BUDDLE FINDLAY

A new medicinal cannabis scheme for New Zealand

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It may seem that the big item on the cannabis law reform agenda is the upcoming referendum on recreational cannabis (which is discussed in more detail in our update here). However, the new Medicinal Cannabis Scheme (the Scheme) that came into effect on 1 April 2020 represents significant law reform in this area.

The Scheme came into effect with the commencement of the Misuse of Drugs (Medicinal Cannabis) Regulations 2019. The primary objective of the Scheme is to improve access to quality medicinal cannabis products for patients. The Scheme does that by making it easier for a wider range of medicinal cannabis products to be approved for prescription, and enabling the cultivation of cannabis, the manufacture of medicinal cannabis products in New Zealand, and the import of overseas products. That is expected to benefit patients, health practitioners wanting to treat their patients with medicinal cannabis products, and medicinal cannabis cultivators, manufacturers, and suppliers wanting to enter the market.

What the Scheme means for patients and health professionals

Before the Scheme

Before the Scheme came into effect, medical practitioners generally needed to obtain pre-approval from the Ministry of Health to use cannabis-based products for medicinal purposes in respect of a specific patient (sometimes called a 'named patient' approval). An exception to that was Cannabidiol products which could be prescribed by medical practitioners without pre-approval. Practitioners were also able to prescribe Sativex™ Oral Spray (a cannabis-based product containing THC) without pre-approval in limited circumstances.

Now

The intention of the Scheme is that, in time, there will be a wider range of medicinal cannabis products available, reducing the risk that patients self-medicate with illicit cannabis that has been grown and processed with no quality controls.

There are two components to the Scheme that widen the range of available medicinal cannabis products. The first is allowing medical practitioners to prescribe medicinal cannabis products without pre-approval from the Ministry of Health, provided that the products:

- Are approved medicines, which means they have been assessed for safety and efficacy, and been consented for distribution under the Medicines Act 1981
- Have been verified by the Medicinal Cannabis Agency as meeting the medicinal cannabis minimum quality standard.

For products that do not meet either of these criteria, medical practitioners must obtain pre-approval by the Ministry of Health.

Currently, Sativex™ is the only cannabis-based product that is an approved medicine. It is unclear how long the new Agency's approval process for products meeting the minimum quality standard will take. We expect, given the novelty of the regime in New Zealand, that the Agency will initially take a cautious approach. Nevertheless, as manufacturers obtain medicinal cannabis licences and get underway, we expect that other medicinal cannabis products will become available over time.

A medicinal cannabis industry in New Zealand?

The second component of the Scheme is a licensing process. Applicants who meet the Medicinal Cannabis Agency's assessment criteria can obtain licences for the commercial cultivation of cannabis for medicinal use, and the manufacture and supply of cannabis-based ingredients, starting material, and medicinal cannabis products.

Prior to the Scheme, only licences to cultivate cannabis for medical and scientific research and development purposes were permitted. As of December 2019, more than ten licences had been issued. These companies have been able to establish facilities and cultivation processes, and so we expect they will have an advantage over competitors not yet established in New Zealand in applying for a medicinal cannabis licence.

Activities that can be licensed

There are five types of activities that a medicinal cannabis licence can authorise the license-holder to carry out:

- The cultivation of cannabis for therapeutic use
- Nursery activities, being the supply of cannabis seeds or plants for cultivation for therapeutic use
- Research about cannabis for therapeutic use
- Possession for manufacture activities, being the production or manufacture of cannabis for therapeutic use
- The supply of:
  - starting material (being fresh or dried cannabis intended to be used in, or for, a medicinal cannabis product) that is not intended for export
  - starting material intended for export, cannabis-based ingredients, or medicinal cannabis products that have been specified in the licence.

Licences cannot be for longer than one year, meaning that licence-holders will need to apply annually for a licence renewal. This short licence period, and the lack of security inherent in it, may disincentivise investment, and could place a significant administrative burden on the Agency. It will be interesting to see if longer licensing periods are introduced once the Scheme is more established.

Applying for a licence

Both individuals and entities can apply for a licence. The eligibility requirements to apply for a licence are largely straightforward, such as the requirement for individuals and directors of entities to be 18 years or older and to not have been convicted of a drug-related offence.

Applicants will also be required to provide information about the locations, security arrangements, and standard operating procedures for the activity for which a licence is sought. Applicants must be able to demonstrate that they have the expertise and resources to comply with the obligations imposed by the Regulations.

Accordingly, as part of the assessment of applications, the Agency will inspect each location listed in the application to ensure that adequate security measures are in place. At the time the Scheme was being developed, it was acknowledged that, if the requirements are too rigid, the development of the medicinal cannabis industry could be stifled. As such, the Agency will take a risk-proportionate approach that will look at the nature and size of the operation, the types and amount of cannabis at the location, and the location's physical security, security of operational procedures and personnel security arrangements. For example, the Agency would have significantly lower expectations of security for the cultivation of low-THC cultivars than it would for high-THC cultivars.

Applicants will need to provide a detailed outline of the arrangements and procedures they will have in place to comply with the requirements of licence-holders such as (amongst other things):

- Suitable record-keeping and reporting arrangements
- The ability to carry out an annual stocktake and report the results to the Medicinal Cannabis Agency
- Notification procedures should their licence or any cannabis be taken or lost, or unauthorised activity take place.

A range of fees are payable as part of the application process, and there is an appeals process if the Agency declines an application.

For further information, including application forms and guidance material, see here.

What the Scheme means for medicinal cannabis in New Zealand

Groups that have advocated for medicinal cannabis to be more easily available to New Zealanders have generally welcomed the introduction of the Scheme. However, the Scheme will need to be in place for some time before it will be possible to assess whether its introduction has resulted in patients having increased access to medicinal cannabis products, as is hoped.

The Ministry of Business, Innovation and Employment has estimated that the Scheme will enable a domestic market valued at up to $70m, and an export market of up to $250m, annually. Investors ready to jump into this market have therefore welcomed the introduction of the Scheme. Given that over 100 entities had indicated to the Ministry of Health that they intend to apply for a licence prior to the Scheme's establishment, it appears that there is considerable demand to enter the market.

It remains to be seen how the costs and benefits of the new industry will materialise and the extent to which the Scheme's objective of more and better-quality products becoming available will be achieved.

New Zealand also has an upcoming referendum on recreational cannabis (covered in our update here). So, in the event of a 'yes' vote and the relevant legislation passing, there will be two regulatory schemes and two product standards for both consumers and industry players to navigate.

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