CallaghanInnovation
New Zealand's Innovation Agency

Medicinal Cannabis

Capability Roadmap

Accessing the right capability to succeed in medicinal cannabis

This roadmap will help you navigate this rapidly evolving industry – identifying the capability required for any business, whether you are focused or vertically integrated.

Providing information and guidance for NZ medicinal cannabis businesses all the way from seed to market.

Enter

Acknowledgements

If you have any feedback or questions about this document, or have contributions to suggest please email us at roadmaps@callaghaninnovation.govt.nz

Version 2.0

Develop your Strategy. Right from the start.

Developing a successful business strategy, R&D/IP strategy and regulatory and market access strategy should be the start point. They are core to establishing a medicinal cannabis business and should be continually revisited as you grow.

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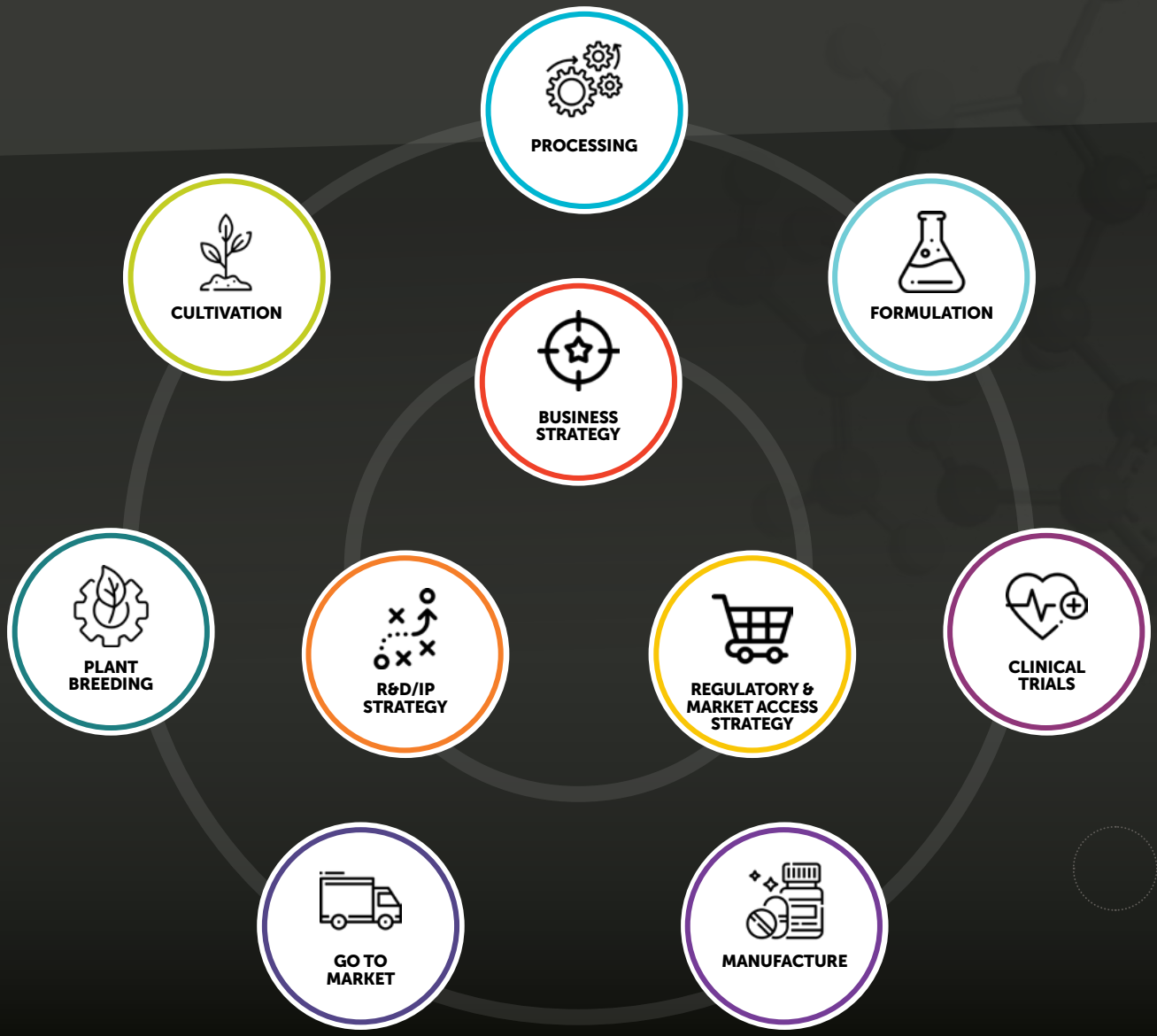

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R&D/IP STRATEGY

This capability refers to a range of activities to identify, create and manage intellectual property (IP) through developing and implementing your IP STRATEGY to gain a competitive advantage in the market place, enabling you to profit and grow your business.

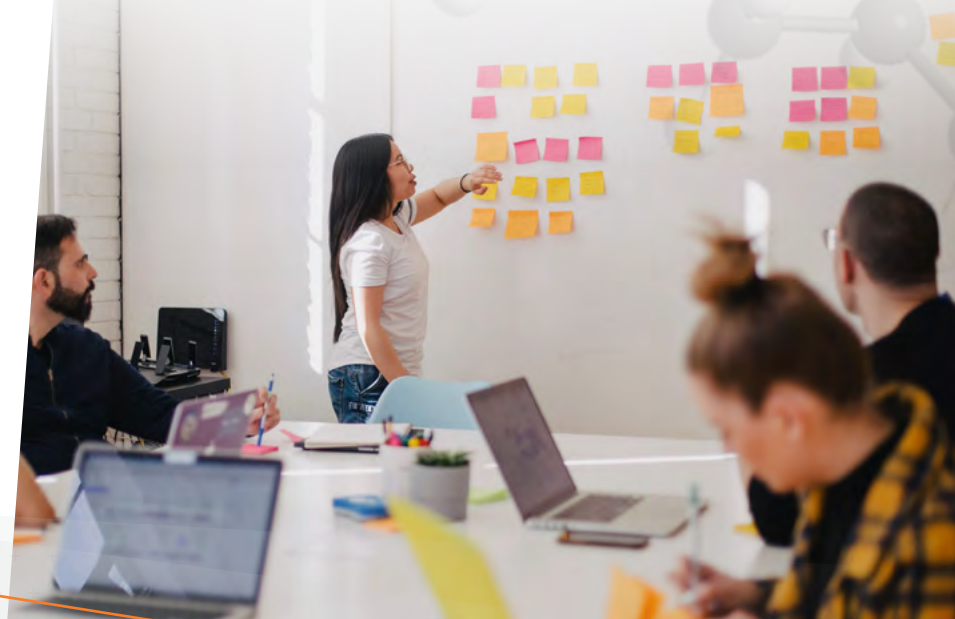
Your IP strategy should answer questions around what to do about IP, including determining what IP you have, how to protect and how to leverage it. It does not have to be expensive and should identify cost effective solutions.

Particularly relevant if you are investing in R&D and new product development, commercializing a new product or innovation, exporting, accessing capital or if selling your business. However, it is also important when dealing with confidential information, when hiring staff, or when outsourcing or licensing.

It is important that you have processes for identifying the IP you create and a strategy for protecting and capitalising on it. It keeps your commercial goals to the fore and provides a framework for when you are deciding on what IP rights to secure and where to spend your money.

WHAT IS NEEDED

- **DEVELOP IP STRATEGY**
- **LEVERAGE IP**
- **MANAGE AND PROTECT**



DEVELOP IP STRATEGY

Identify sources of IP first, which could include:

- Unique genetics/breeds/cultivars
- Cultivation methods (i.e. organic)
- Processing technology
- Unique formulations
- Therapeutic claims (clinical)
- Branding, trademarks, copyrights

Specify confidential information. Trade secrets include processes, customer information, business strategies, and specific formulations.

Understand your IP environment, particularly territory, timing and scope.

Evaluate your company's freedom to operate (FTO) in the initial phase of your product development and systematically prior to launching a new product.

ASK YOURSELF

- Do I have a business strategy in place?
- What impact does this have on my IP strategy?
- Have I identified the different sources of IP?
- Have I conducted an FTO analysis?

ACCESS CAPABILITY

IP SERVICE PROVIDERS

CALLAGHAN INNOVATION
(INNOVATION IP PROGRAMME)

LEVERAGE IP

Evaluate and implement best way to protect your identified IP.

Registration gives you certain exclusive rights over your brand or innovation, completed through a national IP office. Includes:

- Registered trademarks ®
- Patents: new products, formulations, and processes. However, it is a complex legal process requiring expert help from a patent attorney to give you the best chance of securing good protection.
- Plant variety rights (PVRs): exclusive right to produce for sale and to sell propagating material of the variety.

Unregistered IP still offers legal protection and can also protect secret information. It includes:

- Unregistered trademarks ™
- Trade secrets (i.e. recipes and customer databases)
- Confidential information: Secrecy agreements and Copyright ©

Leverage your protected IP through enforcing IP rights or through licensing in/out. It's also important you consider your options at an early stage to minimize the risk of you infringing on another company's rights (FTO).

ASK YOURSELF

- Do I recognise when important IP is being created?
- How do I protect my IP?
- Can our business capture IP?

ACCESS CAPABILITY

- BUSINESS.GOVT.NZ
- INTELLECTUAL PROPERTY OFFICE OF NZ
- IP SERVICE PROVIDERS
- CALLAGHAN INNOVATION (INNOVATION IP PROGRAMME)

MANAGE AND PROTECT IP

Put systems in place to manage your IP.

Tools and support:

- Develop an IP checklist or asset register
- IP management systems: tracking patent due dates, workflows, manage legal requirements etc.

Manage confidential information:

- Add confidentiality clauses when hiring staff or contractors, especially given potential for IP loss through staff
- Insert legal clauses in documents including non- disclosure agreements (NDAs) and confidentiality agreements when out-sourcing work or licensing or distributing your products/services.

IP should be reviewed routinely as one of your managed risks.

ASK YOURSELF

- What systems do we have in place to track IP?
- How well are we managing IP issues when drafting and negotiating agreements?
- Are we actively managing the risk of IP loss?

ACCESS CAPABILITY

- BUSINESS.GOVT.NZ
- IP CHECKLIST
- IP SERVICE PROVIDERS
- EMPLOYMENT AGREEMENT BUILDER
- CALLAGHAN INNOVATION
  INNOVATION IP PROGRAMME

REGULATORY & MARKET ACCESS STRATEGY

This is a REGULATORY and MARKET ACCESS capability which encompasses activities across the entire value chain for medicinal cannabis.

Key regulatory activity is focused on meeting requirements of the Medicinal Cannabis Scheme and the Medicines Act by establishing and meeting minimum quality standards, regulatory approval in export markets, and pharmacovigilance for distributed products. This also extends to any activity that improves patient access to medicinal cannabis products in specific health systems where relevant

Minimum quality standards apply to:

- cannabis-based ingredients
- medicinal cannabis products (dried products or dosage products)
- imported and exported products, and
- starting material intended for export.

WHAT IS NEEDED

- LOCAL MARKET
- INTERNATIONAL MARKETS
- MARKET ACCESS

LOCAL MARKET

What is needed:

It is important you understand the Medicinal Cannabis Scheme and the implications for your business.

Under the scheme a NZ doctor may prescribe a medicinal cannabis product that is not an 'approved' medicine, once the product has been verified as meeting the minimum quality standard.

The scheme covers a full range of activities including nursery, cultivation, research, possession for manufacture (in addition to licence to manufacture under Medicines Act), and supply.

Licensing requirements include assessment of activity, site details, security, tracking and record keeping, procedures for destruction and secure transport.

You will require an import licence if you intend to import cannabis seed, starting material, a cannabis-based ingredient or a medicinal cannabis product.

ASK YOURSELF

- Do I understand the licensing scheme requirements?
- Am I planning for an unapproved or approved medicinal cannabis product?
- What value adding activities am I going to focus on?
- Do I understand the requirements for security as part of my license?

ACCESS CAPABILITY

SECURITY CONSULTANTS

MINISTRY OF HEALTH
MEDICINAL CANNABIS AGENCY

MINISTRY OF HEALTH
REGULATORY CONSULTANTS

NZ MEDICINAL CANNABIS COUNCIL
NZMCC

INTERNATIONAL MARKETS

Regulatory approvals in export markets

You will need to meet the regulatory requirements for any country you intend to export medicinal cannabis products to (starting material, canabi-based ingredient or finished products).

Understand the legal & regulatory framework in each export market to determine the market opportunity. This is especially important given there is currently no harmonisation in regulation across markets.

Export licensing

You will need an export licence if you want to export cannabis starting material, a cannabis-based ingredient or a medicinal cannabis product.

ASK YOURSELF

- What are the regulatory requirements in the export market of interest?
- Do I have a trading partner that holds an import license for required activities?

ACCESS CAPABILITY

- **SECURITY CONSULTANTS**
- **MINISTRY OF HEALTH**
  MEDICINAL CANNABIS AGENCY
- **MINISTRY OF HEALTH**
  REGULATORY CONSULTANTS
- **NZ TRADE & ENTERPRISE**

MARKET ACCESS

You will need to understand opportunities for patients to access medicinal cannabis products in market of interest. This includes public reimbursement or insurance coverage to cover patients' out-of-pocket costs, although to date this is limited.

In New Zealand, patients will access medicinal cannabis products through prescription from their doctor. Once your product meets minimum quality standards you will be included on the scheme. However you will not be able to advertise your product to prescribers.

Understand differences in market opportunity due to how patients access medicinal cannabis products in different markets. For example, in New Zealand cannabis health products or nutraceuticals containing CBD and CBD products containing <2% THC are prescription medicines, whereas in some markets these same products are available over the counter.

ASK YOURSELF

- How do patients access medicinal cannabis product in my target market?
- Do I know how this differs by each market of interest?

ACCESS CAPABILITY

SECURITY CONSULTANTS

MINISTRY OF HEALTH
MEDICINAL CANNABIS AGENCY

MINISTRY OF HEALTH
REGULATORY CONSULTANTS

BUSINESS STRATEGY

Your BUSINESS STRATEGY specifies your core business and sources of competitive advantage in order to create long term value.

You will need to decide on the best strategy to build your advantage, which could be either:

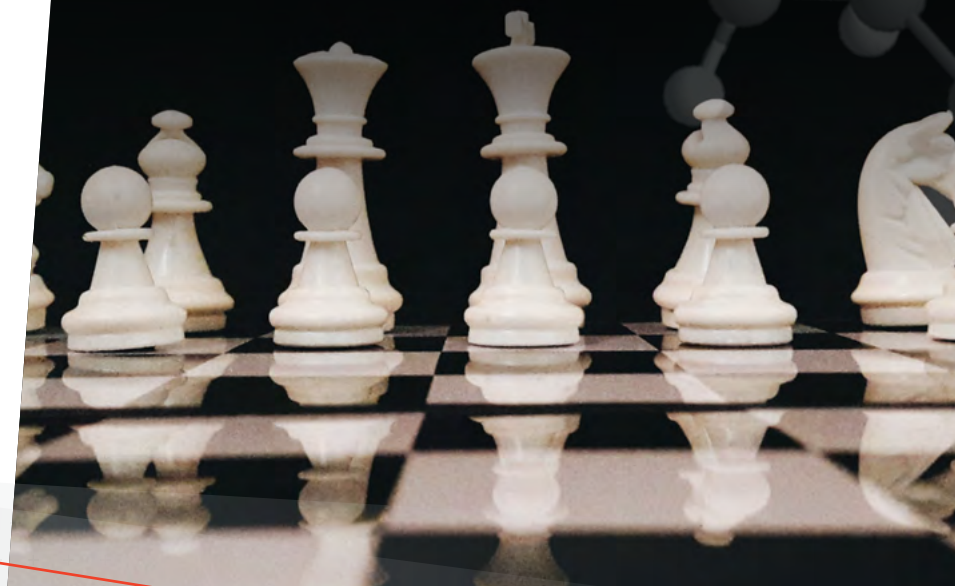
- Market or competition-based: Outwards focused based on current and proposed fit in market
- Business-centred: Inwards focussed leveraging your assets and capabilities
- Innovation-based: Creating your own space by switching strategic focus inwards, outwards, or using a mix of the two.

It is assumed the majority of medicinal cannabis companies in New Zealand will pursue a differentiation strategy through value-added activities. Given this, you will need to focus on those value chain activities where you potentially have a competitive advantage such as IP around cultivars and formulations, brands, unique technologies, and distribution channel share.

Once you've developed your business strategy, it's important to keep it up to date and review in the face of new opportunities.

WHAT IS NEEDED

- MARKET VALIDATION
- BUSINESS STRATEGY
- PEOPLE
- PHYSICAL RESOURCES
- EARLY INVESTMENT STRATEGY
- FINANCIAL AND INVESTMENT STRATEGY



MARKET VALIDATION

You will need to develop an approach to screen, prioritise, and qualify new products or markets.

Conduct a market opportunity assessment: Use available secondary market information to develop in-depth understanding of potential markets, quantify the market opportunity and understand the competitive landscape. Understand how market legalization leading to access to cannabis without prescription may affect future demand in medicinal market. Accelerate learning by connecting with industry associations or government agencies who may have direct experience.

Talk to patients and customers to understand their needs and determine the overall opportunity. This should include defining and sizing the market problem, your target audience and developing and testing unique value proposition based on desired product features.

ASK YOURSELF

- Am I talking to others with market experience?
- Do I understand customers unmet needs?
- Am I validating opportunities with customers?

ACCESS CAPABILITY

- **ICEHOUSE**
  MARKET VALIDATION PROGRAMME
- **NZ MEDICINAL CANNABIS COUNCIL**
  NZMCC
- **NZ TRADE & ENTERPRISE**
- **BIOTECHNZ**

BUSINESS STRATEGY

Start by articulating your vision and mission to help set your direction: Describe what success looks like and what you want to achieve in a way you can break down and measure it.

Understand your situation through a proper assessment that includes environmental, competitive analysis and a SWOT. This will also inform your GO TO MARKET approach.

Make sure to set a single business goal (or strategic objective). From this, you should also detail objectives to help you measure progress, set targets and plan projects that help you reach them.

Reflect your business strategy in your implementation plans (marketing, operations, resourcing). This also may include transitioning over time from product importation to local cultivation.

Put measurements in place. Make sure that these link back to your overall strategy and allow you track your progress.

ASK YOURSELF

- Do I have a vision and mission?
- Have I conducted a market assessment?
- What is my business goal?
- Do I have implementation plans?
- Have I got the right systems in place to track progress?

ACCESS CAPABILITY

- ECONOMIC DEVELOPMENT AGENCY
- BUSINESS.GOVT.NZ
- NZ TRADE & ENTERPRISE
- BANKS

PEOPLE

You will need to specify the people resources you will need to carry out the planned activity.

Determine the people skill sets that you need and whether or not to buy or acquire them. Consider the potential to bring in knowledge agents from related industries (i.e. pharma) or more developed markets (North America). Connect with learning institutions that can provide training experiences.

Ensure you have the right management capability in place including leadership, personnel training, health and safety, sales and business development. This includes planning for leadership changes, i.e. managing the transition from founder to CEO.

Ensure you have governance processes in place.

Continually review your people resource and need to change as you grow and develop your business.

ASK YOURSELF

- Have I got a people resource plan in place?
- Do I have the right team and experience in place?
- What training opportunities can I access for my team?
- What is the capability of my management team? Now and moving forward?
- Am I reviewing my people resource?

ACCESS CAPABILITY

- INSTITUTE OF DIRECTORS
- BUSINESS.GOVT.NZ
- HUMAN RESOURCES INSTITUTE OF NZ HRNZ
- APPOINT BETTER BOARDS
- AUCKLAND UNIVERSITY OF TECHNOLOGY

PHYSICAL RESOURCES

You will need to specify raw materials, buildings and facilities, machinery, energy, and supplies.

This will also inform whether you invest in specific resources, or outsource. This also may be the opportunity to look at strategic partnership arrangements.

Review different technology platforms as a means to innovate and build capability including those that can be transferred from related industries (I.e. hops, forestry). Many of these will are likely to require specialised equipment and additional investment.

Evaluate the role of digital technologies including robotics and automation; traceability; communication; clinical trials to further develop capability.

ASK YOURSELF

- Have I got a physical resource plan in place?
- Do I need to invest or outsource?
- Are there specialised equipment required for technology platform?
- What digital technologies will help deliver my strategy?

ACCESS CAPABILITY

- TECH INCUBATORS
- BUSINESS.GOVT.NZ
- CALLAGHAN INNOVATION GETTING STARTED

EARLY INVESTMENT STRATEGY

Your early investment phase will in most cases focus on important R&D and IP activities to support Business Strategy and mitigate risk for investors in subsequent capital raises

Understand your R&D requirements to generate a proof of concept supporting a differentiated product and how you are going to fund initial activity. This could be from shareholders or from Grants etc.

You need to articulate an R&D Programme and specify the activities you are going to undertake as grant funding can be an enabler for your IP and regulatory strategy without diluting equity at an early stage.

ASK YOURSELF

- How can you get capital outside of equity funding?
- How do I get access to early stage funding?
- Do I have a path to market?
- Am I able to co-fund?
- What is my R&D Programme and what can I afford?
- Have I identified key risks for early stage investors?

ACCESS CAPABILITY

- WASTE MINIMISATION FUND
- BIORESOURCE PROCESSING ALLIANCE
- CALLAGHAN INNOVATION GETTING STARTED
- AGMARDT
- SUSTAINABLE FOOD AND FIBRE FUTURES

FINANCIAL AND INVESTMENT STRATEGY

You will need to specify the financing needed.

Understand the commercialisation process, timeframe, your cash burn rate and whether you need external sources of capital. Or can you use bootstrapping to get to first sale?

Determine your capital structure and financing required to deliver your business strategy. This will depend on the timing of investments and your planned approach to scaling the business.

Understand different options for capital, including how to access or raise capital if required.

If relevant consider strategic alliance such as joint venture or equity alliance to provide additional advantages.

ASK YOURSELF

- What financing arrangement?
- What is my ideal capital structure?
- What is my timeframe to commercialisation?
- What is my cash burn rate?
- What investments are required to effectively scale?
- Do I understand how to access or raise capital?

ACCESS CAPABILITY

- CAPITAL EDUCATION PROGRAMME
- NZ TRADE & ENTERPRISE
- NZ GROWTH CAPITAL PARTNERS

PLANT BREEDING

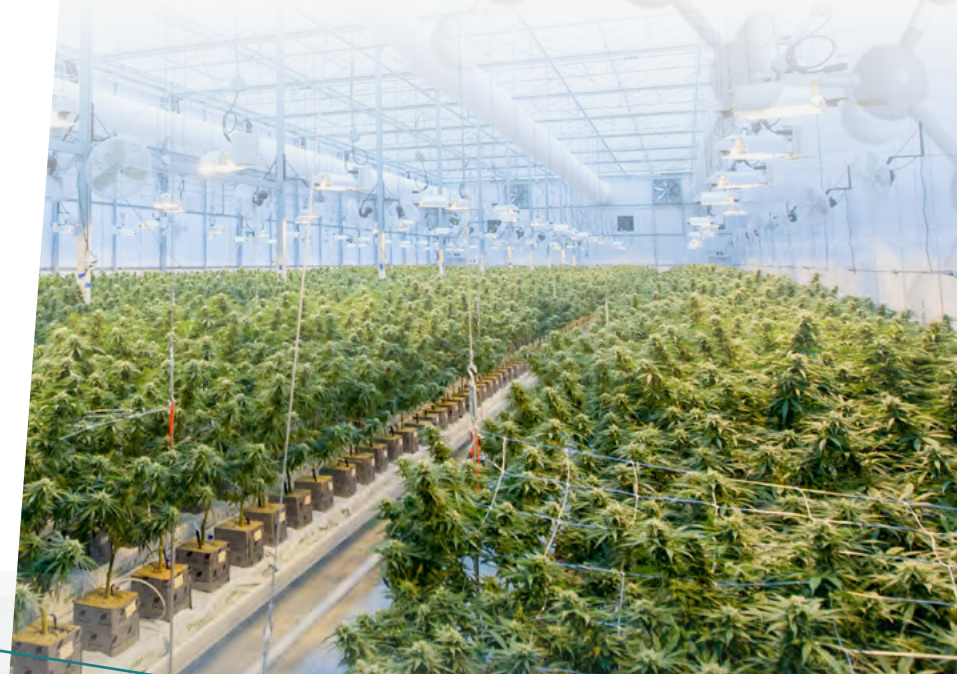
This is a licensed PLANT BREEDING capability which includes supply of seeds and/or plants to another cultivator, export of starting material, or research involving cultivation. It is also an activity that can be undertaken by a licensed cultivator of medicinal cannabis.

The *cannabis sativa* plant has a history spanning thousands of years across the globe with genetic diversity and differences in the many cannabinoids, terpenes and flavenoids present. This diversity allows selection for traits of interest such as size, quantity, smell and colour; as well as potential for accumulating THC or CBD, and terpenes.

Given this, it's important to understand the genetics of your cultivars as well as the role of breeding programmes and record keeping.

WHAT IS NEEDED

- **STARTING MATERIAL**
- **BREEDING PROGRAMMES**
- **LICENSING**



STARTING MATERIAL

It's important to understand the genetics of your starting material, either tissue culture or seeds.

Understand how the scheme will allow for different genetics to enter into the medicinal cannabis legal framework. Potentially you can select for minor cannabinoids, higher cannabinoid levels and other genetics of interest.

While you are able to import seeds as starting material it requires an import licence and needs to meet MPI standards. There are differences in ability to import seed from some countries. It is also important to be aware of international genetic libraries that can be accessed.

Having a good understanding of Plant Variety Rights (PVRs) or other sources of protectable IP due to differentiated cannabis genetics. Be aware that securing PVRs can be challenging for varieties entering from the illicit market

ASK YOURSELF

- Am I aware of the genetics of my cultivars?
- What is the commercial value of the genetics I have?
- Have I investigated overseas sources of starting material?
- Can I obtain plant variety rights?

ACCESS CAPABILITY

- PLANT & FOOD RESEARCH
- MIDLANDS SEED
- INTELLECTUAL PROPERTY OFFICE OF NZ
- MINISTRY FOR PRIMARY INDUSTRIES

BREEDING PROGRAMMES

Start with a good understanding of positive traits that you're interested in developing to bring in new plant varieties for your breeding programme.

Make sure you have a clear breeding goal. This could include genetic stability and reproducibility around sought traits such as bud weight or CBD content.

Implement the appropriate breeding tool which could include one or more of the following: pedigree building, crossing, quantitative selection for genetic gain, genomic selection, tissue culture tools and ploidy.

Maintain accurate record-keeping and data management to understand relationship amongst plants (phenotypes and pedigrees), track the usable crosses you've made. Genetic software can help you manage this including quality of records, crossing plans, measurement of key traits.

ASK YOURSELF

- What traits am I interested in developing?
- Is my breeding programme aligned with my business strategy?
- What breeding tools am I considering?
- What data management systems do I have?

ACCESS CAPABILITY

- PLANT & FOOD RESEARCH
- ABACUS BIO
- LINCOLN UNIVERSITY

LICENSING

You require a licence with nursery activity in order to import, purchase and supply seeds to another licence holder for cultivation.

You can transfer 50 seeds or 20 plants on any one licence which provides the opportunity to introduce new genetics.

Requirements include location and security, which are different based on THC level for the variety.

If you want to cultivate plants for supply you need a licence that specifies the cultivation activity.

Maintain high quality accurate records for full track and trace. This should include records for all seeds that come in, how many seeds and plants and how they are related.

ASK YOURSELF

- Do I have the right license for breeding?
- Do I have record keeping in place?

ACCESS CAPABILITY

MINISTRY OF HEALTH
MEDICINAL CANNABIS AGENCY

SECURITY CONSULTANTS

CULTIVATION

This is a licensed CULTIVATION capability encompassing the entire growth cycle for cannabis from start to harvest.

The purpose of cultivation activity is to provide the cannabis-based ingredient for manufacture of a medicinal cannabis product which includes dried products, extracts, or dosage products. Activity also extends to supply of seeds and/or plants to another cultivator, export of starting material, or research involving cultivation.

Activities considered to be part of cultivation are:

- possession of plant material and seed for the purposes of growing
- growing
- harvesting, collection, trimming or discarding, and drying
- supply of plant material to another licence holder. e.g. a manufacturer

In addition, there are important considerations in relation to security (physical measures, operational procedures).

WHAT IS NEEDED

- SITE SELECTION AND PREPARATION
- SOURCE MATERIAL
- GROWING
- HARVESTING AND DRYING
- LICENSING

SITE SELECTION AND PREPARATION

Assess how your site was previously utilised and if any potential remediation is required prior to cultivating due to residues or toxicities.

Agree the optimal level of environmental control for cultivating activity given a range of considerations including target product, risk of cross-pollination, or environmental exposure.

Look at the different upfront costs, building and material requirements for various cultivation methods:

- **Indoor:** Usually warehouse setting with high upfront costs. Artificial lighting, irrigation systems and use of air conditioning and dehumidification systems.
- **Glasshouse:** Natural and controlled lighting systems (roof covering, electrical lighting). Again, can be significant upfront costs, especially if more environmental control required.
- **Outdoor:** Significantly reduced costs, although electricity may be required for irrigation and security.

Your site will need to meet security requirements with associated costs for surveillance and prevention measures.

ASK YOURSELF

- Have I assessed previous site usage?
- Are there existing buildings suitable for growing?
- What level of environmental control do I need?
- What are my upfront costs for cultivation?
- Does my security solution prevent access?

ACCESS CAPABILITY

SECURITY CONSULTANTS

NZ MEDICINAL CANNABIS COUNCIL
NZMCC

SOURCE MATERIAL

Selection of your source material should be made with a clear idea of the desired profile in terms of CBD/THC etc. It can be obtained:

- from another licence holder (i.e. breeder)
- by importing seeds under license
- from the holder of an industrial hemp licence (limited to 50 seeds and 20 plants)
- by making a declaration of illicit seeds or plants (limited to 50 seeds and 20 plants) of a variety that is established in NZ.

Track and trace is important for security and confirming integrity of supplier source

ASK YOURSELF

- Do I know the CBD/THC profile of the source material?

ACCESS CAPABILITY

MINISTRY OF HEALTH
MEDICINAL CANNABIS AGENCY

MINISTRY FOR PRIMARY INDUSTRIES

GROWING »

You should establish good cultivation standards following Good Agricultural and Collection Practices for Medicinal Plants (GACP). You should also consider yield optimisation, plant protection, sustainable production issues and if you will operate as part of a network.

Understand the production profile, overall cost structure and level of environmental control for your chosen cultivation method(s).

- **Indoor:** Fully controlled cultivation allows for fully standardised cannabis.
- **Glasshouse:** Less environmental control than with indoor.
- **Outdoor:** Produces genetically undefined, non-standardised cannabis.

See next page for more information.

ASK YOURSELF

- Am I operating at GACP standard?
- What production planning processes do I have in place?
- Do I know the overall costs of cultivating?
- Do I operate as part of a co-operative?

ACCESS CAPABILITY

NZ MEDICINAL CANNABIS COUNCIL
NZMCC

« GROWING

	OPEN AIR	GREENHOUSES	INDOOR
CAPITAL COST	Low	Medium-High	High
OPERATING COSTS	Low	Medium	High
ANNUAL YIELD PER M2	Low	High	High
CONSISTENCY	Low	Medium	High
TIME TO HARVEST	Medium	Medium	Medium
ROTATIONS PER YEAR	1-3	3-4	5-8
BENEFITS	- <5% of both capital and operating expenses compared to indoor growing, much larger growing areas available and best environmental credentials	- Longer growing period than Open Air with more control and consistency - Wide market options (medical, recreational flower, etc) - Lower capital and operating costs than indoor.	- Grow year round, consistent output - Widest market options (medical, recreational flower, etc) - Lowest risk of pests and contamination.
LIMITATIONS	- Limited to growing in summer months - Highly weather/soil dependent - Increased risk of pests - Lower control and market options	- Limited to growing Spring to Autumn depending on heating - Higher capital and operating costs than Open Air - Some disease risk	- No risk of weather-related issues - Risks of power supply interruption - Highest capital and operating costs - Some disease risk

HARVESTING AND DRYING

Harvesting: You need to cut off the top part of each flowering stem on the plant and take to the drying room. Although manually intensive, automated trimmers can be used.

Drying: You will then need to dry cannabis biomass to less than or equal to 12% moisture, regardless of whether you require for:

- cannabinoid extraction
- flower biomass for a dried product, or
- dried starting material intended to be exported for use in, or for, a medicinal cannabis product.

Hang upside down on moveable racks or on trays for several days, with temperature controlled to achieve optimum drying rate. Alternatives such as drying tumblers can reduce the drying process from days to a few hours.

Biomass not used in processing can be directed to other value adding activities, minimising waste.

ASK YOURSELF

- Do I have a temperature controllable drying room?
- Have I optimised the drying time through use of technologies?

ACCESS CAPABILITY

NZ MEDICINAL CANNABIS COUNCIL
NZMCC

BIORESOURCE PROCESSING ALLIANCE

LICENSING

You will require a cultivation license which highlights requirements including; location and security, traceability tracking and record keeping, procedures for destruction and secure transport.

This requires that you meet minimum quality standards including those standards required by your processor or manufacturer.

Depending on your intended dosage form you may need to implement the Good Manufacturing Code (GMP) as early as the drying stage and during subsequent steps to reduce risks that could impact product quality.

If exporting bulk starting material, a licence will be required, including verification that quality standard has been met.

ASK YOURSELF

- Have I fulfilled the requirements of the license?
- If relevant, what are the quality standards required by my manufacturing partner or customer?
- Do I need GMP for drying?

ACCESS CAPABILITY

SECURITY CONSULTANTS

MINISTRY OF HEALTH
MEDICINAL CANNABIS AGENCY

MINISTRY OF HEALTH
REGULATORY CONSULTANTS

PROCESSING CAPABILITY

PROCESSING refers to the activities required to separate the components of cannabis from the plant matrix to develop a cannabis-based ingredient. The approach will depend on the target product being sought with the cannabis-based ingredient then used to formulate and manufacture a medicinal cannabis dosage product.

The target product will determine the technique, such as whether a purified extract of cannabis (eg, THC) or a full spectrum extract of cannabis containing multiple constituents is sought. Processing activity can also concentrate chemicals of interest, given more than 550 distinct chemicals have been identified in cannabis, with at least 144 cannabinoids (including CBD and THC) and over 200 terpenes.

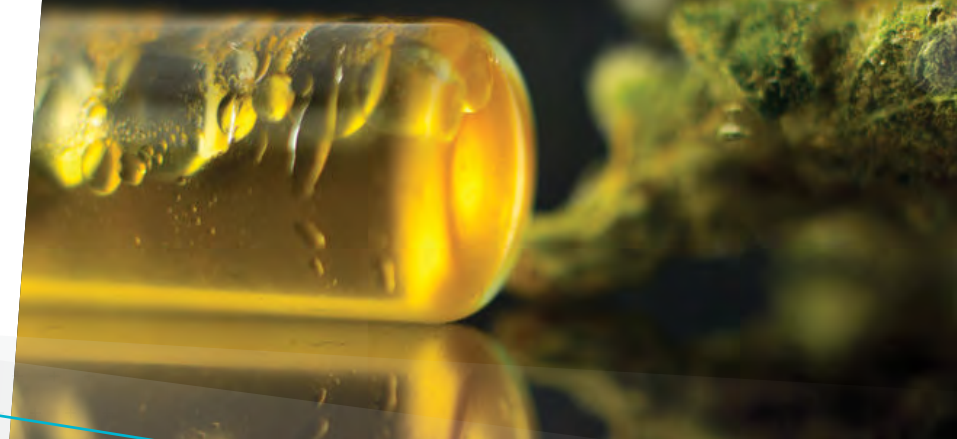
Dried flowers can be an end product, but they are generally further processed into one of the following cannabis-based ingredients:

- Full spectrum extract
- Distillate – full cannabinoid profile
- Isolate – purified cannabinoid

Beyond desired target product, considerations include costs of production, appropriate extraction method, usage of remaining biomass and access to licensed GMP approved processing facility.

WHAT IS NEEDED

- PRE-PROCESSING
- EXTRACTION
- PURIFICATION
- LICENSING



PRE-PROCESSING

Milling

You will need to break cannabis into small pieces of a uniform size through milling, ready for extraction.

- If extracting immediately, usually on site, this can be wet milled.
- If storing for later extraction, or being processed into medicinal products, can be dry milled using mill or pulveriser.

Decarboxylation

You will need to undertake this step if your desired finished product requires neutral cannabinoid forms. Heat in oven (preferably under vacuum) to decarboxylate. While you generally lose terpenes through evaporation, these can be added back in later processing stages if desired.

ASK YOURSELF

- Has the biomass been received from licensed cultivation activity with appropriate quality controls?
- Am I extracting immediately? Or later?
- Are neutral or acid forms preferred?

ACCESS CAPABILITY

NZ MEDICINAL CANNABIS COUNCIL
NZMCC

EXTRACTION

Select the most appropriate extraction method, dependent on compounds of interest required for target final product, as well as overall appeal. Extraction produces a full spectrum cannabis oil (containing 40-50% cannabinoids).

- **Carbon Dioxide Supercritical fluid extraction (SFE):** High pressure and moderate heat are used to turn the CO2 supercritical. While the equipment cost for this method is higher, lipids and cannabinoids are collected solvent-free, with higher yields and less valuable material lost. This is an environmentally friendly process, and CO2 is a safe, clean, cheap and nontoxic solvent.
- **Ethanol (liquid):** Good solvent for cannabinoid extraction that facilitates the subsequent winterisation process. Extraction temperature is a key variable in ethanol extraction in order to minimise co-extraction of undesired compounds.
- **Propane/butane:** These hydrocarbons are pressurised during extraction and turned into liquid solvents. Being "hydrocarbons" their consumer perception can be poor. They are also highly flammable which introduces health and safety considerations in the process. However, they allow highly efficient cannabinoid and terpene extraction. Similarly to SFE, lipids and cannabinoids in extract are collected solvent-free – given solvent turns to gas after extraction.

ASK YOURSELF

- What extraction method is most appropriate?
- Am I planning to extract myself or use a toll processor?
- Are neutral or acid forms preferred?

ACCESS CAPABILITY

- NZ MEDICINAL CANNABIS COUNCIL NZMCC
- CALLAGHAN INNOVATION
- RUA BIOACTIVES

PURIFICATION

Depending on your desired final product, additional processing steps may be undertaken to further refine the extract and increase purity.
Note that contaminants such as heavy metals and pesticides might also be concentrated during this process, along with cannabinoids.

- **Winterisation:** Removing waxes, lipids, chlorophyll and other unwanted plant material through dissolution in warm ethanol, followed by freezing and filtration of precipitated non-soluble waxes. The resulting "winterised cannabis oil" typically contains 50-60% cannabinoids.
- **Distillation:** Purifying winterised extract using molecular distillation produces a distillate containing a full cannabinoid profile, with measurable amounts of CBD, THC and or other cannabinoids such as CBG, CBC, CBN, etc. Typically contains 80-95% cannabinoids.
- **Isolate:** Distillates can be further refined using supercritical chromatography (SFC), centrifugal partition chromatography (CPC) or crystallisation to deliver in a highly concentrated product exceeding 98% for one individual cannabinoid.

Consider innovative methods for purification including molecularly imprinted polymers

ASK YOURSELF

- What is the target product and characteristics I am looking for?

ACCESS CAPABILITY

- NZ MEDICINAL CANNABIS COUNCIL NZMCC
- CALLAGHAN INNOVATION
- LIGAR

LICENSING

You must have a possession for manufacture activity specified on your licence, or you have a suitably licensed toll processor.

If you are processing to manufacturing a finished product for patients to use, you will need to ensure the product meets the minimum quality standard and complies with GMP requirements.

It is also important you have appropriate security arrangements in place for your operations.

ASK YOURSELF

- Do I have the correct licensing?

ACCESS CAPABILITY

MINISTRY OF HEALTH
MEDICINAL CANNABIS AGENCY

FORMULATION

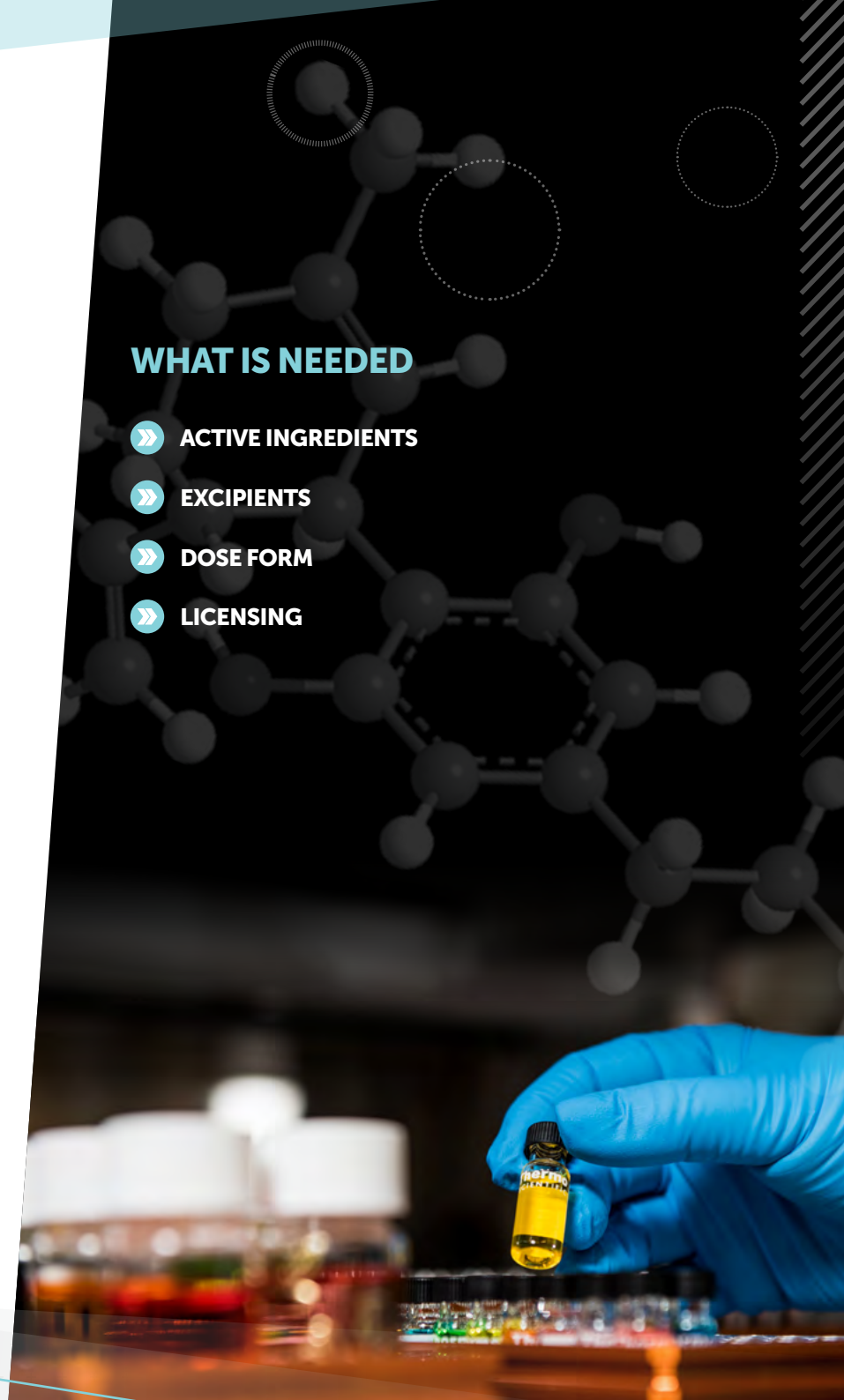
FORMULATING refers to developing formula and specifications for a dosage medicinal cannabis product. This is the product development stage where the processed cannabis-based ingredient is combined in a dose form to achieve desired product activity in a reproducible way. It includes a range of activities to provide proof of concept, test and optimise the formulation through in vitro testing.

It's important to balance the desire for activity with the need for a formulation that is stable and acceptable for a patient to take.

This is a licensed activity that needs to meet the minimum quality standard.

WHAT IS NEEDED

- ACTIVE INGREDIENTS
- EXCIPIENTS
- DOSE FORM
- LICENSING



ACTIVE INGREDIENTS

Initially you will need to characterise the activity of the processed cannabis-based ingredient, especially as it may include new and rare cannabinoids, terpenes, or a full spectrum extract. Includes:

- THC/THCA
- CBD/CBDA
- Other cannabis-based ingredients such as terpenes

Assess desired product activity through in vitro testing in a GMP accredited laboratory. If you are working with a full spectrum product, this may extend to assessment of activity due to the entourage effect.

You will need to assess factors like particle size, pH, and solubility, as all of these can influence bioavailability and activity of a drug.

ASK YOURSELF

- Have I characterised the activity of the active ingredient?

ACCESS CAPABILITY

- NZ MEDICINAL CANNABIS COUNCIL NZMCC
- CALLAGHAN INNOVATION
- GLYCOSYN
- NATURAL HEALTH PRODUCTS NZ
- UNIVERSITY OF OTAGO
- ESR
- HILLS LABORATORIES
- ANALYTICA
- EUROFINS
- ASSUREQUALITY
- RUA BIOSCIENCE

EXCIPIENTS (NON-ACTIVE INGREDIENTS)

Consider the excipients (inactive ingredients) you will use to improve stability, flavours, aromas, colourants or enhance bioavailability.

Combine excipients in a way to ensure that the quantity of active ingredient is consistent in each dosage unit. You also need to ensure that the excipient exists in the European Pharmacopoeia and has a clear function. They include coatings, buffering agents, binding, buffering or emulsifiers.

Evaluate a range of innovations that help bring the lipid and aqueous phases together, such as liposomes. Others include nanoencapsulation and micro-encapsulation.

ASK YOURSELF

- What excipients will help me achieve my target profile?
- Am I clear on the purpose for excipients to be included?

ACCESS CAPABILITY

- NZ MEDICINAL CANNABIS COUNCIL NZMCC
- CALLAGHAN INNOVATION
- GLYCOSYN
- NATURAL HEALTH PRODUCTS NZ

DOSAGE FORM

You will need to ensure your dosage product has properties consistent with the way it is intended to be taken or administered (ie, recommended method of administration).

Selecting the most appropriate dose form should take a number of factors into consideration (assessed in CLINICAL TRIALS using a pilot scale batch) which includes:

- Dosing
- Bioavailability
- Onset of action
- Duration of effect
- Reproducibility
- Safety

Consider different product formats, which include:

- Basic tinctures and oils
- Oral ingestion – oral liquid, tablets, capsules
- Topical – creams, gels and patches
- Sprays
- Vaporisation in approved medical device.

ASK YOURSELF

- How do I intend for the product to be administered?
- Do I know the bioavailability and dosing?
- What is the most appropriate format?

ACCESS CAPABILITY

- NZ MEDICINAL CANNABIS COUNCIL NZMCC
- CALLAGHAN INNOVATION
- GLYCOSYN
- NATURAL HEALTH PRODUCTS NZ

LICENSING

You will require a license that includes possession for manufacture activity if you want to perform laboratory testing for product development.

Formulating will allow you to confirm your product specifications. This will include information about product formulation and composition, name and amount of each ingredient.

Understand the relevant tests for particular dosage forms (e.g. an oral liquid, tablet or capsule) as outlined in the general monograph.

ASK YOURSELF

- Do I have the correct license that allows for formulating?
- Have I confirmed the product specification?

ACCESS CAPABILITY

MINISTRY OF HEALTH
MEDICINAL CANNABIS AGENCY

CLINICAL TRIALS

The CLINICAL TRIALS capability relates to activities to research the efficacy and safety of medicinal cannabis products in human subjects for specified indications.

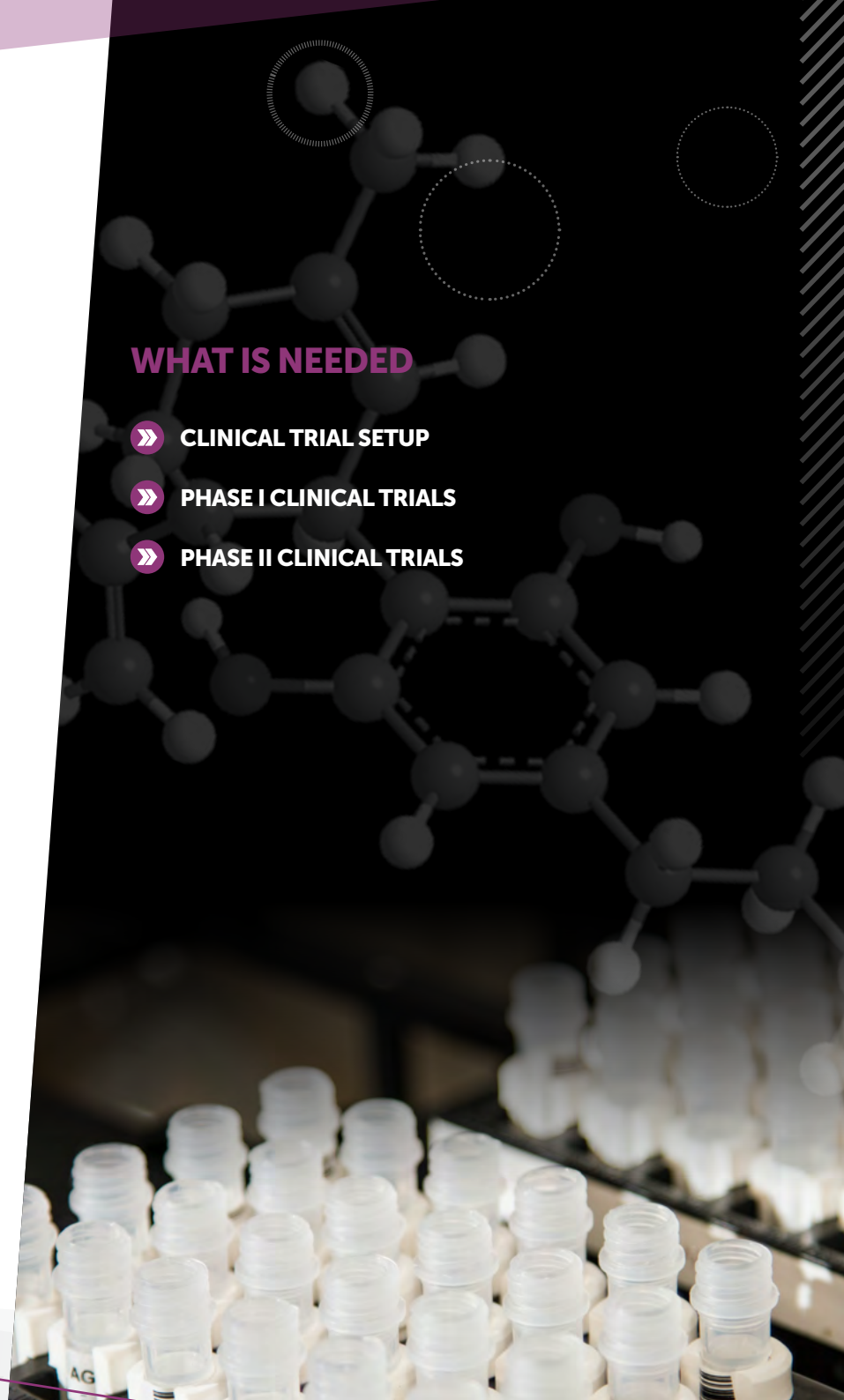
While it is not an absolute requirement that clinical trials are conducted in New Zealand, it is necessary for the generation of specific therapeutic claims and IP.

Approved medicines have been assessed for safety and efficacy for their approved indications, in addition to quality. As of April 2020, there was only one medicinal cannabis product 'approved' for distribution in NZ.

A medicinal cannabis product does not have to be an approved medicine in NZ in order to be prescribed by a doctor, this may not be the case for export markets. For that reason, the product's intended path to market is likely to inform the approach taken to clinical trials.

WHAT IS NEEDED

- CLINICAL TRIAL SETUP
- PHASE I CLINICAL TRIALS
- PHASE II CLINICAL TRIALS



CLINICAL TRIAL SETUP

If you plan to conduct clinical trials then you will most likely need to partner with Clinical Research Organisation (CRO).

You will need assessment of trials and ethics committee approval is required before commencing your clinical trial, with scientific assessment of applications is through the Standing Committee on Therapeutic Trials (SCOTT).

Ensure any clinical trial is conducted in accordance with Good Clinical Practice.

- National Standardised Clinical Trial Research Agreements
- Recruitment and Retention – Patient Information Form and Consent Forms

ASK YOURSELF

- Do I have a clinical trials plan?
- Have I identified a CRO?
- Have I completed the necessary in-vitro work?
- Have I identified a Principal Investigator?
- Can I recruit a patient population?
- How will I fund clinical trials?

ACCESS CAPABILITY

- HEALTH AND DISABILITY ETHICS COMMITTEE
- NATIONAL ETHICS ADVISORY COMMITTEE NEAC
- CLINICAL TRIALS NZ

PHASE I CLINICAL TRIALS

You will need to conduct a Phase I clinical trial to assess the safety, optimal dose and formulation of your product. This testing is in healthy volunteers, recruited into a clinical trial clinic under observation. This is designed to assess the safety (pharmacovigilance), tolerability, pharmacokinetics, and pharmacodynamics of your medicinal cannabis product. It would usually include dose-ranging (dose escalation) studies, so that the best dose can be found. This includes:

- **Accuracy of dosing** – how precise the dosing method is to reach the desired dose, to avoid under-dosing, over-dosing and side effects.
- **Bioavailability** – the fraction of the dose that reaches the bloodstream to provide a therapeutic effect.
- **Onset of action** – the amount of time before the effects of the medicinal cannabis product are felt.
- **Duration of effect** – the length of time the medicinal cannabis product is active.
- **Reproducibility** – the degree to which the product can be given to achieve repeated effects, preferably with good precision.
- **Safety** – easy to use, of good quality and does not cause harm or intolerable side effects.

ASK YOURSELF

- What is the optimal dose?
- Do I know my products bioavailability?
- What is the onset of action?
- How long is the medicine active for?
- How reproducible are the results?
- How safe is the medicine to use?

ACCESS CAPABILITY

- MEDICAL RESEARCH INSTITUTE OF NZ
- NZ ASSOCIATION OF CLINICAL RESEARCH
- MEDSAFE
- CLINICAL TRIALS NZ

PHASE II/III CLINICAL TRIALS

Evaluate whether you need to conduct Phase II/III studies, which determine whether the drug has any biological activity in the indication of interest. Phase II trials are performed on larger groups, designed to assess how well the drug works.

- Phase IIa studies are usually pilots designed to demonstrate clinical efficacy or biological activity ('proof of concept' studies)
- Phase IIb studies look to find the optimum dose at which the drug shows biological activity with minimal side-effects.
- Phase III studies are designed to assess the effectiveness of the new medicinal cannabis product in clinical practice. Phase III studies are randomized controlled multicentre trials with a large number of patients recruited. For this reason they are very expensive.

ASK YOURSELF

- Do I want to supply an approved medicinal cannabis product?
- Do I need to provide evidence of efficacy and safety in people?

ACCESS CAPABILITY

- MEDICAL RESEARCH INSTITUTE OF NZ
- NZ ASSOCIATION OF CLINICAL RESEARCH
- MEDSAFE
- CLINICAL TRIALS NZ

MANUFACTURING

This capability relates to key activities required to MANUFACTURE a medicinal cannabis dosage product that you intend for a medical practitioner to prescribe to a patient.

This requires incorporating your cannabis-based ingredient into a dosage product reproducibly at scale together with packaging and labelling. This could be in a range of dosage forms including:

- Liquids – Tinctures
- Capsules (soft gel, hard shell)
- Inhalers and nebulizers
- Lotions or gels

Skin patches or under the tongue lozenges

The quality standard for the manufacture and packaging of medicinal cannabis products according to GMP is required for the sale of medicinal cannabis in New Zealand and export of finished products to other countries.

WHAT IS NEEDED

- **FINISHED PRODUCT MANUFACTURE**
- **PACKAGING AND LABELLING**
- **PROCESS VALIDATION**
- **LICENSING**

FINISHED PRODUCT MANUFACTURE

Your product will be manufactured to the final dosage form through activities which could include:

- Encapsulating
- Liquid Filling
- Coating
- Powder Filling
- Freeze Drying

You first need to ensure that your medicinal cannabis product meets the minimum quality standard through testing on at least 3 pilot-scale batches (>10% production size).

Assess whether you need additional services from your contract manufacturer (if relevant) which could include:

- Export Assistance
- Listing & Registrations
- Research and Development (formulation development)
- Stability testing

ASK YOURSELF

- Can I manufacture final dosage form at scale?
- Have I completed batch testing?
- What other services do I need?

ACCESS CAPABILITY

CONTRACT MANUFACTURING ORGANISATION
GMP LICENSED

NATURAL HEALTH PRODUCTS NZ

PACKAGING AND LABELLING

You will need to package and label once the final dosage form of your product has been manufactured.

Consider both primary and secondary packaging, with activities including:

- Bottling
- Hot-foil printing
- Label application
- Shrink-wrapping and carton binding
- Packing, labelling for shipment

Make sure you understand important packaging considerations:

- **Packaging compatibility:** absence of chemical reaction with your product
- Tamper-evidence
- Child-proof packaging
- **Stability testing:** Require scientific data to prove that your product is shelf-stable, for how long and under what conditions. This information is then used to determine the expiry date and storage conditions that will be printed on each batch of product
- Printed labelling on your product packaging must comply with the appropriate country regulations, including a package insert

ASK YOURSELF

- What packaging solution do I require?
- Have I conducted stability testing trials?

ACCESS CAPABILITY

- CONTRACT PACKING ORGANISATION GMP LICENSED
- STABILITY TESTING
- ESR
- EUROFINS
- NATURAL HEALTH PRODUCTS NZ

PROCESS VALIDATION

You will need to show your processes can deliver consistent, repeatable, reliable outcomes, with a final dosage form that always contains the right amount of ingredients. Activities include:

- defining a manufacturing batch
- developed specifications for the raw materials, finished product and primary packaging components
- establishing the manufacturing process and written standard operating procedures
- establishing the control points for the process
- finalising batch manufacturing and packing records.

You need to prove that your packaging process will always produce product that will be protected from degradation until the expiry date.

ASK YOURSELF

- Have I completed process validation steps?

ACCESS CAPABILITY

CONTRACT MANUFACTURING ORGANISATION
GMP LICENSED

NATURAL HEALTH PRODUCTS NZ

LICENSING

You require a license that includes possession for manufacture activity if you are manufacturing a medicinal cannabis product, or if you are performing laboratory testing on medicinal cannabis.

You will also need to hold a Licence to Manufacture Medicines, or Licence to Pack Medicines if activities are limited to packing and labelling compliant products.

To obtain these licenses you must be able to demonstrate that you comply with the GMP Code.

ASK YOURSELF

- Do I have the correct licensing to manufacture and or/pack medicinal cannabis products?
- Do my operations comply with GMP?

ACCESS CAPABILITY

MINISTRY OF HEALTH
MEDICINAL CANNABIS AGENCY

GO TO MARKET

The GO TO MARKET capability relates to activities in order to distribute and sell your medicinal cannabis product for the purpose of providing end users or patients with a health benefit. This could be either in New Zealand or overseas, with products including medicinal products and CBD products (including nutraceuticals and cosmeceuticals).

There are numerous global drivers of demand for medicinal cannabis products that shape a rapidly growing opportunity, which includes:

- Aging populations with chronic conditions
- As an alternative to prescription medicines
- Improving access in some markets (retail pharmacies, insurance or reimbursed coverage).

As a global industry, it's likely that margins will be concentrated with those who add value through developing products and brands, creating proprietary technology and specializing in distribution and retail.

Given this, your product needs to be formulated to uniquely deliver health benefits. Decisions on distribution, pricing and level of marketing and promotion will ultimately depend on the target market and, in particular, the changing regulatory and access landscape.

WHAT IS NEEDED

- PRODUCT AND BRAND STRATEGY
- LOCAL GO TO MARKET
- INTERNATIONAL GO TO MARKET
- LICENSING

PRODUCT AND BRAND STRATEGY

Develop your strategy based on the products and categories you plan to focus your development on, including innovative dose forms, together with the evidence required to support their use. This will also depend on your regulatory strategy (approved vs unapproved medicine).

Evaluate how you will evolve from a product led to a brand strategy over time. This generally requires multiple product lines potentially across categories and formats meeting distinct customer needs. This supports a clearly defined brand as important source of IP, with branding especially important in retail markets.

Build your brand by increasing awareness and educating healthcare professionals, or where allowable, patients and retail. Segmenting your customers will help you identify and focus efforts on those likely to specialise in medicinal cannabis within your target market.

ASK YOURSELF

- What is my products value proposition?
- How can I communicate brand value?
- How does my communication vary by segment?

ACCESS CAPABILITY

- BUSINESS.GOVT.NZ
- MARKETING ASSOCIATION
- NZ TRADE & ENTERPRISE

LOCAL GO TO MARKET

Patients cannot access NZ manufactured medicinal cannabis products without a prescription from their doctor and must visit a pharmacy to fill their prescription.

To minimise patient risk there are expectations you have complaints and recall procedures and effective batch release and distributed stock tracking in place.

Establish your distribution network using approved wholesalers such as CDC and/or Propharma, to reach licensed pharmacies for dispensing across New Zealand.

Under current scheme marketing and promotion of medicinal cannabis products are not possible.

ASK YOURSELF

- Have I got a recall plan in place?
- Do I have tracking of stock in place?
- Have I identified a wholesaler?

ACCESS CAPABILITY

- MINISTRY OF HEALTH
  MEDICINAL CANNABIS AGENCY
- CDC PHARMACEUTICALS
- PROPHARMA

INTERNATIONAL GO TO MARKET

Understand what different jurisdictions permit in terms of product, distribution, marketing and promotion. These can vary between federal and state and distribution by product type and composition. e.g. THC/CBD.

Understand how to access patients, where allowable, to support patient use through awareness, evidence-based education and promotion activities. Also investigate Doctor channel groups to support this activity in some markets.

Establish agreements with overseas distributors. This could include a range of additional services to support GO TO MARKET activity.

Develop and implement your distribution and pricing strategies in market, being aware of important channel trends. e.g. in some market's products will move to be increasingly sold in pharmacies as a behind-the-counter product. Also access will expand through broadening of health insurance plan coverage.

ASK YOURSELF

- Am I aware what's allowed in market?
- Have I got a distribution partner?
- Am I aware of new channel trends?
- What are the needs and preferences of my buyers and end users?

ACCESS CAPABILITY

- COSMETICS NZ
- NATURAL HEALTH PRODUCTS NZ
- NZ TRADE & ENTERPRISE
- BIOTECHNZ

LICENSING

You will need to list your medicinal cannabis products on the licensing scheme so they can be prescribed by a doctor as an unapproved medicine.

Domestic supply: Requires license indicating supply activity for your medicinal cannabis product and product assessment. This must be completed, and the product must be specified on your licence. Products need a Drug Master File that includes shelf-life stability data and relevant literature on the formulation.

Supply for export: You will need to be licensed to supply medicinal cannabis products, obtain a controlled drug export licence for each consignment and make sure an import licence is issued by the importing country.

ASK YOURSELF

- Do I know the licensing requirements?
- Have I obtained the right import/export licenses?

ACCESS CAPABILITY

MINISTRY OF HEALTH
MEDICINAL CANNABIS AGENCY