it must overcome to be successful.

Pharmaceutical production requires significant experience in quality systems and regulatory matters.

It is very important to understand whether the team has the skills and capabilities to operate in a GMP-based environment.

Does the company have the facilities of the required standard to meet GAP/GACP or GMP requirements?

If a company is just starting on its journey, how long will it take to build the team and facilities to become compliant and operational? For manufacturing this is a multiyear process if there is no existing GMP framework and facilities.

Beware of early claims of large offtake agreements and profit projections, especially when they are announced prior to the construction of facilities. Yes, there may be good demand and margins for those companies which successfully navigate the complex regulatory and quality barriers, but agreements are worthless until a company can reach the required operating standards and obtain licensing and quality certification.

Where is Cannasouth at in its development?

- Team built
- Licences secured*
- Research and development capability built
- Research funding secured
- Preclinical research programs underway
- First imported products being assessed by the MCA
- GACP and GMP designed production facilities in final stages of development

*Please refer table on the next page

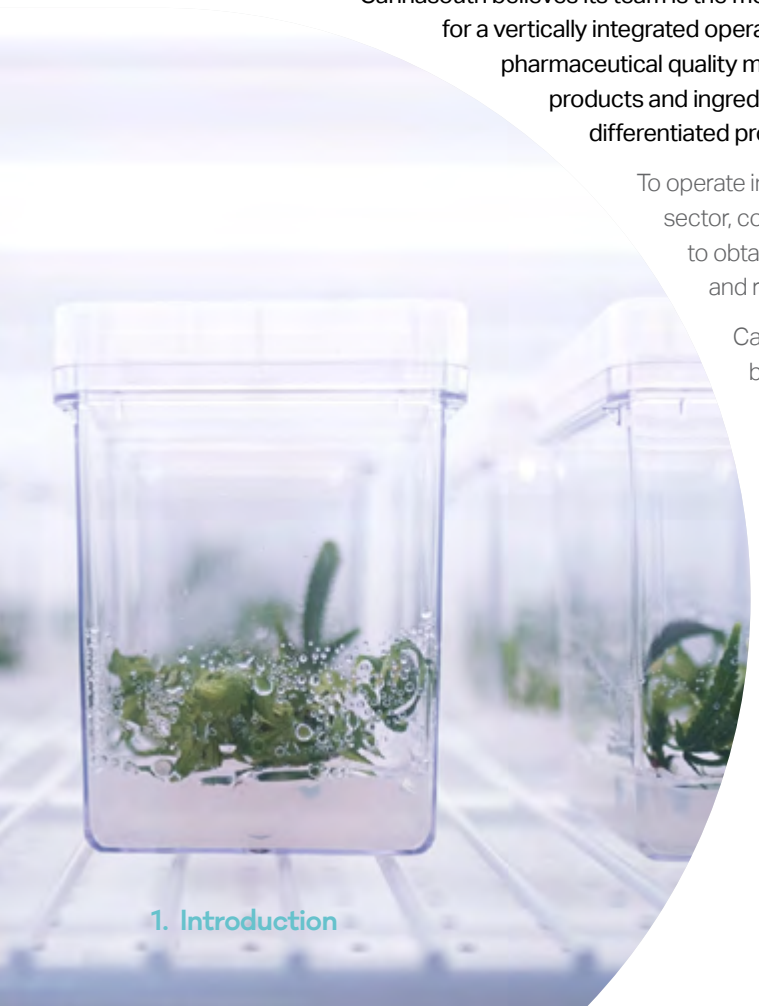
Next steps

- Commissioning, validation, and certification of its cultivation facility
- Sales of imported, own-brand products in New Zealand
- Export sales of premium, compliant cannabis biomass
- Completion and certification of extraction and GMP medicine manufacturing facilities
- Export of Cannabis-Based Ingredients (CBI's)
- Introduction of own next generation medicines (FDF) for local and export sales
- Commercialisation of further R&D pipeline projects
- Clinical trials

Where is Cannasouth at in its development?

Cannasouth has spent the last three years assembling a team of the highest quality and of a global standard covering corporate governance, finance, research and development, cultivation, manufacturing, quality, and regulatory compliance.

Cannasouth believes its team is the most complete in New Zealand for a vertically integrated operation intending to produce pharmaceutical quality medicinal cannabis finished products and ingredients and develop genuine differentiated products and defendable IP.



To operate in the medicinal cannabis sector, companies need to be able to obtain the required Licences and regulatory approvals.

Cannasouth has a history of being a New Zealand leader in regulatory compliance. The founders acquired some of the first Licences in 2002 to cultivate and research industrial hemp. Cannasouth was one of the first non-academic organisations to have received a Licence to Deal in Controlled Drugs (tetrahydrocannabinols) which was received in 2018.

Currently the Cannasouth Group has the following Licences:

Entity	*Licence	Status	Licencer
CBL	Medicinal Cannabis Licence (Cultivation, Possess for Manufacture, and Supply Activities)	Approved	Ministry of Health
CBL	Licence to deal in controlled drugs	Approved	Ministry of Health
CBL	Own brand imported medicinal cannabis product registration applications (x3)	Submitted	Ministry of Health
CCL	Medicinal Cannabis Licence (Cultivation Activity)	Approved	Ministry of Health
CCL	Medicinal Cannabis Licence (Supply Activity)	Planned	Ministry of Health
MW	Medicinal Cannabis Licence (Possess for Manufacture and Supply Activities)	Planned	Ministry of Health
MW	GMP Manufacturing Medicines Licence	Planned	Ministry of Health
MW	GMP Wholesale Licence	Approved	Ministry of Health
MW	GMP Licence to pack Medicines	Approved	Ministry of Health
MW	CTFA (Cosmetic) GMP Licence	Approved	Cosmetics New Zealand
MW	Biogro Organic Certification	Approved	BioGro New Zealand
MW	NP3 (Food Act 2014) Licence to Manufacture Food Products	Approved	Hastings District Council

Where is Cannasouth at in its development?

We believe the potential market size of pharmaceutical GMP quality medicinal cannabis products will continue to grow at an exponential rate over the coming years with most markets still in their infancy.

The range of products, which includes Cannabis-Based Ingredients (CBI's) and Finished Dosage Form (FDF's) will expand over time, and the industry will become global as each local market matures and the regulatory regime evolves in different countries.

However, there is an immediate hurdle for New Zealand companies.

New Zealand's regulations only support pharmaceutical quality production and much of the industry will be unable to achieve this standard.

Pharmaceutical quality is a high barrier to entry because it requires purpose-built facilities, a suitable QMS including suitably experienced personnel, all of which requires a substantial amount of capital and time to develop.

GMP manufacturing facility construction and commissioning is a complex multiyear process and there are no shortcuts. Companies starting that journey now will likely be two or three years away from sales depending on the area of the supply chain they are targeting.

In addition to the above, entering export markets is also a complex and multi-year process for most companies.

Export flower material must meet both the New Zealand Minimum Quality Standard (NZMQS) and the quality standard required by the importing country, often GACP/GMP. All commercial exports from New Zealand must meet the NZMQS.

Overcoming these hurdles requires companies to have a strategy, which will have multiple phases, including a supporting Research and Development (R&D) function to ensure moving beyond early generic products.

From its inception, Cannasouth has focused on the future of cannabinoid medicinal development and has invested in the capabilities to extract and isolate, to high purity, any compound found in sufficient quantity within the plant material to feed into its research and product development programs.

Cannasouth believes it has the most advanced technology in-house of any competitor in New Zealand for research and product development.

Cannabinoid Research: a new area of therapeutics

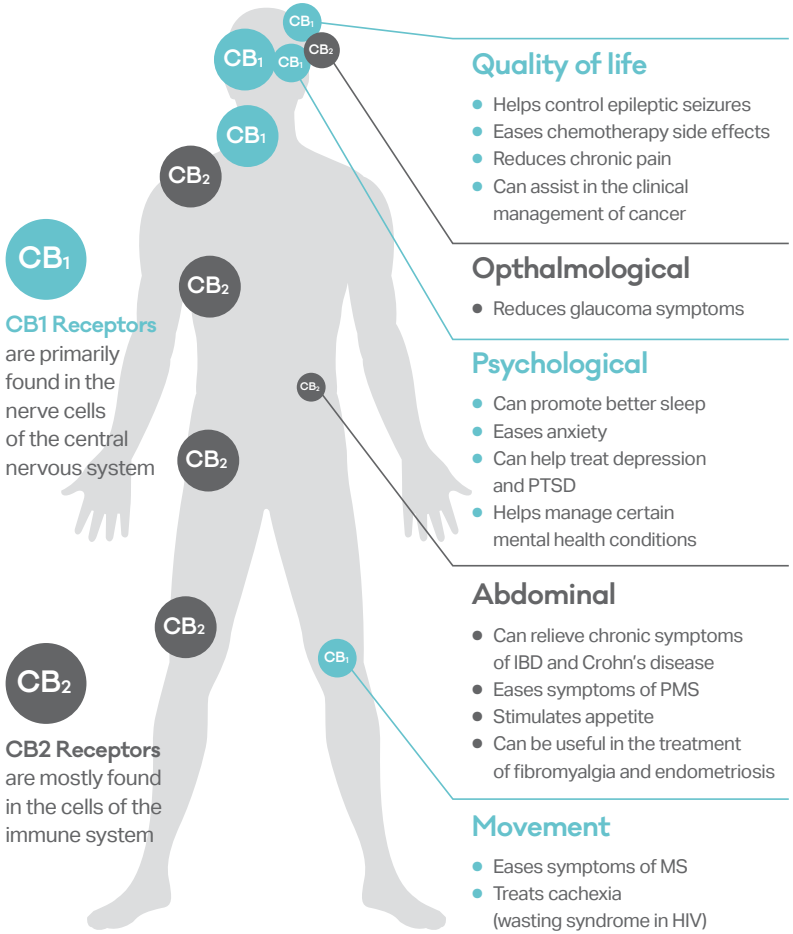
Although Cannabis is one of the oldest medicinal plants,[1] from the 1960's until relatively recently, political concerns and regulation have meant there has been very limited research into, and development of, medicinal cannabis.[2] The wave of prohibition worldwide resulted in various international restrictions including the Single Convention on Narcotic Drugs signed in 1961. Cannabis use for medical and research purposes was very restricted in various countries[3] creating a significant knowledge gap.
In recent years this has changed, creating the opportunity to apply modern technologies to identify, isolate, and characterise different compounds found in the cannabis plant which have pharmacological activity. This situation opens a wide range of possibilities for medicinal cannabis companies like Cannasouth to develop and clinically test the next generation of cannabinoid therapeutics.

Medicinal cannabis is not the first time a plant derived molecule has led to a major breakthrough in medicine. It is estimated that about 25% of all modern medicines are derived from plants. In some cases, such as antitumoral and antimicrobial drugs, about 60% of pharmaceutical medicines are currently derived from natural products[4] using unique plant secondary metabolites.[5] For example, morphine and codeine were extracted from the opium poppy in the early 1800's which eventually led to the discovery of the opioid receptors in mammals (1970's)[6] The first approved use of morphine was 1938, but its use accelerated following the first efficacy studies in the 1960's.[7]

25%
of all modern medicines are derived from plants

60%
of pharmaceutical medicines are currently derived from natural products

The Endocannabinoid (ECS) System



Cannabinoid Research: a new area of therapeutics

Morphine and its derivatives are now the most important analgesic drugs available in the world for moderate to severe pain. Even with the growing safety concerns and proposed restrictions related to addiction potential, the human pharmaceutical opioid market is forecast to reach annual sales of USD$57 billion by 2030.[8] For cannabis medicines, which have a much higher safety profile than opioids, the size of the global medicinal market is forecast to be worth USD$44.4 billion by 2025.[9]

Like opium, the historic use of cannabis eventually led to the discovery of the Endo-Cannabinoid System (ECS) in the 1990s, while researchers were trying to understand the psychoactive effects of the cannabis plant (phytocannabinoids).[3] The ECS is a biological system found in all vertebrates and comprises neurotransmitters naturally produced by the body (endocannabinoids) and an intricate network of biological receptors found throughout the peripheral nervous system and in the brain. Although two distinct receptors have been identified to date (CB1 and CB2), the ECS is still relatively unstudied. What is known is that the ECS is a key modulator of many important processes in the human body, including appetite, pain, inflammation, immune function, motor control and stress responses, offering huge medical potential.[10]

To date, it is known that at least two phytocannabinoids (CBD and THC) mimic the endocannabinoids produced in the body and can integrate with the ECS system to provide therapeutic effects. It is expected there are many more important cannabis derived bioactives yet to be studied. Unlike other neurotransmitters, cannabinoids appear to be made by the body as required rather than being stored and released when needed.

$57B
forecast annual sales (USD) for human pharmaceutical opioid market

$44.4B
forecast annual sales (USD) of the global medicinal cannabis market

There are over 400 natural components found within the cannabis plant, of which over 100 have been classified as cannabinoids. The main differences between the various cannabinoids are determined by the degree to which they are psychoactive or intoxicating. Three classes of cannabinoids, the CBC, CBG and CBD are not known to have such an effect. THC, CBN, CBDL and some of the other cannabinoids are known to be psychoactive to different degrees.

Global scientific research into the therapeutic effects of cannabinoids is still in its infancy. There is a continuous stream of new discoveries on the application of cannabis including clinical trials. We believe that the potential exists for medicinal cannabis products to become a staple of modern medicine in human and veterinary healthcare.

Products Overview: Pharmaceutical grade

Worldwide, there is increasing pressure on governments from patient groups and prescribers to allow access to legal cannabis-based medicines. **Currently 42 countries allow some kind of legal access, although many of them are in the very early stages of development.**

For New Zealand, the primary objective of the Medicinal Cannabis Scheme (MCS) is to increase access to quality medicinal cannabis products. However, New Zealand's regulations only allows import, manufacture, and export of pharmaceutical quality products.

Creating a regulated market with a suitable quality standard allows patients to access medicinal cannabis products in a more controlled and safer manner than if they were accessing crude products on the illicit market with no guarantee of product quality. However, it is important to note that a traditional drugs development process for a new lead compound can cost millions of dollars, and involves different stages including R&D, formulation, and clinical development.

Regulatory agencies around the world have implemented different regulatory regimens to regulate medicinal cannabis. As a strategy to reduce the cost of these medicines to patients, many countries have adopted a legal medicinal cannabis market (including New Zealand, Australia, Israel, and Germany) that allows "unapproved" products to be prescribed that comply with GMP, but without the full clinical trial data normally required for a medicine registration. These products are considered unapproved as they do not have the full clinical support for efficacy and safety as for any other pharmaceutical.

New Zealand has adopted a regime where products are evaluated against the New Zealand Minimum Quality Standard (NZMQS)[11] which aligns with GMP and is the gold standard for pharmaceutical manufacturing.

In comparison, in other countries such as the U.S where there is little regulatory oversight by the Federal Food Drug Administration (FDA), some cannabis products like supplements, cosmetics and food additives are available in the open market.

For New Zealand medicinal cannabis companies, the only option for manufacturing and developing products is in the "pharmaceutical" category and complying with NZMQS. It is expected, as the industry matures and regulations are reviewed, opportunities to enter new markets such as supplements might develop.

Currently

42

countries allow some kind of legal access

2

Products and Services

Products and Services

This section gives a high-level review of the products and services in the medicinal and wellness cannabis industry.

Saleable products, depending on local regulations and services include:

Cannabis Flower: Biomass

Bulk Extracts and Ingredients

Animal Health products

Processing Services

Human Health Products

Pharmaceuticals – Medicines

Supplements, Wellness & Lifestyle Products

Cannabis Flower: Biomass

Cannabis flower can be categorised as either start material (biomass) or as a Finished Dosage Form (FDF).

The quality of the plant material is the pillar for the quality of a herbal product. Consistency and reproducibility of any herbal medicine can only be assured if the plant material is defined in a rigorous manner.[12] The quantity of CBD and THC (and other components) will vary from plant to plant, but commercial growers must establish crops which produce a high degree of consistency in composition.

Start material (biomass) in most cases is dried and trimmed and may also be milled. It is used for further processing including extraction and refining into ingredients for finished products. Cannabis flower can also be used as Finished Dosage Form (FDF) and will commonly be used by the patient directly, including for vaping. These products are generally supplied in individual patient packs such as tins or pottles containing just a few grams. FDF is generally trimmed and not milled.

Depending on the next steps in the manufacturing process, several factors need to be considered for quality control of the starting material, including accurate macroscopical and microscopical characterisation, environmental factors, inter/intra species, variation of plants, and time of harvesting.

For use as an input in pharmaceutical GMP, a robust quality assurance system for the cultivation, harvest, and primary processing is critical. The GMP code "Annex 7 Manufacture of Herbal Medicines Products" recommends establishing Good Agricultural and Collection Practices (GACP)[12] as a quality standard for herbal starting materials. However, this is not required in every market. In addition, companies intending to supply cannabis flower as FDF are also required to have stability data for all packaging formats.

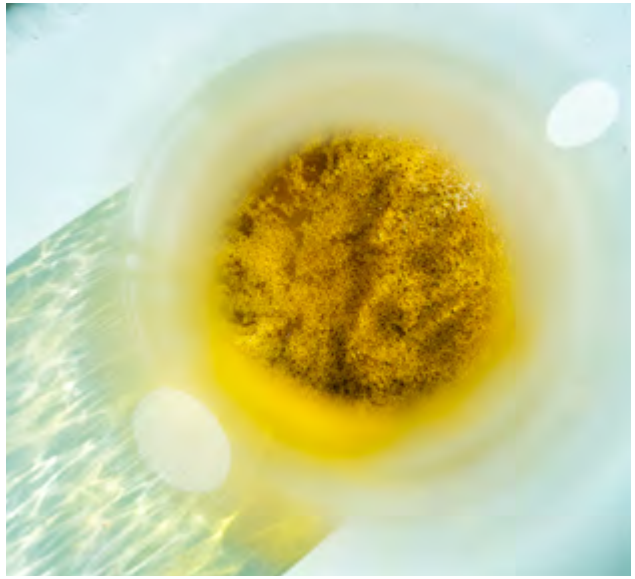
We discuss in more detail the quality standards and cultivation processes relating to cannabis flower later in this update.

Bulk Extracts & Ingredients

These raw materials might be described interchangeably as an Active Pharmaceutical Ingredient (API) or a Cannabis-Based Ingredient (CBI), depending on purity and the regulatory environment.

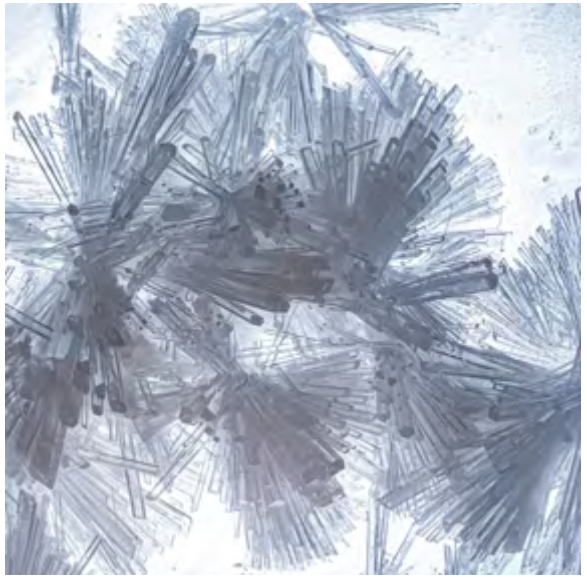
Essentially these are the pharmacologically active ingredients which will go into manufacturing a finished dosage product or medicine.

These raw materials can be supplied as either:



Crude Extract:
This is a crude concentrated plant extract containing all cannabinoids and other ingredients such as terpenes.

Distillate:
This is a purified distillate high in a particular cannabinoid but with a low level of other ingredients.



Isolate:
This is a further purified cannabinoid isolate which is the purest form of one particular compound.

Human Health Products

Cannabis products for human health can be categorised into two groups:

Pharmaceuticals - Medicines

Non Pharmaceuticals - Supplements, Wellness, and Lifestyle Products

Pharmaceuticals - Medicines: Finished Dosage Forms (FDF)

A Finished Dosage Form is the end-product or medicine which will be used by the patient. The dosage form is developed to provide a stable, safe, and efficacious dose of the medicine in a convenient format for the patient. There are many approved or recognised ways to deliver a medicine including:

- Oral (liquids, tablets, capsules, chewables)
- Injection (intravenous, intramuscular, subcutaneous)
- Skin (topical and transdermal gels, creams patches)
- Mucosal membranes (intranasal, rectal, intravaginal)
- Inhalation (vaping, aerosols)
- Innovative drug delivery systems (nanoparticles, polymers)

Current dosage forms of medicinal cannabis products are generally unsophisticated. They are typically based on recreational products such as flower and ingestible oils, although some new drug delivery systems are being tested in clinical situations.

Cannabinoids are very challenging compounds with inherently poor chemical stability and poor absorption by the body. CBD and THC are highly metabolised in the gut and the liver resulting a very low (<10%) oral bioavailability (the amount available at the target site to induce the therapeutic effect). **Improving bioavailability can, in essence, reduce the amount of drug required by the patient to be therapeutic and hence reduce things like cost, side effects and pack size.**

This area of drug development offers one of the greatest opportunities to improve and expand the pharmaceutical market and generate new technology, formulations, devices, clinical protocols and data, all potentially leading to the generation of Intellectual Property (IP). To progress in this field, dedicated resources and a greater clinical understanding is needed into how and where these compounds interact with biological systems.

Cannasouth has a commercially focused R&D facility based in New Zealand which is involved in multiple areas of research, from chemistry (identification, extraction, and isolation of bioactives) to biological sciences (pre-clinical investigations) and new product development (drug delivery technology).

Cannasouth's R&D team is currently working with Government funding via Callaghan Innovation and in collaboration with academic centers of excellence in New Zealand in the following areas:

Grant Type	Research	Status
Fellowship Grant	PhD: the Extraction of bioactives using Supercritical Fluid CO2 extraction, short path molecular distillation and purification research	In final year of three-year programme
	MSc: Tissue Culture to identify and optimize cultivation processes	Submitted February 2021
	MSc: To create a cannabinoid and receptor docking library using computational chemistry	Commenced March 2021
Project Grant	PhD: Drug Discovery, Neuropathic pain research In-house Research: Improved Drug Delivery technologies	Half-way into a three-year programme
Career Grant	Placement of a Fellowship Grant MSc student into full-time R&D role	February to August 2021

Currently, medicinal cannabis products are generally prescribed to patients as registered, unapproved products, or under special schemes in countries where medicinal cannabis is legal. Most of the prescribed medicines are unapproved products as they are supplied without any indication claims. Therefore, significant opportunities will arise from the development of approved medicines - those which have undergone the traditional clinical trials route, allowing claims to be made for named diseases or conditions.

This will provide greater confidence to doctors and may lead to funding by governments and/or private medical companies.

There is also growing pressure to down-regulate the non-psychoactive cannabinoids such as CBD.

Australia has recently lowered to Schedule 3 the use of low dose CBD as non-prescription medicines sold by pharmacists Over-The-Counter (OTC)[13] These OTC products will require clinical proof mainly for efficacy. Cannasouth is investigating clinical indications that would fit with the maximum defined dose and are working to identify the most appropriate clinical protocols.

Non-Pharmaceuticals: Supplements, Wellness & Lifestyle Products:

There is no supplements, wellness and lifestyle cannabis product category in New Zealand and companies are prohibited from producing and exporting these products.

This is because, in New Zealand, any product containing more than trace levels of cannabinoids, including CBD, are considered either prescription medicines or controlled drugs (and it is illegal to obtain them without a prescription).

The only products containing cannabinoids that can be manufactured in New Zealand must meet the New Zealand Minimum Quality Standard (NZMQS) assessed by the New Zealand Medicinal Cannabis Agency (MCA) and intended for pharmaceutical purposes.

However, this could be a potential opportunity once the New Zealand market evolves and regulations align with international markets.

Products in the category generally contain CBD as the main active ingredient however other non-intoxicating cannabinoids are beginning to be incorporated as well. Often the CBD is produced from industrial hemp cultivation and is produced to a lower food grade quality standard.

The global CBD market is expected to reach

$13.4B

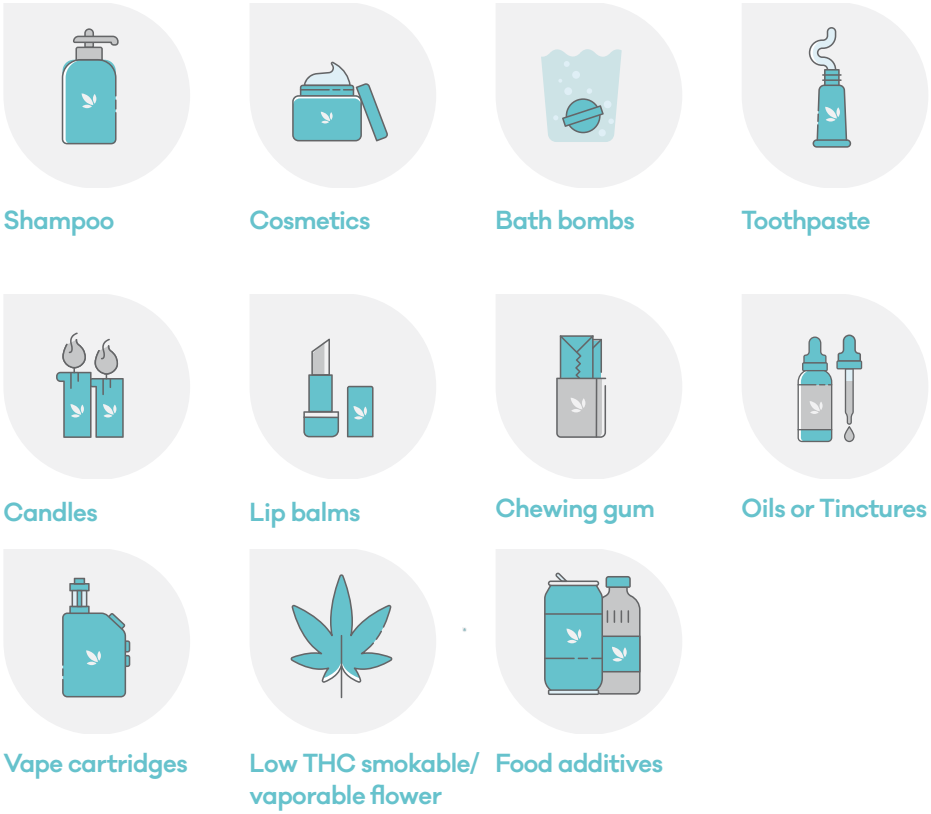
(USD) by 2028

The market is expected to expand at a CAGR of

21.2%

from 2021 to 2028

Some offshore markets have cannabis supplements, wellness and lifestyle product categories including:



Non-pharmaceutical CBD products are developing into a large sector globally with huge potential for growth over the coming years. The global CBD market is expected to reach USD 13.4 billion by 2028. The market is expected to expand at a Compound Annual Growth Rate (CAGR) of 21.2% from 2021 to 2028.[9] In the US there is currently very little regulatory oversight of these products and the US Federal and Drug Administration (FDA) is reviewing this with the possibility of increased regulation on the horizon.

Animal Health Products

In addition to human products, there is a growing interest in the use of CBD in particular as a veterinary medicine, primarily for companion animals. The veterinary market has significant potential in the coming years and will likely be split into either pharmaceutical therapeutic products or general wellness products, depending on what is permitted by regulators in each jurisdiction.

Although there is currently no defined regulatory pathway in New Zealand for animal health products, there is a growing interest from pet owners and veterinary practitioners. Cannasouth is engaged in preliminary talks with specialist vets to identify opportunities.

Services

The potential exists for a variety of services to the industry to be developed, including product testing, toll extraction and/or isolation, contract research, genetics and new product development.

KEY POINTS:

There are a wide range of products currently being developed in the pharmaceutical cannabis industry:

- Biomass (cannabis flower)
- Bulk extracts and ingredients
- Pharmaceuticals (FDF)

Significant opportunity exists in the development of approved medicines and innovative delivery systems to improve and expand the pharmaceutical market and generate Intellectual Property (IP).

Cannasouth has a commercially focused R&D facility based in New Zealand, involved in multiple areas of research, some supported by the New Zealand Government via funding from Callaghan Innovation and in collaboration with academic centres of excellence.

While New Zealand regulation currently only allows the development and manufacturing of pharmaceutical products for human health, there are significant future opportunities in:

- Supplements, wellness and lifestyle products
- Animal health sector

This will require changes to the regulatory regime in New Zealand.

3

Product Quality: Pharma vs non-Pharma

Product Quality: Pharma vs non-Pharma

In this section we discuss product quality in particular, pharmaceutical grade versus non-pharmaceutical grade.

Pharmaceutical products: Quality Standard

In New Zealand, medical prescribers can prescribe medicinal cannabis products registered under the Medicinal Cannabis Scheme (MCS) which have been assessed as meeting the New Zealand Minimum Quality Standard (NZMQS) for any condition which the prescriber feels it is appropriate. The quality standard established by the MCA is based on the GMP code.

Since its inception, Cannasouth has been focusing on developing the necessary infrastructure and resources to comply with the high regulatory requirements for pharmaceutical-grade production. While this has been capital intensive, Cannasouth is now well positioned to produce high quality products that meet all the regulatory requirements for New Zealand and key export markets.

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A Closer Look at Quality

Definition: GxP is a collection of quality guidelines and regulations (current Good Practices) created to ensure that bio/pharmaceutical products are safe, meet their intended use, and adhere to quality processes during manufacturing, control, storage, and distribution.

Note: the "c" means "current", "G" means "Good" and the "P" means Practices. Examples are cGL^{aboratory}P, cGM^{anufacturing}P, cGC^{linical}P, cGS^{torage}P, cGD^{istribution}P, cGR^{eview}P.

All companies must guarantee that the manufacture of medicinal products is done under the suitable quality standards that fit the intended purpose. For medicines, the gold standard to achieve this quality objective is GMP. The quality standards must be designed and correctly implemented based on a Pharmaceutical Quality System that incorporates GMP and quality risk management[14] This mitigates risk and guarantees reliable and consistent batches that are fully documented and can be easily traced back to the origin of the materials used.

GMP applies to the lifecycle stages from the manufacture of investigational medicinal products, technology transfer, and commercial manufacturing, through to product discontinuation. These practices must be applied across all company departments from pharmaceutical product development to distribution to the end-user. [15]

Quality and regulatory requirements change from country to country, and companies must meet the current standards defined by the regulatory authorities in each of the relevant markets to be able to sell its products. Companies are inspected and certified by the appropriate authority for GMP, unless there is a Mutual Recognition Agreement (MRA) in place. The Company (and any contractors) will be inspected routinely to ensure continued compliance.

Non-Pharmaceutical Products: Supplements, Wellness & Lifestyle Products

Products such as supplements, cosmetics, and food additives have lower standards than the pharmaceutical GMP code. In other countries, particularly the USA, many of these products are currently being sold with very little regulatory oversight. There are frequent reports of products which do not meet the label claim for the quantity of active ingredient, or are inconsistent with the labelling, including higher than acceptable levels of THC which is a controlled drug. Harmful byproducts such as pesticide residues have also been found to be present in some products.[16]

Many of these products provide little therapeutic benefit and fall firmly into the fad category because the levels of the active ingredient are too low, or the mode of action and administration is ineffective.

However, some of these products, such as supplements manufactured to a high-quality supplement standard with stated active ingredients are legitimate products that can provide genuine benefits to the consumer.

In unregulated markets it is very much buyer beware as products are emerging which are simply cashing in on CBD's popularity.

However, countries that have until now provided very little regulatory oversight are starting to change their position. The United Kingdom is a good example.

In January 2019, the UK declared CBD as a novel food.[17] All suppliers must produce a dossier which provides detailed information about their products, including composition, nutritional information, and toxicology information.

The United States FDA is also investigating whether effects of very high daily doses from using multiple unregulated products is elevating liver enzymes. FDA is asking the industry to define upper daily dose limits. This area is being monitored very closely and increased regulation will likely follow in the USA.[18]

KEY POINTS:

- Manufacture of medicinal products is done under the suitable quality standards that fit the intended purpose. For medicines, the gold standard to achieve this quality objective is GMP.
- GMP applies to the lifecycle stages from the manufacture of investigational medicinal products, technology transfer, and commercial manufacturing, through to product discontinuation.
- Since its inception, Cannasouth has been focusing on developing the necessary infrastructure and resources to comply with the high regulatory requirements for pharmaceutical-grade production.
- Products such as supplements, cosmetics, and food additives have lower standards than the pharmaceutical GMP code. In other countries, particularly the USA, many of these products are currently being sold with very little regulatory oversight.
- In unregulated markets it is very much buyer beware as products are emerging which are simply cashing in on CBD's popularity.
- While food grade CBD is quickly becoming commoditised, because the barriers to entry are much lower than pharmaceutical quality standards, many countries including the UK and USA are reviewing their regulatory oversight of these products which presents opportunities for companies that are able to produce high-quality products.

4

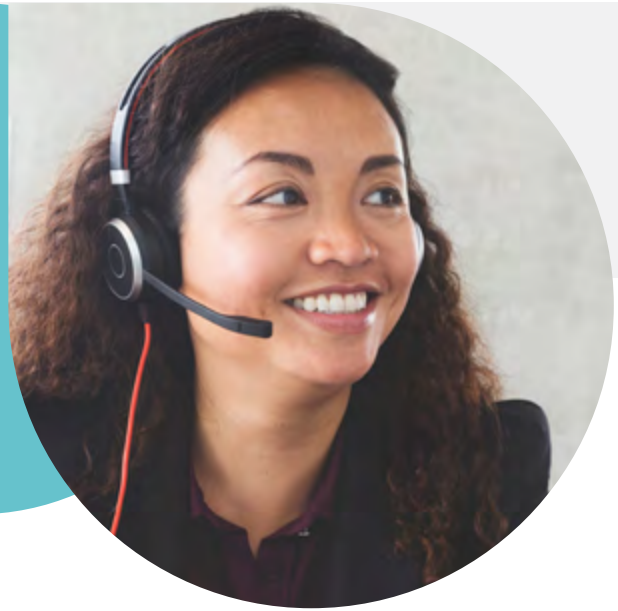
Patients: Challenges and Opportunities

Patients: Challenges and Opportunities

The underlying demand for access to medicinal cannabis from the public is immense and was the main driving force for the Misuse of Drugs (Medicinal Cannabis) Amendment Bill passing in New Zealand in 2018, and the subsequent creation of the Medicinal Cannabis Scheme (MCS). A global trend, in almost all regions where medicinal cannabis becomes available, are the initial barriers to patient access which include:

- Lack of prescriber education and/or stigma attached to prescribing these medications.
- Lack of approved or registered products due to lack of clinical trials, safety and efficacy data.
- Pricing and supply. Initial products are relatively expensive due to limited supply, current product classification and the requirement for specialist approval.
- Overly restrictive and/or evolving regulatory policies.

The global COVID-19 pandemic has paved the way for more 'telehealth' consultations.



Prescriber Education & Telehealth

Prescriber education is a very large barrier to patient access.

A study carried out at the University of Auckland in 2020 investigated the prescribing perception and behaviors from medical practitioners towards cannabis. This study highlighted significant gaps in knowledge regarding safety, efficacy, and suitable indications by the professionals who are authorised to prescribe in New Zealand.[19] Prescribers must understand how to use these products, which conditions they are suitable for, their safety, potential contraindications, and the clinical science that underpins them.

This barrier will take years to fully break down. Many prescribers put these medicines in the too hard basket, or too high risk due to lack of knowledge about them. There is also significant historical stigma around cannabis, increasing the barrier to access and prescriber resistance.

Running counter to this is the creation of specialist clinics that have prescribers educated in the use of these medicines. This trend is happening in New Zealand and is prevalent in markets like Australia.

The benefit of these clinics is that the prescriber is well versed in medicinal cannabis uses, potential adverse reactions, and appropriate product selection for best therapeutic outcome.

The global COVID-19 pandemic has also paved the way for more 'telehealth' consultations, which can be particularly beneficial for patients seeking medicinal cannabis treatments.

Often with the stigma attached to cannabis-based medicines, patients may be reluctant to ask their regular GP about these products or may not want to visit a physical cannabis clinic. In many cases, the conditions for which cannabis-based medicines are prescribed are chronic and ongoing. It is likely they have been previously diagnosed, which means a physical examination is not necessary. The trend to online consultations is likely to continue and significantly increases patient access.

Clinical Trials: Safety and Efficacy Data

Currently, the supply of medicinal cannabis products to patients is very restricted because they are considered unapproved medicines. Sativex™ is one of the few cannabis medicines that received consent under the Medicines Act 1981(registered) and costs circa 1100-1400 NZD per month, depending on the dose.

Most countries that have legalised cannabis for medical purposes are allowing unapproved medicines in the market, however clinical development is crucial to increase access to patients. Market growth continues to be fueled by the significant amount of research currently being undertaken globally to produce clinical data to support the use of medicinal cannabis for a range of conditions.

Currently in the United States there are over 20 clinical trials either being conducted or about to start into pain management alone.[20] In Europe, there are currently 35 clinical trials being conducted with cannabinoid-based products.[21] In addition, there is a large amount of anecdotal data from small uncontrolled studies.

Unfortunately, clinical trials using plant extracts are extremely challenging when each extract may have a different composition. This is why 'controlled' pharma products is the best way to generate consistent study data to support registration.

Pricing Barriers

Currently medicinal cannabis products are not funded in many parts of the world, including New Zealand. New Zealanders are used to paying very little for their prescriptions and the financial cost presents one of the biggest barriers for many patients. Currently, depending on the dosage required the cost for products meeting the New Zealand Minimum Quality Standard (NZMQS), but unapproved for specific conditions, (i.e. Section 29 products), range from $5 to $10 per day or $150 to $300 per month. Cost is likely to drop when the local industry matures, and manufacturing volumes increase through exports to other markets.

Cannabinoids are lipophilic substances which means they are not easily absorbed. With the current methods of administration most of the active ingredients are not utilised by the body and are processed by the liver.

Future improvements in drug delivery and bioavailability will reduce the quantity required by the patient, which will in turn reduce the monthly cost and improve efficacy. Cannasouth is actively focused on the drug delivery and bioavailability area of pharmaceutical development.

A 2012/2013 New Zealand health survey [22] reported that around 5% of New Zealanders over the age of 15 use cannabis medicinally.

A number that is sure to have risen and continues to rise following the recent popularisation of, and scientific evidence, supporting medicinal cannabis.

Longer-term, once products are approved and clinical data is available to support efficacy claims, some products may attract subsidies or funding.

Germany is one market where patients can access medicinal cannabis, which is subject to some price controls and is funded by medical insurance.[23] This approach is supporting growth in the market, although some other access barriers still exist.

Australia recently started funding an approved cannabis-based medicine for treatment of Dravet syndrome.[24]

Cannasouth believes the trend for insurance company support will increase internationally once prescriber understanding improves, and there is further acceptance of cannabis-based medicines.

Shortage of Supply and Prescription vs Illicit

Due to a shortage of supply, combined with a reluctance for prescribers to issue prescriptions, many patients are forced to access products from the illicit market. This presents a number of potential risks.

These include:

- Whether the product contains the expected active ingredient(s);
- Limited control of cannabinoid dosage
- The risk the product is contaminated with microbials, bacteria, solvents, pesticides or other harmful substances.

The potential consequence of taking sub-standard products is greater for those patients who are already immune compromised.

The fact that many patients are prepared to take this risk shows many are desperate to access cannabis-based medicines. Producing medicines to GMP standards will ensure registered products will be of a consistent quality and free from contaminants.

Accessing these products with a prescription will also ensure that patients do not risk prosecution for possessing illegal cannabis.

There is no doubt that some patients will continue to take the risk and use simple, illicit market, preparations. However, the clear trend internationally is for patients to move away from the illicit market to higher quality, convenient, consistent, efficacious and cost-effective prescription products. When access barriers are reduced and more product choices exist.

As more data is produced to demonstrate efficacy and safety, medical professionals and regulators are becoming more comfortable with regulating access to, and prescribing products, further increasing the market size and rate of growth.

Restrictive Regulatory Policies

Cannabis carries a difficult history as an illicit recreational drug due to its psychoactive effects making its medicalisation a very highly regulated process.

Cannabis and cannabis-related substances have, for many years, been included in the schedules of the Single Convention on Narcotic Drugs of 1961 as amended by the 1972 Protocol. As a result, New Zealand has obligations under the United Nations Drug Conventions to control the commercial production and supply of cannabis for medical use and to report to the International Narcotics Control Board (INCB) manufacturing and supply volumes.[25]

In December 2020, cannabis and cannabis resin was voted to be deleted from Schedule IV of the 1961 Convention.

KEY POINTS

- Underlying demand for medicinal cannabis was the main driving force for the Misuse of Drugs (Medicinal Cannabis) Amendment Bill passing in New Zealand in 2018.
- However, there are barriers to patient access, including:
  - Lack of prescriber education
  - Lack of approved or registered products
  - High pricing
  - Low supply; and overly restrictive and or evolving regulatory policies.
- Solutions to patient access, include:
  - Government and industry led prescriber education
  - Specialist clinics are leading the way
  - Telehealth options
  - Further development of safety and efficacy data
  - Insurance and/or government funding
  - Evolving regulation
- The prescription market, once fully developed, will provide safer and more effective products without the risk of prosecution for patients.
- The trend internationally is for patients to move away from the illicit market to higher quality, convenient, consistent, efficacious and cost-effective prescription products.
- Currently products can be expensive and are not always easily absorbed by the body. Cannasouth is focused on drug delivery and the bioavailability of pharmaceutical products to both reduce quantities required and cost.
- Cannasouth anticipates products will become more affordable once supply increases and local manufacturing comes onstream.

5

Geographic Markets

New Zealand

Medicinal cannabis is legal in New Zealand with the Medicinal Cannabis Scheme (MCS) being launched on 1 April 2020. The MCS is overseen by the Medicinal Cannabis Agency (MCA) which is a division within the New Zealand Ministry of Health.

The MCS allows prescribers to prescribe medicinal cannabis and oversees importation and local manufacture of these medicines. All products prescribed under the MCS must be assessed as meeting the New Zealand Minimum Quality Standard (NZMQS).

These registered products are classified as 'unapproved' medicines, unless they have supporting clinical trials data to support a specific therapeutic claim. These unapproved products fall under Section 29 of the Medicines Act, which means they must be prescribed by a doctor or specialist on a named patient basis.

Section 29 of the Medicines Act also prohibits promotion in any way of unapproved medicines. This is the reason that Cannasouth cannot mention products it may have available for sale. However, prescribers can request information from a supplier.

More information can be found here:

www.medsafe.govt.nz/profs/Rlss/unapp.asp

In New Zealand, prescribers can prescribe products registered under the MCS for any condition they feel it is appropriate for. This approach is a significant advantage for patients in New Zealand, compared with some overseas jurisdictions which may only allow prescriptions for specified clinical conditions and or require a specialist to approve.

Prior to the launch of the MCS in New Zealand, some CBD products were available to prescribers and patients. To avoid patients not having access to similar products while new products are being assessed by the agency, a transitional period was created during which those existing products either need to be assessed and registered by the MCA or phased out.

As an indication of how difficult it is to source products meeting the NZMQS, the transitional period has been extended twice and now expires in September 2021. At the beginning of May 2021, over a year since the scheme was launched, only four products have been assessed as meeting the standard and registered for use here.

Cannasouth currently has product assessment applications being processed for its first imported products which will be sold under its own brand.

Patient demand for medicinal cannabis remains high in New Zealand. Once products have been assessed by the MCA and registered, the main barrier to access for patients will be prescriber education. Several specialist clinics have already emerged, which has been the trend in other countries adopting a prescriber/pharmacy access model.

Currently, most of the medicinal cannabis products being dispensed in New Zealand are CBD due to the lack of availability of products containing THC (Tetrahydrocannabinol) which has a controlled drug status.

Once products containing THC are assessed by the MCA, doctors will be able to prescribe these for a much larger number of clinical indications and the market is expected to grow at a consistent pace over the coming years.

As mentioned earlier in this update, all products containing cannabinoids, including CBD products, are prescription only in New Zealand, and therefore the importation or accessing these without a prescription is illegal.

Products containing CBD must also be produced to pharmaceutical quality standards. Australia is implementing changes that will allow some low-dose pharmaceutical quality CBD products to be accessed over the counter (OTC), but they must be registered with the Therapeutic Goods Administration (TGA) and provide clinical data support for efficacy. New Zealand may follow at some point in the future, but the regulatory pathway for this is not yet clear. For the down scheduling of CBD, an application for rescheduling is required. Some of the restrictions for this process are related to the fact the product is an unapproved medicine. Also, there is reluctance to remove CBD from the Medicines Act, if there is not enough clinical data to support its safety and efficacy.

CBD is not allowed to be used in food, supplements, or cosmetics. Pet products incorporating CBD in New Zealand would need to be registered as medicines and approved by ACVM (Agricultural Compounds and Veterinary Medicines) before being released to the market.

Section 25 of the Medicines Act

Section 25 of the Medicines Act allows prescribers to "procure the sale or supply of any medicine for a particular patient in his or her care."[26] This exemption exists to allow prescribers to access medicines not available in New Zealand for their patient or for clinical trials.

This exception is currently being exploited by some prescribers who are importing CBD products which bypasses the NZMQS and pharmaceutical GMP practices.

The responsibility for the quality of the product is placed on the prescriber. There is no direct regulator oversight of the quality. There is potential for patients to be at risk of receiving low-quality products, which is particularly concerning for the medicinal cannabis patients who have compromised immune systems.[27]

The current medicinal cannabis regulations require improvement, as we describe in the Regulatory Environment section. It is expected that the MCA will start a process of consultation on amendments to the regulation sometime in 2021.

Australia

The Australian medicinal cannabis market has been operational since 2016. However, regulatory prescribing complexities and differences between states has reduced patient access and slowed the initial growth of the market. These issues have been largely resolved and the market continues to grow very strongly with an estimated market value of AUD $95 million in 2020 growing to over AUD $150 million in 2021[28] The number of medical cannabis prescriptions approved by the TGA under the Special Access Scheme (SAS) Category B, was around 116,000 between May 2020 to April 2021.[29]

Australia operates a regulatory model similar to New Zealand, incorporating a traditional prescription/pharmacy model. Australian law also requires GMP for locally manufactured products. However, they have allowed a different quality standard for imports, which has created challenges for local manufacturers.

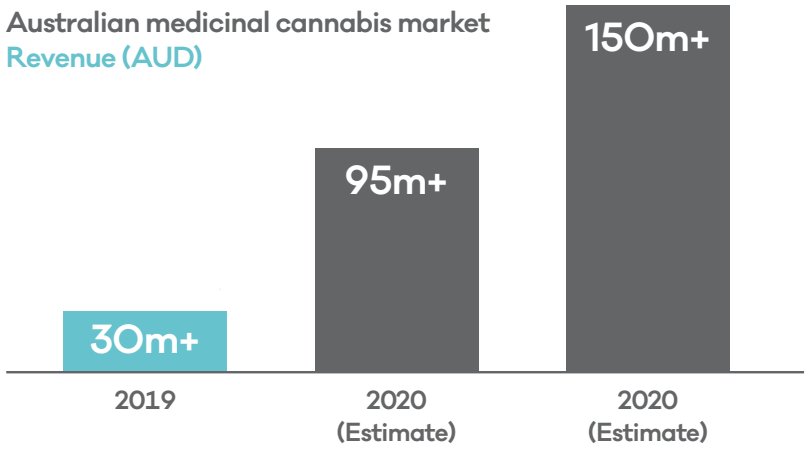
This difference in standards is now being reviewed with the possibility of bringing import standards into line with GMP[30] Australia is a key target market for Cannasouth due to its close proximity and close alignment of regulations and quality standards.

The total Australian market is estimated to reach

$150m

(AUD) by 2021

Australian medicinal cannabis market
Revenue (AUD)



Europe and the United Kingdom

The European medicinal cannabis market is in an early phase of development and represents a major area of interest for Cannasouth. Access to medicinal cannabis in this region is tightly regulated with a high degree of physician oversight, access by pharmacy prescription only, and strict GMP pharmaceutical quality standards.

The European market is currently dominated by Germany. In 2020, the value of the German medicinal cannabis market was estimated to be USD$267 million and expected to grow to USD$2.1 billion by 2025.[31]

Several factors explain the growth in use of medicinal cannabis in Germany, including its cost being covered by some health insurers, and government and prescriber education initiatives designed to increase patient access to these products. Despite these initiatives there are still barriers for patients and the market has significant room for growth as these are reduced over time.

Like most new markets, the UK has had a slow start to its medicinal cannabis scheme. Despite this the UK has also been tipped to become a major market over the coming years with an estimated 2020-2025 Compound Annual Growth Rate (CAGR) of 98%. The total European market is estimated to reach a value of just under USD 3 billion by 2025.[31]

The total European market is estimated to reach

$3B

(USD) by 2025

The market is expected to expand at a CAGR of

98%

from 2020 to 2025

Asia

The Asian medicinal cannabis market is also starting to develop. Strict laws prohibiting cannabis use in many of these countries means that medicinal cannabis access is being tightly controlled as schemes are developed with a preference for pharmaceutical quality products.

Most Asian countries have a long history of traditional medicine use, often from natural plant-based sources. Thailand and South Korea have both legalised medicinal cannabis use, with some other countries in the region allowing access to products containing CBD. The region's close proximity to New Zealand, combined with New Zealand's trusted reputation for quality, traceability and good manufacturing standards creates excellent export opportunities for Cannasouth over the coming years.

KEY POINTS

New Zealand:

- Medicinal cannabis is legal in New Zealand and prescribers can prescribe registered medicines that have been assessed by the MCA as meeting the NZMQS for any condition they feel it is appropriate.
- CBD is a prescription medicine and cannot be used in food, supplements or cosmetics.
- Cannabis-based medicines assessed by the MCA as meeting the NZMQS are considered as unapproved medicines (Section 29) and cannot be promoted or advertised in any way.
- Some CBD products available before the launch of the MCS are allowed to be sold until September 2021 at which time they must be removed from the market unless they have been assessed as meeting the NZMQS.
- Sourcing products internationally that meet the NZMQS is difficult. In May 2021 only four products have been assessed as meeting the NZMQS
- Cannasouth currently has three products being assessed by the MCA.
- Patient demand is high and once more products are available the New Zealand market is expected to grow strongly.
- Some prescribers are exploiting Section 25 to import CBD products that have not been assessed as meeting the NZMQS.

Australia:

- Despite a slow start and initial regulatory complexities, the Australian market is growing at a rapid rate. Sales in 2020 were estimated at reaching AUD $95 million, predicted to reach over AUD $150 million in 2021.
- Australia operates a regulatory model similar to New Zealand incorporating a prescription/pharmacy pathway.
- Australia is allowing some low-dose pharmaceutical quality CBD products to be accessed over the counter (OTC).
- Australia is a key target market for Cannasouth due to its proximity and close alignment of regulations and quality standards.

Europe and the United Kingdom:

- Access to medicinal cannabis in this region is tightly regulated with a high degree of physician oversight, access by pharmacy prescription only, and strict GMP pharmaceutical quality standards.
- The European market is currently dominated by Germany. In 2020, the value of the German medicinal cannabis market was estimated to be USD $267 million and expected to grow to USD $2.1 billion by 2025.
- The UK has had a slow start to its medicinal cannabis scheme. Despite this the UK has also been tipped to become a major market over the coming years.
- The total European market is estimated to reach a value of just under USD $3 billion by 2025.

Other Markets:

- Other markets including Asia continue to develop and are generally in their very early stages.

6

Cultivation and Pharmaceutical Manufacturing

Cultivation

Many companies are looking to establish cultivation facilities in New Zealand to supply either the local or export medicinal cannabis markets.

Cannabis flower produced for the local or export markets depending on the intended use will have different quality and regulatory requirements that a cultivator must meet.

Start Material Export Requirements:

Cannabis flower that is intended as a start material for export must:

Be assessed by the MCA as meeting the New Zealand Minimum Quality Standard (NZMQS) which requires testing for:

- microbial contamination
- heavy metals
- pesticides
- absence of aflatoxins
- ochratoxin A
- foreign matter
- loss on drying
- total ash
- residual solvents

The testing requirements and maximum limits are based on the European Pharmacopoeia (10th edition), which provides quality standards for medicines and their components.

Additionally, the flower will also need to meet the requirements of the export country/ customer who will likely require production to Good Agriculture and Collection Practice (GACP) and or Good Manufacturing Practice (GMP) standards, depending on the end use.

Exporters need to be able to navigate complex regulatory hurdles. Cannabis flower, including low THC biomass, cannot be exported for the recreational or supplements/ wellness categories, only for medicinal or scientific purposes.

Start Material Local Supply Requirements:

In New Zealand the manufacturer that will further process the flower sets the standard of the cultivated flower to be used as a start material. This has caused confusion amongst cultivators wanting to enter the industry as there is no clear guidelines or quality standard for them to follow. Manufacturers of Cannabis-Based Ingredients (CBI's) and/or Finished Dosage Forms (FDF) need to operate to GMP standards. GMP requires risk management and documentation of the complete production process. Flower is a key input in this process as such manufacturers will likely require cultivators to have an established Quality Management System (QMS) and be operating to Good Agricultural Practice (GAP) or GACP so that there is adequate supporting documentation of quality control to enable them to produce a compliant end product. Just producing "high quality" flower will likely not be enough for a cultivator wanting to supply biomass to a GMP manufacturer.

The manufacturing process itself will dictate what levels of microbial or other residuals can be tolerated. If for example high levels of pesticide or heavy metal residues are found during manufacturing, the GMP facility will require an expensive shutdown and decontamination. Contaminants found in finished medicines will require complete product recall and have the potential to cause harm to patients.

Compounding the challenge for cultivators is the likelihood only a small number of local manufacturers in the short to medium term will establish GMP operations in New Zealand.

Flower as a Finished Dosage Form (FDF):

Flower to be exported or sold locally as a FDF will be required to comply with PE 009-8 (Part I) PIC/S GMP Guide (Part I: Basic Requirements for Medicinal Products).

To determinate which step of the manufacturing process to implement the GMP code, a risk assessment should be carried out to support the starting point. Also, stability data for thee manufacturing batches will be required.

Cultivators wanting to enter the industry need to have these quality considerations in mind from the beginning. Failure to do so may lead to retrospective alterations to facilities, equipment, processes, and key personnel to meet the requirements of the export customer or local manufacturer.

Cultivation Strategies

Cannabis is a unique crop with large dense flowers which hold the majority of the desired cannabinoid compounds. The flower is extremely vulnerable to molds and fungus in the late stages of production, especially if humidity is too high. A crop can be rendered largely worthless if molds and fungus or other contamination levels are too high for it to meet NZMQS for export or for GMP processing by local manufacturers. Flower biomass is a key input in manufacturing CBI's and FDF.

From here we will look at the pros and cons for the following primary cultivation strategies:

Outdoor Cultivation

Covered Crops

Vented Greenhouses

Indoor Cultivation

Controlled Environment Agriculture (CEA) Sealed Greenhouses

Outdoor Cultivation

Outdoor cultivation is the lowest cost of production of biomass. However, it comes with many potential risks for GMP pharmaceutical inputs. Firstly, crops exposed to the natural environment are at risk of significant crop loss or failure due to adverse weather events. With generally only one crop per season, this can be fatal. There is also heightened risk of contamination from heavy metals, pesticide (overspray), and foreign matter, including insect and bird waste. Also, outdoor cultivation may produce plants with dissimilar genetic composition, increasing the variability factors. An uncontrolled growing environment can permit cross-pollination which reduces the quantity and quality of cannabinoids.[1]

In a GMP supply chain, this material is generally only viable as a start material for extractions. Elevated contamination levels may mean this material cannot be exported or utilised by local GMP manufacturers.

Outdoor cultivation is the lowest cost of production of biomass

Growing low THC crops outdoors does not come with high security costs, but if a cultivator wants to cultivate high THC crops, they will need to invest a significant amount in security controls surrounding an area that may only yield one crop per year therefore increasing the overall costs of the crop.

Another challenge with outdoor cultivation is harvest processing constraints. Large amounts of the crop become ready for harvest in a short time period and must be processed and dried quickly to avoid further quality issues. This involves a large investment in processing infrastructure for facilities which may be sitting idle for the rest of the year.

Storage and shelf life can also be an issue with large amounts of seasonal biomass produced.

The prices achieved for this quality of product will reflect the lower-grade commodity status of the material and cultivators will need to operate at scale to be competitive.

"An uncontrolled growing environment can permit cross-pollination which reduces the quantity and quality of cannabinoids."[1]

Covered Crops

Netted and partially covered crops.

Although this method will reduce some of the exposure problems of the outdoor uncovered crops, it does not necessarily reduce mold risks or harvest challenges and significantly increases the capex costs. While not necessarily increasing the value of the biomass it may reduce some of the other exposure risks faced by outdoor crops.

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"Greenhouses cover a wide spectrum and can include more advanced fan forced climate control, evaporative wet walls for cooling, and humidity control equipment."

Vented Greenhouses

Traditional vented greenhouses.

These greenhouses can range from very basic to very sophisticated and provide more protection and crop certainty. They can increase the number of crops that can be produced per year (potentially year-round) depending on the investment that is put into supplemental lighting, heating/cooling or and black-out curtains. The addition of insect netting and air filtration will reduce the risk of foreign matter contamination. Without humidity control, risk remains for molds and mildew because of a combination of high heat and humidity in the final weeks of flowering.

Greenhouses cover a wide spectrum and can include more advanced fan forced climate control, evaporative wet walls for cooling, and humidity control equipment.

Depending on the level of investment in environmental controls, the output is still at risk of seasonal variation or failure to meet export or local manufacturers required quality standards. Most greenhouse will produce material suitable as a start material, and this will compete with outdoor grown biomass. Higher specification facilities may produce FDF flower, but this will require specialist post-harvest and drying processors and equipment and operating to GACP/GMP depending on the end market.

Indoor Cultivation

To produce a premium quality product able to be utilised as either start material or as a FDF consistently year-round, indoor growing has been the gold standard to date. There are several advantages of this style of cultivation depending on the level of investment in the facilities. Facilities suitably designed can provide complete control of light levels, temperature, humidity, water quality and biosecurity. These are the main advantages allowing the standardisation of the cannabis flowers. This means product can be produced consistently year-round. To produce flower as a FDF requires the facility to be specifically designed for this purpose and cultivators operating to GACP/GMP standards. Failure to meet these standards will mean the material is only suitable as start material.

The downsides of indoor cultivation include the very high capital expenditure required to establish facilities. These facilities also use large amounts of energy per gram of flower produced and it is difficult to claim any unique provenance in city-grown indoor material. Scaling of these operations can also be challenging, as often these facilities are located in warehouses in cities with either too much space or not enough and with high land costs.

To justify the high setup and operational costs the material needs to be produced to FDF quality or will be competing with lower cost outdoor or greenhouse start material flower.

"Scaling of these operations can also be challenging, as often these facilities are located in warehouses in cities with either too much space or not enough and with high land costs."

Controlled Environment Agriculture (CEA) Sealed Greenhouse

Cannasouth has chosen to construct a controlled environment agriculture (CEA) sealed greenhouse. This approach takes all the precise climate and biosecurity control features of an indoor environment but introduces sunlight as the primary light source. This design combined with purpose built GMP post-harvest processing equipment and facilities enables the production of premium plus FDF quality product year-round.

These facilities are cutting edge, complex to design and construct as unlike indoor facilities, seasonal variations with solar gain must be factored into the environmental control equipment. The initial capex cost is similar to an indoor facility. The upside of the CEA approach is a facility designed to scale as required without interrupting existing operations and located on less expensive rural land, using greatly reduced energy and overall production costs per gram when compared with indoor flower. This approach is better able to tap into the "New Zealand cache" than the traditional indoor model.

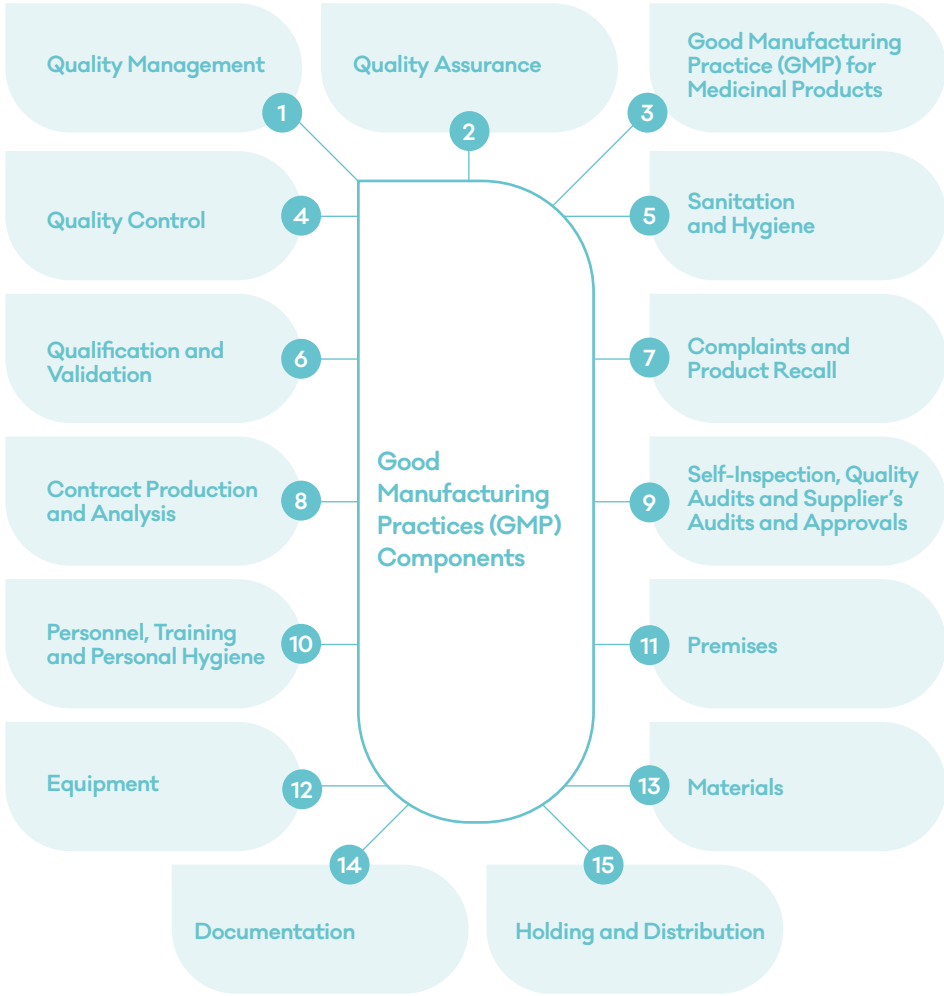
This design combined with purpose built GMP post-harvest processing equipment and facilities enables the production of premium plus FDF quality product year-round.

Pharmaceutical Manufacture

To manufacture, pack, store and distribute medicinal products, including CBI, API and FDF's requires a dedicated purpose-built facility with certified compliance to current GxP's. Certification is gained following a successful inspection by the relevant regulatory authority. The Company must demonstrate ongoing compliance to current quality guidelines from regular regulatory audits and inspections. Failure to comply can result in removal of Licences.

These quality guidelines contain relatively clear concepts **BUT** is expensive to implement and maintain, and requires significant skills and resource as summarized in the diagram below.

- Facility is designed for its intended purpose and meets the requirements of cGxP's.
- Requires specific skills and experience.
- All equipment and processes must be qualified and validated.
- Typically involves larger capital investment.
- Significant ongoing commitment by staff and management.
- Ongoing inspections and audits to ensure standards are maintained.
- Is successful when a company-wide quality culture is achieved.



There are no short cuts in this process. As a result, only well-resourced and well-structured businesses will successfully establish operations to meet the pharmaceutical quality standards.

In addition to the GxP's, companies must also ensure that products comply with the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). This is a set of guidelines aimed at aligning international regulatory authorities. It covers all areas of product safety and efficacy including product shelf-life (stability), the validation of all analytical test methods and the product registration dossier which will be required by the end customer and the relevant regulatory authority.

These quality guidelines contain relatively clear concepts **BUT** can be expensive to implement & maintain, In summary:

- cGxP requires specific skills, knowhow, equipment, and facilities.
- Typically involves larger capital investment.
- Significant ongoing commitment by staff and management.
- Ongoing inspections and audits to ensure standards are maintained. (Compliance failure will close production).
- Is successful when a company-wide quality culture is achieved.

KEY POINTS

- The quality of the plant material is the pillar for the quality of herbal medicines. Cultivators need to understand the quality requirements for either local or export markets and should consider operating to GAP/GACP standards.
- It is challenging to export cannabis flower. The material needs to meet both the NZMQS and the often-higher standards of the export market likely GACP and or GMP.
- There are a number of cultivation options from outdoor crops/covered crops, vented greenhouses, sealed greenhouses and indoor cultivation, each with its own benefits, drawbacks and costs. The gold standard is consistent control in temperature, humidity, water quality and biosecurity.
- Low to medium grade start material flower is likely to be oversupplied to the market in the short to medium term. A large number of cultivators are entering this area of production and with a likely limited number of local GMP manufacturers and challenges associated with export, a glut in the local market is likely.
- Premium GACP/GMP quality flower may come under pricing pressure in the future but the barrier to entry is much higher with the investment and time required in establishing facilities and processes able to produce to these quality standards. Key markets including Australia have recently reported product shortages in this category.
- Key lessons from offshore markets include focusing on quality over quantity, scaling to meet the market rather than building oversized facilities. Producing to pharmaceutical GACP/GMP with a premium plus product ensures a growing global demand rather than low-mid grade flower which is more easily commoditised.
- To manufacture, pack, store and distribute medicinal products, including CBI, API and FDF's requires a dedicated purpose-built facility with certified compliance to current GxP's.
- There are no shortcuts in establishing GMP manufacturing operations. As a result, only well-resourced and well-structured businesses will successfully establish operations to meet the pharmaceutical quality standards.

7

Regulatory Environment in New Zealand

Regulatory Environment in New Zealand

This section discusses the key issues arising from the New Zealand regulatory regime.

Firstly, Cannasouth wishes to acknowledge the effort from the Ministry of Health (MoH) and the Medicinal Cannabis Agency (MCA) in the development of the regulatory framework for the Medicinal Cannabis Scheme (MCS). The MCA has adopted a collaborative approach with stakeholders in developing the MCS, keeping in mind the challenging timeframe and high expectations from the public, healthcare professionals and the industry. The MCS became operational in April 2020, tasked with improving access to high-quality and affordable medicinal cannabis products in New Zealand.

However, access to affordable and high-quality cannabis medicines remains problematic. There is a high barrier of entry to develop and manufacture medicinal cannabis products under the regulated pharmaceutical pathway, this necessitates the industry to make significant levels of investment. This process also takes time to complete compliant facilities, processes and end products. The domestic market is expected to be too small to support a sustainable future for local companies, and access to international markets is essential to support a viable business model. Fortunately, the MCS requirement for New Zealand manufacturers to operate to Good Manufacturing Practice (GMP) allows access to high value, fast growing offshore markets.

There is a high barrier of entry to develop and manufacture medicinal cannabis products under the regulated pharmaceutical pathway. This necessitates the industry to make significant levels of investment.

Licences focus on security – Licences are just the start!

The licensing part of the MCS is not the highest barrier. Licensing primarily focuses on security arrangements, not whether Licence holders have the facilities, equipment, suitably experienced personnel, or Quality Management System (QMS) required to enable companies to meet the New Zealand Minimum Quality Standard (NZMQS) and the requirements of export markets.

Learnings from other regulatory regimes

There is a real opportunity to learn from other regulatory regimes that were implemented around the world prior to New Zealand. For example, in the US, even though cannabis for medical purposes has been legalised in 36 states, distribution of medicinal cannabis products containing THC is still considered a federal offence[32] with the exception of Sativex™ which has been granted marketing authorisation by the Food and Drug Administration (FDA). The initial lack of oversight from the regulator has resulted in wide distribution of low-quality CBD products into the market, presenting real challenges for the FDA to control. As a result, it has been found that many products do not contain the levels of CBD claimed. The FDA is also investigating reports of CBD products containing unsafe quantities of pesticides and heavy metals.[33]

Cannasouth believes to protect patients the quality of medicinal cannabis products should be non-negotiable in the New Zealand market and products that do not meet the prescribed standards should be phased out as soon as practical.

In the UK, despite the legalisation of medical cannabis in 2018, only a very small number of patients have been provided treatment within the National Health Service, meaning that medicinal cannabis remains currently inaccessible for most patients in need.

Cannabis for medical purposes has been legalised in

36 states

in the US, distribution of medicinal cannabis products containing THC is still considered a federal offence

In contrast to the UK, Germany has made medical cannabis products available to patients in a relatively short space of time since it was legalised in 2017. Germany has established a regulatory framework that provides better access to medicinal cannabis using a medicinal herbal product approach and has become the leading prescriber in Europe for conditions where other treatments are not available, or where standard treatments cannot be used because of potential side effects.[34]

It is essential the MCS draws on this overseas experience. Although the present scheme has focused on providing high-quality medicines to patients, the system has not addressed the ability to increase patient's access to affordable cannabis medicines. There are important areas of development such as:

- Aligning further our quality standards to the herbal medicines approach of Germany.
- Minimising the risk of patients accessing non-GMP manufactured products.
- The need to provide education, training, and support to prescribers and health care professionals.
- Improving the evidence base through real-world data collection.
- Addressing stigma around medicinal cannabis.
- Improving affordability for patients.

Cannasouth believes to protect patients the quality of medicinal cannabis products should be non-negotiable in the New Zealand market.

New Zealand operates to highest pharmaceutical standards

All CBIs and FDFs imported or manufactured in New Zealand must be assessed as meeting NZMQS before they can be supplied to patients or exported commercially. This means they must be manufactured to GMP standards and tested according to European Pharmacopoeia (Ph. Eur) specifications. The testing site must also be GMP certified and have validated analytical methods and stability in accordance with the International Council for Harmonisation of Technical Requirements for Pharmaceutical for Human Use (ICH) quality guidelines.

These include:

- Q1A(R2) Stability Testing of New Drug Substances and Products; and
- Q2(R1) Validation of Analytical Procedures: Text and Methodology

Export opportunities only for pharmaceutical grade products

The current regulations do not allow products being exported from New Zealand for anything other than pharmaceutical quality medicinal cannabis products or qualifying research. This is paramount for all companies operating in the sector here, as those companies which are unable to operate to these standards will not be able to sell product, either locally or for export, except for research material purposes.

Not only do companies need to meet the NZMQS, if they intend to export, they must also meet the required standards and regulatory compliance requirements of the destination country. Each country has different regulations, and a strong quality and regulatory team is essential to navigate this complex process.

Cannasouth has established its business to pharmaceutical GMP standard to allow access to high quality, high margin export markets. This has been a pillar of its QMS development since inception and all its facilities have been designed and established to meet the highest global standards.

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KEY POINTS

- The MCA has adopted a collaborative approach with stakeholders in developing the MCS, keeping in mind the challenging timeframe and high expectations from the public, healthcare professionals and the industry. It is expected a regulatory review process will take place during 2021.
- There is a high barrier of entry to develop and manufacture medicinal cannabis products under the regulated pharmaceutical pathway adopted by New Zealand and many emerging and key markets.
- Fortunately, the requirement for New Zealand manufacturers to operate to Good Manufacturing Practice (GMP) allows access to high value, fast growing offshore markets.
- Cannasouth believes to protect patients the quality of medicinal cannabis products should be non-negotiable in the New Zealand market.
- The licensing part of the MCS is not the highest barrier. Licensing primarily focuses on security arrangements, not whether Licence holders have the ability to meet the New Zealand Minimum Quality Standard (NZMQS) and or the requirements of export markets.
- Further improvements are required to increase patient access and affordability. There is opportunity to learn from other jurisdictions including Germany to further improve New Zealand's MCS and align to key offshore markets.
- The current regulations do not allow products being exported from New Zealand for anything other than pharmaceutical quality medicinal cannabis products or qualifying research and those exports must meet the NZMQS and further requirements of the export market.

8

Closing Remarks

Lessons Learned

There is a perception that New Zealand is late to the party for medicinal cannabis regulation when compared (for example) to USA and Canadian markets.

However, from a business perspective there is a certain advantage in being able to learn from the experience of other markets. The "early" markets seem to be plagued by poor profitability which is the result of a gold rush mentality. Specifically, they have been dogged by oversupply of low-quality biomass and over investment in assets and systems which are not fit for purpose or scaled correctly.

The Canadian market is dominated by adult use and most producers are focusing on this area. Although medicinal use is widespread, the quality standard does not require Good Manufacturing Practice (GMP), meaning many operations are not GMP compliant. Expensive process changes and refits are required to meet this more global standard for export to key markets. Many Canadian operations have focused on scale over quality.

Cannabis use in the USA is still federally illegal. Despite this many states allow adult use and medicinal cannabis access. This mismatch in legal status has created a complex array of varying regulations from state to state. Although medicinal cannabis is available in many states, few companies produce products to GMP standards. Like Canada much of the focus is on the adult uses area of cannabis supply.

Cannasouth believes it has avoided these mistakes by learning from international operators.

Fit For Purpose.

Cannasouth has focused on developing GACP and GMP compliant facilities and processes from the beginning which once certified will allow access to key high growth export markets.

Quality Over Scale.

Developing compliant facilities, focusing on meeting GMP standards first and then scaling once key markets are accessed, is a key pillar of Cannasouth's strategy.

Focused Strategy.

Cannasouth has a clear focus on producing pharmaceutical GMP quality medicines and ingredients for fast growing international markets and is not distracted by the adult use or FMCG categories.

Cannasouth will shortly provide a market update focusing on creating genuine advances in the medicinal cannabis industry, and Cannasouth's growth strategy, timelines, and competitive advantage that make it a leader in the New Zealand market.

Cannasouth's Environmental Statement

Cannasouth is committed to the highest level of environmental sustainability across all aspects of its research, cultivation, manufacturing and business processes. It has a goal to become one of New Zealand's most sustainable and environmentally friendly commercial medicinal cannabis entities and to lead by example to inspire others to incorporate sustainably focused policies throughout their organisations.

The planet is precious – there is no Plan B. Cannasouth believes immediate change is needed to address world-wide sustainability and environmental issues, and it starts with us – the people who walk this planet and use its finite resources.

Cannasouth is committed to sustainability and environmental stewardship through:

- Using chemical free growing techniques whenever possible to produce its research compounds and medicines.
- Producing cannabinoid compounds through the most environmentally friendly methods possible.
- Constantly developing and improving its cultivation and manufacturing production systems to reduce energy and water use and reducing its carbon footprint.
- Building cultivation facilities to adhere to worldwide GACP.
- Incorporating sustainable practices across all levels of the organisation, including waste minimisation, packaging, and recycling.
- Developing medicinal cannabis products that are accessible and affordable for all patients who need them.

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