Misuse of Drugs (Medicinal Cannabis) Regulations 2019

Governor-General

Order in Council

At Wellington this day of 2019

Present:
in Council

These regulations are made under sections 37 and 37A of the Misuse of Drugs Act 1975 and section 105 of the Medicines Act 1981—

(a) on the advice and with the consent of the Executive Council; and

(b) on the recommendation and advice of the Minister of Health given in accordance with section 37A of the Misuse of Drugs Act 1975 and section 105 of the Medicines Act 1981.

Contents

Regulations

1 Title

These regulations are the Misuse of Drugs (Medicinal Cannabis) Regulations 2019.

2 Commencement

These regulations come into force on 1 April 2020.

3 Purpose

The purpose of these regulations is to enable the research, manufacture, and supply of medicinal cannabis products and related ingredients, and the cultivation of cannabis for the products and ingredients, by providing for—

(a) a minimum quality standard relating to the cannabis, ingredients, and products; and

(b) a licensing regime that ensures that cannabis intended for other purposes is not cultivated and supplied under the guise of this purpose.

4 Interpretation

In these regulations, unless the context otherwise requires,—

active ingredient means each of the following ingredients in a cannabis-based ingredient or medicinal cannabis product:

(a) delta-9-tetrahydrocannabinol and its corresponding acid:

(b) cannabidiol and its corresponding acid:

(c) any other ingredient that is derived from cannabis and whose stated content is at least 1.0% by weight or volume of the ingredient or product

batch means a production-scale quantity of any cannabis-based ingredient or medicinal cannabis product that—

(a) is made during a single cycle of manufacture; and

(b) has a uniform composition, method of manufacture, and probability of chemical or microbial contamination

cannabis means—

(a) any part of any plant of the genus *Cannabis*; and

(b) any fruit or seed of such a plant

cannabis-based ingredient means an ingredient that—

(a) is extracted from cannabis; and

(b) is intended to be used in, or for, a dosage product

Director-General means the chief executive of the responsible department

dosage product means a medicinal cannabis product covered by paragraph (a)(ii) of the definition of that term

dried product means a medicinal cannabis product covered by paragraph (a)(i) of the definition of that term

European Pharmacopoeia means the 10th edition of the *European Pharmacopoeia*, including supplement 10.1, as published at 1 April 2020

GST means goods and services tax

medicinal cannabis licence or **licence** means a licence issued under Part 2

medicinal cannabis product means a product—

(a) that—

(i) is dried cannabis; or

(ii) contains 1 or more cannabis-based ingredients and is in a pharmaceutical dosage form (such as a tablet, a capsule, or an oral liquid); and

(b) that contains no prescription medicine (as defined by section 3 of the Medicines Act 1981) or controlled drug other than cannabis or a cannabis-based ingredient; and

(c) whose purpose is therapeutic, rather than recreational or anything else

minimum quality standard means the minimum quality standard imposed by Part 1

responsible department means the department that is, with the authority of the Prime Minister, for the time being responsible for the administration of these regulations

starting material means fresh or dried cannabis that is intended to be used in, or for, a medicinal cannabis product

stated content means an ingredient's quantity in, or proportion of, a cannabis-based ingredient or medicinal cannabis product that is stated by the label, packaging, or description that accompanies the ingredient or product

therapeutic means intended to prevent, diagnose, monitor, alleviate, treat, cure, or compensate for a disease, ailment, defect, or injury in a person

type of licensed activity, for a medicinal cannabis licence, means a type of licensed activity described by regulation 22.

5 Transitional, savings, and related provisions

The transitional, savings, and related provisions set out in Schedule 1 have effect according to their terms.

Part 1
Minimum quality standard relating to medicinal cannabis products

Overall requirements

6 Minimum quality standard imposed

(1) This Part imposes a minimum quality standard that the following must comply with:

(a) any starting material that is intended for export:

(b) a cannabis-based ingredient:

(c) a medicinal cannabis product, whether a dried product or dosage product.

(2) However, a cannabis-based ingredient or medicinal cannabis product need not comply with the minimum quality standard if—

(a) it is supplied under a medicinal cannabis licence for a supply activity, and procured under a medicinal cannabis licence for a research activity, for the purpose of being administered to a person who is a research subject; or

(b) it is a medicine whose sale, supply, use, or distribution has received the consent or provisional consent of the Minister in accordance with the Medicines Act 1981; or

(c) it is prescribed, supplied, or administered—

(i) by a medical practitioner for the treatment of a particular patient currently under their care; and

(ii) with the approval of the Minister under regulation 22 of the Misuse of Drugs Regulations 1977; or

(d) it is imported by a pharmacist for a prescription to which paragraph (c) applies.

7 Requirements for testing with maximum limits

(1) The table in this regulation sets out—

(a) which of the following items, or categories of those items, must be tested:

(i) starting material that is intended for export:

(ii) cannabis-based ingredients:

(iii) medicinal cannabis products, whether dried products or dosage products; and

(b) what the items, or categories of items, must be tested for; and

(c) the chapter or chapters of the *European Pharmacopoeia* that set out the testing method that must be used; and

(d) the maximum limit that the test result must not exceed (where any chapter reference is to the *European Pharmacopoeia*); and

(e) whether the testing method must be validated under regulation 9(2).

(2) In the following table, **ppm** means parts per million:

Items tested	What is tested for	Testing method	Maximum limit	Validation of testing method
All	Microbiological contamination	Chapters 2.6.12,	The limits specified by chapters 5.1.4 and 5.1.8	Yes

Items tested	What is tested for	Testing method	Maximum limit	Validation of testing method
		2.6.13, and 2.6.31		
All	Heavy metals	Chapter 2.4.27	3.0 ppm of arsenic 0.5 ppm of cadmium 5.0 ppm of lead 0.5 ppm of mercury	Yes
Cannabis-based ingredient, or medicinal cannabis product, that is imported	Pesticides	Chapter 2.8.13	The limits specified for each pesticide specified by chapter 2.8.13	Yes
Starting material for export, cannabis-based ingredient, or medicinal cannabis product, that is not imported	Pesticides	Chapter 2.8.13	0.020 ppm of Abamectin 0.020 ppm of Bifenazate 0.100 ppm of Bifenthrin 0.010 ppm of Chlormequat chloride 0.020 ppm of Daminozide 0.020 ppm of Etoxazole 0.020 ppm of Fenoxycarb 0.010 ppm of Imazalil 0.020 ppm of Imidacloprid 0.020 ppm of Myclobutanil 0.020 ppm of Paclobutrazol 0.050 ppm of Pyrethrins (I and II) 0.010 ppm of Spinosad (Spinosyn A and Spinosyn D) 3.000 ppm of Spiromesifen 0.020 ppm of Spirotetramat 0.020 ppm of Trifloxystrobin	Yes
All	Absence of aflatoxins	Chapter 2.8.18	2 µg/kg of aflatoxin B1 4 µg/kg for the sum of aflatoxins B_1, B_2, G_1, and G_2	Yes
All	Ochratoxin A	Chapter 2.8.22	20 µg/kg	Yes
Starting material for export or dried product	Foreign matter	Chapter 2.8.2	2%	No
Starting material for export or dried product	Loss on drying	Chapter 2.2.32	10%	No
Starting material for export or dried product	Total ash	Chapter 2.4.16	20%	No
Cannabis-based ingredient or dosage product	Residual solvents	Chapters 2.4.24 and 5.4	The limits specified by chapter 5.4	Yes

8 Other requirements

The table in this regulation sets out—

(a) which of the following items must comply with a requirement:

(i) starting material that is intended for export:

(ii) cannabis-based ingredients:

(iii) medicinal cannabis products, whether dried products or dosage products; and

(b) the name of the requirement; and

(c) the regulation that sets out the requirement; and

(d) for a requirement that involves testing, whether the requirement's testing method must be validated under regulation 9(2).

Items that must comply	Requirement	Regulation with requirement	Validation of testing method
Cannabis-based ingredient or any medicinal cannabis product	Shelf life and storage conditions	r 10	–
Starting material for export or dried product	Identification of cannabis	r 11	No
Cannabis-based ingredient or any medicinal cannabis product	Identification of active ingredients	r 12	Yes
Cannabis-based ingredient or any medicinal cannabis product	Assay limits for active ingredients	r 13	Yes
All	No adulteration	r 14	–
Cannabis-based ingredient or any medicinal cannabis product	Container material	r 15	–
Any medicinal cannabis product	Sources of active ingredients and cannabinoids	r 16	–
All	Restrictions on decontamination	r 17	–
All	Pesticides	r 18	–
Any medicinal cannabis product	Labelling	r 19	–
Any medicinal cannabis product	Form and dosage form	r 20	Yes
Dosage product	Excipients and other ingredients	r 21	No

9 Testing and validation of testing method

(1) Any testing required by regulation 7, or by a requirement covered in regulation 8, must be carried out by a GMP-certified manufacturer or laboratory.

(2) If regulation 7 or 8 requires the testing method to be validated, it must be validated by a GMP-certified manufacturer or laboratory.

(3) In this regulation, **GMP-certified** means certified by the following as complying with the requirements of good manufacturing practice set out in the *New Zealand Code of Good Manufacturing Practice for Manufacture and Distribution of Therapeutic Goods*:

(a) the Director-General; or

(b) an authority in another country that the Director-General recognises as a certifier of the compliance.

Details of other requirements

10 Shelf life and storage conditions

(1) A cannabis-based ingredient or medicinal cannabis product must remain compliant with the requirements of this minimum quality standard relating to the following during its shelf life:

(a) microbiological contamination:

(b) loss on drying:

(c) assay limits for active ingredients:

(d) form and dosage form.

(2) Stability testing must be done on the ingredient or product in accordance with the ICH Q1A Guideline to determine its—

(a) shelf life; and

(b) recommended storage conditions.

(3) In this regulation, **ICH Q1A Guideline** means the *Q1A(R2) Guideline on Stability Testing of New Drug Substances and Products* published by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use, as published at 1 April 2020.

11 Identification of cannabis

The following must be positively identified as cannabis by using both macroscopic and microscopic examination:

(a) any starting material that is intended for export:

(b) a dried product.

12 Identification of active ingredients

The active ingredients in the following must be positively identified by using chromatographic or spectroscopic methods, or both:

(a) a cannabis-based ingredient:

(b) a medicinal cannabis product (including a dried product).

13 Assay limits for active ingredients

(1) This regulation applies to a cannabis-based ingredient or medicinal cannabis product.

(2) Each active ingredient in the ingredient or product must be assayed using chromatographic or spectroscopic methods.

(3) For a dried product, each active ingredient must assay at—

(a) no less than 80% of its stated content; and

(b) no more than 120% of its stated content.

(4) For a cannabis-based ingredient or dosage product, each active ingredient must assay at—

(a) no less than 90% of its stated content; and

(b) no more than 110% of its stated content.

14 No adulteration

(1) The following must not contain any substance that adulterates it:

(a) any starting material that is intended for export:

(b) a cannabis-based ingredient:

(c) a medicinal cannabis product.

(2) In this regulation, **adulterate** means to add or substitute any substance that is extraneous to the composition of the material, ingredient, or dried product, or the formulation of the dosage product, other than incidental minor excipients, whether or not the intention is to improve, fortify, or debase the material, ingredient, or product.

15 Container material

A cannabis-based ingredient or medicinal cannabis product must be packed in a container of a material that complies with chapters 3.1 and 3.2 of the *European Pharmacopoeia*.

16 Sources of active ingredients and cannabinoids

The following ingredients contained in a medicinal cannabis product must be extracted only from cannabis:

(a) an active ingredient:

(b) a cannabinoid.

17 Restrictions on decontamination

Any treatment to decontaminate any of the following must not adversely affect the quality of the material, ingredient, or product, or use or contain ethylene oxide:

(a) any starting material that is intended for export:

(b) a cannabis-based ingredient:

(c) an ingredient of a medicinal cannabis product.

18 Pesticides

The following must not have been treated with a pesticide unless the pesticide is a trade name product that is registered under the Agricultural Compounds and Veterinary Medicines Act 1997 for use on cannabis:

(a) any starting material that is intended for export:

(b) cannabis from which a cannabis-based ingredient is extracted:

(c) an ingredient of a medicinal cannabis product.

19 Labelling

A medicinal cannabis product that is a medicine must comply with the requirements relating to a medicine in Part 4 of the Medicines Regulations 1984, but with the following modifications:

(a) that Part applies as if active ingredient had the same meaning as it has in these regulations:

(b) regulations 23 and 13(1)(k)(i) and (l) of those regulations do not apply (meaning that the rest of regulation 13, and regulations 16(1) and 22, of those regulations always apply to the product):

(c) regulation 16(1) of those regulations applies as if it also required the principal display panel of the product's label to contain the words "MEDICINAL CANNABIS PRODUCT".

20 Form and dosage form

(1) A medicinal cannabis product must not be in a form intended for smoking.

(2) A dosage product—

(a) must be in a pharmaceutical dosage form for which there is a monograph in the *European Pharmacopoeia*; and

(b) must comply with the requirements of the monograph; but

(c) must not be in a sterile dosage form.

21 Excipients and other ingredients

(1) A dosage product must not contain an excipient for which there is no monograph in the *European Pharmacopoeia*.

(2) The dosage product must comply with the requirements of the monograph in the *European Pharmacopoeia* for each excipient that it contains.

(3) The dosage product must not contain an ingredient that—

(a) is derived from an animal; and

(b) is contaminated with any transmissible spongiform encephalopathy.

Part 2
Medicinal cannabis licences

Types of licensed activity

22 Types of licensed activity

A medicinal cannabis licence authorises the licence holder to carry out 1 or more of the following types of licensed activity:

(a) a cultivation activity:

(b) a nursery activity:

(c) a research activity:

(d) a possession for manufacture activity:

(e) a supply activity.

23 Cultivation activity

(1) A **cultivation activity** means any activity listed in subclause (2) that—

(a) is specified in the licence; and

(b) is done for a purpose relating to—

(i) the cultivation of cannabis for therapeutic use; and

(ii) if specified in the licence, the cultivation of only approved cultivars under the Misuse of Drugs (Industrial Hemp) Regulations 2006.

(2) The activities are—

(a) to cultivate cannabis:

(b) to procure the following within New Zealand:

(i) any cannabis from the holder of a medicinal cannabis licence that authorises its supply:

(ii) no more than 50 seeds and 20 plants from each holder of a licence issued under the Misuse of Drugs (Industrial Hemp) Regulations 2006 that authorises their supply:

(iii) no more than 50 seeds and 20 plants (from any other source) of a variety of cannabis that is established in New Zealand and that the applicant has declared under regulation 35:

(c) to procure cannabis by import into New Zealand under a licence to import controlled drugs issued under the Misuse of Drugs Regulations 1977:

(d) to produce starting material, including by harvesting or drying cannabis:

(e) to supply cannabis within New Zealand to a person who is authorised to receive it by any enactment or a medicinal cannabis licence for a cultivation, nursery, research, possession for manufacture, or supply activity:

(f) to possess cannabis.

24 Nursery activity

(1) A **nursery activity** means any activity listed in subclause (2) that—

(a) is specified in the licence; and

(b) is done for a purpose relating to the supply of cannabis seeds or plants for cultivation for therapeutic use.

(2) The activities are—

(a) to procure cannabis—

(i) within New Zealand from the holder of any medicinal cannabis licence that authorises its supply; or

(ii) by import into New Zealand under a licence to import controlled drugs issued under the Misuse of Drugs Regulations 1977:

(b) to supply cannabis seeds and plants within New Zealand to a person who is authorised to receive it by any enactment or a medicinal cannabis licence for a cultivation activity:

(c) to possess cannabis.

25 Research activity

(1) A **research activity** means any activity listed in subclause (2) that—

(a) is specified in the licence; and

(b) is done for a purpose relating to research about cannabis for therapeutic use.

(2) The activities are—

(a) to procure any starting material, cannabis-based ingredient, or medicinal cannabis product—

(i) within New Zealand from the holder of any medicinal cannabis licence that authorises its supply; or

(ii) by import into New Zealand under a licence to import controlled drugs issued under the Misuse of Drugs Regulations 1977:

(b) to produce or manufacture a cannabis-based ingredient or medicinal cannabis product:

(c) to supply or administer a medicinal cannabis product to a person who is a research subject:

(d) to possess any starting material, cannabis-based ingredient, or medicinal cannabis product.

26 Possession for manufacture activity

(1) A **possession for manufacture activity** means any activity listed in subclause (2) that—

(a) is specified in the licence; and

(b) is done for a purpose relating to production or manufacture from cannabis for therapeutic use.

(2) The activities are—

(a) to procure any starting material, cannabis-based ingredient, or medicinal cannabis product—

(i) within New Zealand from the holder of any medicinal cannabis licence that authorises its supply; or

(ii) by import into New Zealand under a licence to import controlled drugs issued under the Misuse of Drugs Regulations 1977:

(b) any of the following manufacturing activities, but only to develop or test the related processes or products or to validate that testing:

(i) extracting a cannabis-based ingredient:

(ii) manufacturing or packing a medicinal cannabis product:

(iii) testing any cannabis or medicinal cannabis product:

(c) to possess any starting material, cannabis-based ingredient, or medicinal cannabis product.

27 Supply activity

(1) A **supply activity** means any activity listed in subclause (2) that—

(a) is specified in the licence; and

(b) is done for a purpose relating to the supply of—

(i) any starting material not intended for export; or

(ii) any starting material intended for export, cannabis-based ingredient, or medicinal cannabis product that is specified in the licence.

(2) The activities are—

(a) to procure any starting material, cannabis-based ingredient, or medicinal cannabis product—

(i) within New Zealand from the holder of any medicinal cannabis licence that authorises its supply; or

(ii) by import into New Zealand under a licence to import controlled drugs issued under the Misuse of Drugs Regulations 1977:

(b) to supply any starting material, cannabis-based ingredient, or medicinal cannabis product within New Zealand to a person who is authorised to receive it under 1 of the following:

(i) any enactment:

(ii) a medicinal cannabis licence:

(iii) a licence issued under the Misuse of Drugs Regulations 1977:

(iv) a licence issued under the Medicines Act 1981:

(c) to supply any starting material, cannabis-based ingredient, or medicinal cannabis product by export from New Zealand under a licence to export controlled drugs issued under the Misuse of Drugs Regulations 1977:

(d) to possess any starting material, cannabis-based ingredient, or medicinal cannabis product.

28 Licences under other enactments

(1) A medicinal cannabis licence does not remove any need for its holder to also hold any of the following relevant licences:

(a) a licence to manufacture medicines, a licence to pack medicines, a licence to sell medicines by wholesale, or a licence to sell medicines by retail issued under the Medicines Act 1981 (*see* section 109 of that Act):

(b) a licence to import controlled drugs, or a licence to export controlled drugs, issued under the Misuse of Drugs Regulations 1977.

(2) A medicinal cannabis licence does not affect—

(a) any of those licences; or

(b) any other licence issued under the Medicines Act 1981; or

(c) any other licence issued under the Misuse of Drugs Regulations 1977; or

(d) any licence issued under the Misuse of Drugs (Industrial Hemp) Regulations 2006.

(3) This regulation is for the avoidance of doubt.

Eligibility requirements

29 Individuals who are eligible to hold licences

An individual is eligible to hold a licence if the individual—

(a) has completed an application for the licence; and

(b) is 18 years or older; and

(c) satisfies both of the following, or does not satisfy both of the following but is approved by the Minister:

(i) they have never held a licence issued under the Misuse of Drugs Act 1975, or any regulations made under that Act, that has been revoked:

(ii) they have never been convicted of an offence against the Misuse of Drugs Act 1975 or any other drug-related offence; and

(d) resides in New Zealand; and

(e) is entitled to use the location or locations specified in the application for the licence for the types of licensed activity sought; and

(f) is familiar with, and has the expertise and the resources to comply with, the obligations that these regulations impose on the holder of a licence for the types of licensed activity sought.

30 Bodies corporate and partnerships that are eligible to hold licences

A body corporate or partnership (an **entity**) is eligible to hold a licence if—

(a) an application for the licence has been completed for the entity by a person authorised to do so; and

(b) every director or partner of the entity is 18 years or older; and

(c) both of the following are satisfied, or both of the following are not satisfied but the entity is approved by the Minister:

(i) neither the entity, nor any director or partner of the entity, has held a licence issued under the Misuse of Drugs Act 1975, or any regulations made under that Act, that has been revoked:

(ii) neither the entity, nor any director or partner of the entity, has been convicted of an offence against the Misuse of Drugs Act 1975 or any other drug-related offence; and

(d) the body corporate is incorporated in New Zealand or the partners of the partnership reside in New Zealand; and

(e) the entity is entitled to use the location or locations specified in the application for the licence for the types of licensed activity sought; and

(f) the entity has nominated 1 or more individuals to be responsible persons, being individuals who are eligible under regulation 31; and

(g) 1 or more directors or partners of the entity have the expertise, and the entity has the resources,—

(i) to comply with the obligations that these regulations impose on the holder of a licence for the types of licensed activity sought; and

(ii) to carry out the types of licensed activity for which the licence is sought.

31 Eligibility of responsible person

An individual is eligible to be approved under these regulations as a responsible person if the individual—

(a) is authorised by the entity concerned to control the activities for which the licence is sought, and to communicate with the Director-General on behalf of the entity; and

(b) is familiar with, and has the expertise to comply with, the obligations that these regulations impose on the holder of a licence for the types of licensed activity sought; and

(c) is 18 years or older; and

(d) satisfies both of the following, or does not satisfy both of the following but is approved by the Minister:

(i) they have never held a licence issued under the Misuse of Drugs Act 1975, or any regulations made under that Act, that has been revoked:

(ii) they have never been convicted of an offence against the Misuse of Drugs Act 1975 or any other drug-related offence; and

(e) resides in New Zealand.

Making and assessment of applications

32 Application for licence

(1) An application for a licence must be in a form provided by the Director-General.

(2) The form must require the following:

(a) the name, address, and contact details of the applicant:

(b) in the case of a body corporate or partnership,—

(i) the name of every director or partner; and

(ii) the name, address, and contact details of each person nominated to be a responsible person:

(c) the 1 or more types of licensed activity to be added to the licence:

(d) a declaration from each person nominated to be a responsible person that they are eligible under regulation 31.

(3) The form must also require the following information for each type of licensed activity for which the licence is sought:

(a) the following information about the location or locations to be used for the activity:

(i) a description:

(ii) the address:

(iii) the geographical co-ordinates:

(iv) a plan or map, if required to identify a location:

(b) the details of adequate arrangements for physical and procedural security, and the security of staff members, at the location or locations of the activity:

(c) the details of standard operating procedures for the activity, including for—

(i) tracking and recording any starting material, cannabis-based ingredient, or medicinal cannabis product; and

(ii) destroying waste material:

(d) the place where the records of the activities will be kept:

(e) adequate additional information to enable the Director-General to assess whether the applicant is eligible to hold a licence for the activity:

(f) the additional information specified for the activity (if any) by the following table:

Type of licensed activity	Additional information
Cultivation activity	Whether the cannabis to be cultivated is only approved cultivars under the Misuse of Drugs (Industrial Hemp) Regulations 2006. Whether the purpose of the activity is to cultivate cannabis for a nursery, research, possession for manufacture, or supply activity. Evidence to satisfy the Director-General that the applicant— (a) holds, or has applied for, a licence for a nursery, possession for manufacture, or supply activity; or (b) has an agreement to supply cannabis to the holder of a licence for a cultivation, nursery, possession for manufacture, or supply activity.
Research activity	A detailed description of the research proposal.
Possession for manufacture activity	Details of the manufacturing activities described by regulation 26(2)(b) that are to be carried out.
Supply activity	Details of each consignment of starting material for export, or each cannabis-based ingredient or medicinal cannabis product, to be supplied. For each consignment of starting material for export to be specified in the licence, evidence (including the results of all required testing) to satisfy the Director-General that a representative sample of the consignment complied with the minimum quality standard. For each cannabis-based ingredient or medicinal cannabis product to be specified in the licence, evidence (including the results of all required testing) to satisfy the Director-General that a representative sample of at least 10% of each of 3 batches of the ingredient or product complied with the minimum quality standard. The following information for each cannabis-based ingredient or medicinal cannabis product to be specified in the licence: (a) evidence (if any exists) that approval of, or consent to, its distribution in any country other than New Zealand has been given, or declined, by the appropriate authorities in that country: (b) its trade name, which— (i) must be unique (whether proprietary, non-proprietary, or a word or code); and (ii) must not be misleading about its therapeutic effects, safety, or composition; and (iii) must not cause confusion with another medicine in New Zealand: (c) a full-scale colour image, or (if requested) a physical specimen, of every label or description that will accompany it: (d) a full statement of its composition, or its formulation (meaning its ingredients and the quantity or proportion of each ingredient): (e) details of its method of manufacture (including packing and testing): (f) details of its container closure system: (g) evidence that the facilities for its manufacture (including packing and testing) are GMP-certified (as defined by regulation 9):

Type of licensed activity	Additional information
	(h) a detailed recall plan:
	(i) details of the recommended method of administering, applying, or using it.

(4) Every address specified in the application must be in New Zealand.

(5) The application must be signed and dated by or on behalf of the applicant.

33 Locations must have adequate security arrangements

The locations specified in an application must have the adequate security arrangements described in the application.

34 Fees for applications

(1) This regulation applies to an application for a new licence or to renew a licence (*see* regulation 47 for a change to a licence while it is in force).

(2) The following table sets out—

(a) the types of application for which 1 or more fees are payable:

(b) the fee payable for the initial check of whether an application appears to be in order:

(c) if the initial check confirms that an application for a new licence, or addition of a new type of licensed activity to a licence, or both, appears to be in order,—

(i) the fee payable for consideration of an application for a new licence:

(ii) the fee payable for consideration of an application to add each new type of licensed activity:

(d) if the initial check confirms that an application to renew a licence, or to renew a type of licensed activity for a renewed licence, or both, appears to be in order,—

(i) the fee payable for consideration of an application to renew a licence:

(ii) the fee payable for consideration of an application to renew each type of licensed activity:

Application for	Fee for initial check	Fee for consideration if new	Fee for consideration if renewal
Anything (licence and any activities)	$300		
Licence		$2,250	$2,250
Cultivation activity		$4,750	$2,950
Nursery activity		$650	$650
Research activity		–	–
Possession for manufacture activity		$2,700	$2,300

Application for	Fee for initial check	Fee for consideration if new	Fee for consideration if renewal
Supply activity		$5,550	$5,150

Example

If someone applies for a new licence for a cultivation and supply activity, they must initially pay $300 for the initial check of the application.

If the initial check confirms that the application appears to be in order, the applicant must then pay $12,550, comprising—

(a) $2,250 for consideration of the new licence; and

(b) $10,300 for consideration of the 2 new types of licensed activity ($4,750 for the cultivation activity + $5,550 for the supply activity).

If the application is for supply of a new dosage product, the applicant must also pay a further $13,400 under regulation 36.

All amounts exclude GST.

(3) All fees are specified exclusive of GST.

(4) The fee for the initial check must be paid when the application is submitted.

(5) The other fees under these regulations must be paid only if the initial check confirms that the application appears to be in order.

(6) The Director-General may waive or refund any fee under these regulations, in whole or part and in any particular case or class of cases, if satisfied that the waiver or refund—

(a) will better match the fees paid with the costs of the services for which they are paid; or

(b) is in the public interest.

35 Other fees: licence for cultivation (or to cultivate prohibited plant)

(1) This regulation applies when a person—

(a) is applying for a cultivation activity in relation to a medicinal cannabis licence; or

(b) holds a medicinal cannabis licence for a cultivation activity; or

(c) holds a licence to cultivate a prohibited plant, for scientific or research purposes, that was issued under the Misuse of Drugs Regulations 1977 and held at the commencement of these regulations.

(2) The person may declare in writing that, in accordance with the licence, they will procure no more than 50 seeds and 20 plants of a variety of cannabis that is established in New Zealand.

(3) However, the person can make more than 1 declaration for each variety of cannabis.

(4) The person must pay a fee of $650, exclusive of GST, when providing each declaration.

(5) For a licence described by subclause (1)(c), on the making of the declaration, the licence is treated as permitting the holder to possess and cultivate the declared seeds and plants, despite any condition in the licence.

36 Other fees: licence for supply activity

(1) This regulation applies when an applicant is applying for a supply activity in respect of any of the following that are not already specified in their licence (or in the licence that they are renewing):

(a) a consignment of starting material for export:

(b) a cannabis-based ingredient:

(c) a medicinal cannabis product, whether a dried product or dosage product.

(2) The applicant must pay the fee specified in the following table (exclusive of GST) for the assessment of the consignment of starting material, or the ingredient or product, under regulation 40(5):

What is assessed	Fee for assessment
Consignment of starting material for export	$5,250
Cannabis-based ingredient	$6,700
Dried product	$6,700
Dosage product	$13,400

(3) To avoid doubt, the fee for assessment of a dosage product also covers the assessment of its cannabis-based ingredients.

37 Director-General's initial check of applications

(1) On receipt of an application, the Director-General must check whether the application appears to be in order.

(2) If the application does not appear to be in order, the Director-General must return the application to the applicant and advise them that—

(a) the application is incomplete and that a new application will be required; or

(b) they do not appear to be eligible to hold the licence sought.

38 Director-General may verify adequate security arrangements at locations

The Director-General may inspect every location specified in the application to verify that it has the adequate security arrangements described in the application.

39 Director-General to ask Ministry of Justice for information about applicant

In order to ascertain whether an applicant, any director or partner of an applicant, or any individual nominated as a responsible person has a conviction for a crime or an offence referred to in this Part, the Director-General must ask the

chief executive of the Ministry of Justice to check whether the person has a conviction of that type.

Issue and renewal of, and changes to, licences

40 Decision to issue licence or to decline licence

(1) The Director-General may approve an application if the Director-General—

(a) is satisfied that the applicant is eligible, under these regulations, to hold the licence sought; and

(b) approves at least 1 nominated individual as a responsible person; and

(c) is satisfied that the activities for which the licence is sought are intended to be done for the proper purpose of those types of licensed activity; and

(d) is satisfied that every location specified in the application has the adequate security arrangements described in the application; and

(e) is satisfied with the information described in regulation 32(3) that is provided in the application.

(2) If, after considering an application, the Director-General is not satisfied about any of those matters or does not approve at least 1 nominated individual as a responsible person, the Director-General must decline the application.

(3) In deciding whether to approve an application, the Director-General may have regard to whether the applicant, any director or partner of the applicant, or any individual nominated as a responsible person has been convicted of—

(a) a crime involving dishonesty within the meaning of the Crimes Act 1961; or

(b) an offence outside New Zealand that, if committed in New Zealand, would fall within paragraph (a) or regulation 29(c)(ii).

(4) If the Director-General decides to decline an application, the Director-General must notify the applicant of the decision and the reasons for the decision.

(5) The Director-General must not approve the following to be specified in a licence for a supply activity unless, after assessing the evidence in the application, the Director-General is satisfied of the matter specified:

(a) for a consignment of starting material for export, that a representative sample of the consignment complied with the minimum quality standard; or

(b) for a cannabis-based ingredient or medicinal cannabis product, that a representative sample of at least 10% of each of 3 batches of the ingredient or product complied with the minimum quality standard.

41 Review of decision to decline licence

(1) An applicant whose application is declined under regulation 40 may apply to the Director-General for a review of the decision.

(2) The applicant must apply no later than 14 days after the day on which the notice of decision is given to them.

(3) The Director-General must appoint a person to conduct the review (the **reviewer**), who may be an employee of the responsible department but must not have had any previous involvement in the case.

(4) If, after conducting the review, the reviewer—

(a) considers the decision to decline the licence well founded, the reviewer must recommend that the decision be confirmed:

(b) does not consider the decision to decline the licence well founded, the reviewer must recommend that the decision be cancelled and reconsidered.

(5) After considering the recommendation given by the reviewer, the Director-General must—

(a) confirm the decision, or cancel and reconsider the decision; and

(b) give notice to the applicant of the confirmed or new decision.

(6) A notice under subclause (5) has effect as soon as it is given to the applicant.

42 Director-General may impose conditions

(1) In issuing or changing a licence, the Director-General may impose any conditions, in addition to the conditions imposed by these regulations, that the Director-General considers, in the circumstances of the particular case, necessary or desirable to meet the purpose of these regulations.

(2) Any conditions imposed when a licence is changed must relate to the changes.

43 Issue and form of licence

(1) As soon as practicable after approving an application, the Director-General must issue a licence that states the following:

(a) the name of the licence holder:

(b) if the licence is issued to a body corporate or a partnership, the name of every responsible person:

(c) the types of licensed activity, and the specific activities of each type, that are authorised:

(d) for each type of licensed activity, each location where any cannabis, cannabis-based ingredient, or medicinal cannabis product may be—

(i) stored; and

(ii) if applicable, cultivated; and

(iii) if applicable, produced, manufactured, or possessed for manufacture:

(e) for a licence for a cultivation activity, whether cultivation is restricted to approved cultivars under the Misuse of Drugs (Industrial Hemp) Regulations 2006:

(f) for a licence for a supply activity, each consignment of starting material for export, or cannabis-based ingredient or medicinal cannabis product, to which the licence applies:

(g) the period for which the licence is in force:

(h) any conditions imposed by the Director-General.

(2) The Director-General must sign and date the licence and give or send it to the licence holder.

44 Duration of licence

(1) A licence is in force for the period stated in the licence.

(2) The stated period must not exceed 1 year.

45 Renewal of licence

(1) If an application for renewal of a licence is made no earlier than 90 days, and no later than 30 days, before the expiry of the licence, the licence continues in force until the application for renewal is determined.

(2) These regulations apply to an application for a renewal of a licence as if it were an application for a new licence, except for the fees payable in relation to types of licensed activities.

(3) A licence issued on an application under this regulation—

(a) must be treated as a licence issued under regulation 43; and

(b) starts when the earlier licence expires.

46 Surrender of licence

A licence holder may, at any time, surrender the licence to the Director-General, in which case the licence expires on the date on which the licence is received by the Director-General.

47 Certain changes not to be made without approval of Director-General

(1) A licence holder must not change any of the following matters without the prior approval of the Director-General:

(a) the composition of the board of directors of the body corporate or partners of the partnership:

(b) anything at the locations specified in the licence that affects a location's security arrangements:

(c) the activities, or types of licensed activity, authorised by the licence:

(d) any responsible person:

(e) for a licence for a supply activity, any of the following matters relating to a consignment of starting material for export, or any cannabis-based ingredient or medicinal cannabis product, specified in the licence:

(i) its trade name:

(ii) the label or description that will accompany it:

(iii) its composition, or its formulation (meaning its ingredients and the quantity or proportion of each ingredient):

(iv) its method of manufacture (including packing and testing):

(v) its container closure system:

(vi) the facilities for its manufacture (including packing and testing):

(vii) the recommended method of administering, applying, or using it:

(viii) its shelf life or storage conditions.

(2) A licence holder cannot change the locations specified in the licence.

(3) An approval under this regulation must be sought by a written application, in a form provided by the Director-General, that—

(a) includes the new information for the matters sought to be changed that would be required in an application for a licence; and

(b) is accompanied by the licence; and

(c) is made at least 60 days before a proposed change is to take effect.

(4) The Director-General must consider whether the application satisfies the requirements of this Part that relate to the matters that are sought to be changed.

(5) If the Director-General approves a change described in any of subclause (1)(c) to (e), the Director-General must amend the licence or issue a replacement licence to reflect the approved change.

(6) Fees are payable if the application is for—

(a) the addition of 1 or more new types of licensed activity to the licence; or

(b) any change relating to a location used for a type of licensed activity, if the Director-General is satisfied that the change affects the location's security arrangements.

(7) The fees that are payable are—

(a) the fee payable under regulation 34 for the initial check of whether an application appears to be in order:

(b) if the initial check confirms that the application appears to be in order, the fee payable under regulation 34 for the consideration of an application to add each new type of licensed activity to which subclause (6) applies.

(8) Fees are also payable—

(a) under regulation 35 if the applicant makes a declaration under that regulation when applying; or

(b) under regulation 36 if the application relates to a supply activity and—

(i) is an application for a change described in subclause (1)(e), in which case the consignment, ingredient, or product that is being changed must be assessed under regulation 40(5) as if it were not already specified in the licence; or

(ii) that regulation otherwise applies.

48 Replacement of responsible person

(1) This regulation applies if there is no responsible person in respect of a licence held by a body corporate or partnership because the individual who was the responsible person has—

(a) died, become incapacitated, or for any other reason has become unable to hold the position of responsible person; or

(b) ceased to be a responsible person as a result of a cancellation of approval under regulation 49.

(2) The licence holder must, as soon as practicable, seek the Director-General's approval, under regulation 47, for an eligible individual to replace the individual who has ceased to be a responsible person.

49 Cancellation of approval of responsible person

(1) The Director-General may cancel the approval of an individual given under regulation 40 if the Director-General is satisfied that the individual—

(a) has ceased to be eligible under regulation 31; or

(b) has breached a provision of these regulations or a condition of the licence.

(2) Before cancelling the approval of an individual, the Director-General must—

(a) notify the individual of the proposal to cancel the approval; and

(b) give the individual an opportunity to make submissions on the proposal within a reasonable period; and

(c) take into account any submissions received within that period.

(3) The Director-General must give notice of a cancellation under this regulation to the individual and to the licence holder.

50 Certain changes to be notified to Director-General

Whenever there is a change in the place where a licence holder's records are kept or a change in the address or the contact details of a licence holder or responsible person, the licence holder must, no later than 15 days after the change, give the Director-General notice of the change.

51 Licence must be securely kept

The licence holder must keep their licence in a secure place at all times when the licence is not required to be produced under these regulations.

Terms and conditions relating to authorised activities

52 Activity may be carried out only in specified locations

An activity authorised by a licence may be carried out only in the location or locations specified for the activity in the licence.

53 Activity must be carried out under control of licence holder or responsible person

An activity authorised under a licence may be carried out only if it is carried out under the control of—

(a) the licence holder, if the licence holder is an individual; or

(b) a responsible person, if the licence holder is a body corporate or a partnership.

54 Cannabis, ingredients, and products to be dealt with responsibly

Every licence holder and every responsible person must deal with any cannabis, cannabis-based ingredients, and medicinal cannabis products that are in their possession or control in a way that effectively guards against the risk of misuse for unlawful purposes.

55 Compliance with conditions and provisions

(1) Every licence holder and every responsible person must—

(a) comply with all conditions imposed on the licence holder by or under these regulations and with all other provisions of these regulations; and

(b) take all reasonable steps to ensure that every employee, agent, and contractor complies with the conditions and provisions.

(2) The expenses incurred in complying with the conditions and provisions must be met by the licence holder.

56 Security of cannabis, ingredients, and products

(1) A licence holder must ensure that all cannabis, cannabis-based ingredients, and medicinal cannabis products are securely protected against access by unauthorised individuals and any animals.

(2) A licence holder must take all reasonable steps to ensure that cultivated cannabis does not spread outside the locations to which the licence applies.

57 Police and Director-General to be notified of unauthorised removal, loss, or activity

(1) This regulation applies if—

(a) the licence of a licence holder is removed without authority or lost; or

(b) any cannabis, cannabis-based ingredient, or medicinal cannabis product that is in the licence holder's possession or control is removed without authority or lost; or

(c) there is any unauthorised activity at a place where cannabis is cultivated or stored.

(2) After the licence holder, or any employee or agent of the licence holder, becomes aware of the removal, loss, or activity, the licence holder must report it—

(a) immediately to a member of the Police; and

(b) as soon as practicable, but within 3 days, to the Director-General.

58 Locations must be available for inspection

(1) If an authorised person wishes to inspect, at a reasonable time, a location specified in a licence, the licence holder must permit the authorised person to enter the land that comprises or includes the location.

(2) The licence holder and every employee or agent of the licence holder must give an authorised person who inspects a location any reasonable assistance that the authorised person requires for the purposes of the inspection.

(3) In subclause (2), **assistance** includes—

(a) giving the authorised person records kept under these regulations; and

(b) copying those records or permitting the authorised person to remove those records for copying; and

(c) co-operating with the authorised person in the inspection of the premises, processes, and materials at the location, and the taking of samples of cannabis, cannabis-based ingredients, or medicinal cannabis products.

(4) An authorised person who carries out an inspection under this regulation must carry identification and other documentation that confirms the person's authority to inspect, and must show that identification and authorising documentation on request.

(5) In this regulation, **authorised person** means a person authorised in writing by the Director-General to exercise the powers under this regulation.

59 Samples taken for testing

(1) The Director-General may, at any time, take samples of the following from a location specified in the licence holder's licence:

(a) any cannabis:

(b) a cannabis-based ingredient:

(c) a medicinal cannabis product:

(d) any label, packaging, or description relating to those things.

(2) The samples may be taken only for the purposes of examining or testing them.

60 Destruction of cannabis, ingredients, and products

(1) The licence holder must, at their own cost, destroy each of the following that they have and that is not required, or to be supplied, under the licence:

(a) any cannabis:

(b) a cannabis-based ingredient:

(c) a medicinal cannabis product.

(2) The licence holder must provide evidence of the destruction to the Director-General on request.

61 Abandoned cannabis

(1) If the Director-General believes on reasonable grounds that a current or former licence holder has abandoned any growing or harvested cannabis that is subject to the licence holder's licence, the Director-General may treat the cannabis as surrendered to the Director-General.

(2) The Director-General may recover from the licence holder any costs incurred in managing or disposing of the cannabis.

(3) This regulation applies whether or not the licence of the licence holder has expired or been revoked.

Record-keeping and reporting

62 Records for cultivation activity

(1) The holder of a licence for a cultivation activity must keep records of the amounts of cannabis that the holder, under the licence,—

(a) cultivates; or

(b) maintains for the purposes of propagation; or

(c) produces and stores; or

(d) supplies within New Zealand to the holder of a licence; or

(e) destroys or disposes of.

(2) The holder must also keep records of the following for activities authorised by the licence:

(a) a failure by the holder, in any season, to sow cannabis seeds intended for sowing:

(b) a failure of any cannabis seeds sown by the holder to germinate, or of any crop of cannabis plants to attain maturity, for any reason.

63 Records for nursery activity

The holder of a licence for a nursery activity must keep records of—

(a) the amounts of cannabis seeds and cannabis plants that the holder supplies under the licence; and

(b) the amounts of cannabis seeds and cannabis plants that the holder possesses under the licence.

64 Records for research activity

The holder of a licence for a research activity must keep records of—

(a) the amounts of each medicinal cannabis product that the holder supplies or administers under the licence; and

(b) the amounts of starting material, cannabis-based ingredients, and medicinal cannabis products that the holder possesses under the licence.

65 Records for possession for manufacture activity

The holder of a licence for a possession for manufacture activity must keep records of the following for activities carried out under the licence:

(a) the amounts of medicinal cannabis products that the holder possesses after manufacturing them:

(b) the amounts of starting material and cannabis-based ingredients that the holder possesses.

66 Records for supply activity

The holder of a licence for a supply activity must keep records of—

(a) the amounts of starting material, cannabis-based ingredients, and medicinal cannabis products that the holder supplies under the licence; and

(b) the amounts of starting material, cannabis-based ingredients, and medicinal cannabis products that the holder possesses under the licence.

67 Records of stocktake for any activity

(1) This regulation applies in respect of each of the following (a **material**) that a person possesses in accordance with a licence at the end of any year (the **time of stocktake**):

(a) any cannabis:

(b) a cannabis-based ingredient:

(c) a medicinal cannabis product.

(2) The person must—

(a) record the actual amount of the material that they possess at the time of stocktake; and

(b) prepare an account that compares the recorded amounts of the material that they possess during the year with the actual amount at the time of stocktake, including an explanation of any differences between the recorded and actual amounts.

(3) The records and account must be completed by 31 January after the time of stocktake.

68 Keeping of records

(1) Every matter that must be recorded must be kept up to date.

(2) The records must be retained for at least 5 years after they are made.

(3) The records may be kept on paper or in electronic form.

(4) The records must be readily accessible, retrievable, and secure from tampering.

69 Copy of records to be provided on request

(1) Every licence holder must provide to the Director-General a copy of any record as soon as practicable after the Director-General requests a copy.

(2) The copy may be provided on paper or in electronic form.

70 Returns for export or supply

Regulation 47 of the Misuse of Drugs Regulations 1977 applies to any export or supply under a medicinal cannabis licence—

(a) as if the holder of the medicinal cannabis licence were a person licensed under those regulations to deal in controlled drugs; and

(b) as if that regulation applied to disposal by wholesale or retail; and

(c) with any other necessary modifications.

Suspension and cancellation of licences

71 Suspension of licence

(1) The Director-General may, by notice to the licence holder, suspend a licence if satisfied that the licence holder has—

(a) provided any false information in the application for the licence or for a change to the licence; or

(b) breached any condition of the licence or provision of these regulations.

(2) The notice must provide the following information:

(a) the start date of the suspension (which must not be before the date on which the notice is given to the licence holder):

(b) the end date of the suspension (which must not be more than 30 days after the start date):

(c) the false information that was provided or the breach that has occurred:

(d) the corrective action to be taken to remedy or mitigate the false information or breach:

(e) the right of the licence holder to apply for a review of the suspension.

(3) The notice must also state that—

(a) the Director-General will, unless the suspension is cancelled on review, keep a record of the suspension:

(b) the record will be taken into account in the consideration of any future application that involves the licence holder, any directors or partners of the licence holder, or any individual who is a responsible person for the licence.

72 Duration of suspension

(1) The period of suspension starts on the date stated in the notice.

(2) The period of suspension ends on the date stated in the notice unless at any time during that period the Director-General, by notice to the licence holder,—

(a) extends that period by a further period of no more than 30 days; or

(b) substitutes an earlier end date for the period.

(3) The Director-General may extend the period of suspension only once.

(4) The Director-General may, under subclause (2)(b), substitute an earlier date only if satisfied that the licence holder has taken the corrective action stated in the notice given under regulation 71 or that the action is not, or no longer, required.

73 Effect of suspension

(1) While the licence of a licence holder is suspended, the licence holder—

(a) is not authorised to carry out any authorised activity under that licence without the prior written permission of the Director-General; but

(b) may tend growing cannabis and, if necessary, harvest it, if those are authorised activities under the licence.

(2) A permission given under subclause (1)(a) may be subject to any stated restrictions or conditions, or both.

74 Revocation of licence

(1) The Director-General may, by notice to the licence holder, revoke the licence of the licence holder if satisfied that—

(a) the licence holder has, within any period during which the licence holder's licence was suspended, failed to take the corrective action stated in the notice given under regulation 71; or

(b) the licence holder or any director or partner of the licence holder has been convicted of an offence against the Misuse of Drugs Act 1975 or any other drug-related offence; or

(c) the licence holder has knowingly provided any false information in the application for the licence or for a change to the licence; or

(d) the licence holder has deliberately breached a condition of the licence imposed by or under these regulations.

(2) The notice must provide the following information:

(a) the date on which the revocation takes effect (which must not be before the 14th day after the date on which the notice is given to the licence holder):

(b) the reasons for the revocation:

(c) the right of the licence holder to apply for a review of the revocation.

(3) The notice must also state that—

(a) the Director-General will, unless the revocation is cancelled on review, keep a record of the revocation:

(b) the record will be taken into account in the consideration of any future application that involves the licence holder, any directors or partners of the licence holder, or any individual who is a responsible person for the licence.

75 Duty to return licence when revocation takes effect

(1) As soon as the revocation of a licence takes effect, the person who held that licence must return the licence to the Director-General.

(2) For the purposes of these regulations, the revocation of a licence takes effect on the date stated under regulation 74(2)(a) unless the licence holder concerned applies for a review in accordance with regulation 76, in which case it takes effect if and when notice is given, under regulation 76(5), that the decision to revoke has been confirmed.

76 Review of suspension or revocation

(1) A licence holder whose licence has been suspended under regulation 71 or revoked under regulation 74 may apply to the Director-General for a review of the suspension or revocation.

(2) The licence holder must apply no later than 14 days after the day on which the notice of suspension or revocation is given to them.

(3) The Director-General must appoint a person to conduct the review (the **reviewer**), who may be an employee of the responsible department but must not have had any previous involvement in the case.

(4) If, after conducting the review, the reviewer—

(a) considers the decision to suspend or revoke the licence well founded, the reviewer must recommend that the decision be confirmed:

(b) does not consider the decision to suspend or revoke the licence well founded, the reviewer must recommend that the decision be cancelled.

(5) After considering the recommendation given by the reviewer, the Director-General must, by notice to the licence holder, confirm or cancel the decision.

(6) A notice under subclause (5) has effect as soon as it is given to the licence holder.

(7) In the period starting on the day on which an application for review of the revocation of a licence is lodged and ending at the end of the day on which the application is withdrawn or determined, the applicant—

(a) is not authorised to carry out any authorised activity under that licence; but

(b) may tend growing cannabis and, if necessary, harvest it, if those are authorised activities under the licence.

77 Record of suspensions and revocations

(1) The Director-General must keep a record of every suspension and revocation of a licence that has not been cancelled on review.

(2) The Director-General may, to the extent that it is relevant to do so, use the record—

(a) to determine the eligibility of an applicant for a licence; and

(b) to take into account the suitability of a person as a licence holder or as a responsible person.

Offences

78 Offence to knowingly provide false information in application

A person commits an offence if they knowingly provide any false information in an application for a licence or for a change to a licence.

79 Offence to supply to unauthorised persons

A person commits an offence if, acting or purporting to act under a medicinal cannabis licence, they—

(a) supply any cannabis, cannabis-based ingredient, or medicinal cannabis product within New Zealand to a person who is not authorised to procure or receive it under any of the following:

(i) any enactment:

(ii) a medicinal cannabis licence:

(iii) a licence issued under the Misuse of Drugs Act 1975 or any other regulations made under that Act; or

(b) export any cannabis, cannabis-based ingredient, or medicinal cannabis product from New Zealand to a person in an overseas country who is not authorised, under the law of that country, to procure it.

80 Offence to breach conditions

A person commits an offence if, being the licence holder of a licence or a responsible person, they breach a condition of the licence imposed by or under these regulations.

81 Penalty

A person who commits an offence against these regulations is liable to a fine not exceeding $500, and, if the offence is a continuing one, to a further fine not exceeding $20 for every day or part of a day during which the offence has continued.

Notices

82 Giving of notices

(1) A notice that is required to be given to a person under these regulations must be in writing and be given to the person in 1 of the following ways:

(a) by giving it to the person:

(b) by leaving it at the person's place of residence or place of business:

(c) by sending it to the person by email.

(2) A requirement under these regulations to give a notice to a licence holder who is a body corporate or a partnership is satisfied if the notice is given, in accordance with subclause (1), to an individual who is a responsible person for the licence.

Part 3
Amendments to other regulations

Amendments to Medicines Regulations 1984

83 Amendments to Medicines Regulations 1984

Regulations 84 and 85 amend the Medicines Regulations 1984.

84 New regulation 4A inserted (Standard for CBD products)

After regulation 4, insert:

4A Standard for CBD products

(1) The minimum quality standard imposed by Part 1 of the Misuse of Drugs (Medicinal Cannabis) Regulations 2019 applies to a CBD product as if it were both a cannabis-based ingredient and a medicinal cannabis product under those regulations.

(2) However, the minimum quality standard does not apply to a CBD product that is imported by—

(a) a medical practitioner whose purpose is to prescribe, supply, or administer it for the treatment of a particular patient under their care; or

(b) a pharmacist for a prescription to which paragraph (a) applies.

(3) Subclause (4) applies to a CBD product of a type that, at the commencement of this regulation, has been imported into New Zealand by the holder of a licence issued under the Medicines Act 1981.

(4) The minimum quality standard does not apply to any of that product of the licence holder during the 6-month period that starts at the commencement of this regulation.

(5) In this regulation, **CBD product** has the meaning given by section 2A of the Misuse of Drugs Act 1975.

85 New regulation 45B inserted (Licences that relate to CBD products)

After regulation 45A, insert:

45B Licences that relate to CBD products

(1) A licence to manufacture medicines, to sell medicines by wholesale, to pack medicines, or to operate a pharmacy that is issued under these regulations does not apply to a CBD product (as defined by section 2A of the Misuse of Drugs Act 1975) unless expressly authorised by the licence.

(2) The licence must not be issued, or amended, to expressly authorise its application to a CBD product unless the product has been assessed as complying with the minimum quality standard under the Misuse of Drugs (Medicinal Cannabis) Regulations 2019.

(3) A product is assessed as complying with the minimum quality standard under those regulations if—

(a) an application is made under those regulations to assess the CBD product, in which case those regulations (including the requirement to pay fees) apply for that purpose as if the product were being assessed as a medicinal cannabis product; and

(b) the Director-General assesses the evidence in the application and is satisfied that a representative sample of at least 10% of each of 3 batches of the product complied with the minimum quality standard.

Amendments to Misuse of Drugs Regulations 1977

86 Amendments to Misuse of Drugs Regulations 1977

Regulations 87 to 89 amend the Misuse of Drugs Regulations 1977.

87 New regulation 3C inserted (Application to medicinal cannabis products)

After regulation 3B, insert:

3C Application to medicinal cannabis products

A licence to cultivate a prohibited plant, or to possess controlled drugs, must not be issued under these regulations in respect of any of the following, as defined by the Misuse of Drugs (Medicinal Cannabis) Regulations 2019:

(a) any starting material:

(b) a cannabis-based ingredient:

(c) a medicinal cannabis product.

88 Regulation 7 amended (Import and export licences)

After regulation 7(8), insert:

(9) A licence to import, or a licence to export, controlled drugs must not be granted in respect of any starting material, cannabis-based ingredient, or medicinal cannabis product (all as defined by the Misuse of Drugs (Medicinal Cannabis) Regulations 2019) unless—

(a) the applicant holds a medicinal cannabis licence (as defined by those regulations); or

(b) the applicant is a medical practitioner whose purpose is to import the controlled drugs to prescribe, supply, or administer them for the treatment of particular patients under their care, and the Minister gives written approval to the grant of the licence; or

(c) the applicant is a pharmacist whose purpose is to import the controlled drugs for a prescription to which paragraph (b) applies.

89 Regulation 22 amended (Restriction on supply of certain controlled drugs)

After regulation 22(2)(b), insert:

(c) any of the following that have been assessed as complying with the minimum quality standard, and specified in a medicinal cannabis licence accordingly, under the Misuse of Drugs (Medicinal Cannabis) Regulations 2019:

(i) a consignment of starting material for export:

(ii) a cannabis-based ingredient:

(iii) a medicinal cannabis product.

Amendment to Misuse of Drugs (Industrial Hemp) Regulations 2006

90 Amendment to Misuse of Drugs (Industrial Hemp) Regulations 2006

Regulation 91 amends the Misuse of Drugs (Industrial Hemp) Regulations 2006.

91 New regulation 8A inserted (Limited supply of hemp for medicinal cannabis products)

After regulation 8, insert:

8A Limited supply of hemp for medicinal cannabis products

(1) This regulation applies to a licence holder of 1 or more licences (whether a general or a research and breeding licence) that authorise the supply within New Zealand of industrial hemp.

(2) The licence holder is also authorised to supply, within New Zealand, no more than 50 seeds and 20 plants of industrial hemp to each holder of a medicinal cannabis licence for a cultivation activity under the Misuse of Drugs (Medicinal Cannabis) Regulations 2019.

(3) However, a licence issued under these regulations does not authorise the licence holder to carry out any activity for which a medicinal cannabis licence is required under those regulations.

Schedule 1
Transitional, savings, and related provisions

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Part 1
Provisions relating to these regulations as made

1 Existing licences to import controlled drugs

(1) This clause applies to a medicinal cannabis product of a type—

(a) that, at the commencement of these regulations, has been imported into New Zealand by the holder of a licence to import controlled drugs issued under the Misuse of Drugs Regulations 1977; and

(b) for which that licence holder has applied for a medicinal cannabis licence for a supply activity no later than 30 days after the commencement of these regulations.

(2) The minimum quality standard does not apply to any of that product of the licence holder during the 6-month period that starts at the commencement of these regulations.

2 Existing licences to possess controlled drugs

(1) This clause applies to a person who, at the commencement of these regulations, holds a licence to possess controlled drugs that is issued under the Misuse of Drugs Regulations 1977 and authorises any activity for which a medicinal cannabis licence is required under these regulations.

(2) The person may continue to act in accordance with the licence only until the later of the following:

(a) the date that is 30 days after the commencement of these regulations:

(b) the time when an application for a medicinal cannabis licence that was made within those 30 days is determined.

3 Existing licences to cultivate for scientific or research purposes

(1) This clause applies to the holder of a licence to cultivate a prohibited plant, for scientific or research purposes, that was issued under the Misuse of Drugs Regulations 1977 and held at the commencement of these regulations.

(2) If the licence holder also becomes the holder of a medicinal cannabis licence for a cultivation activity, they may retain all cannabis seeds and no more than 50 cannabis plants for the purposes of the medicinal cannabis licence, despite any condition in the licence to cultivate a prohibited plant.

Clerk of the Executive Council.

Explanatory note

This note is not part of the regulations, but is intended to indicate their general effect.

These regulations—

- impose a minimum quality standard for medicinal cannabis products and related material and ingredients (*Part 1*); and
- provide for medicinal cannabis licences that authorise various activities relating to medicinal cannabis products and related material and ingredients (*Part 2*).

The regulations come into force on 1 April 2020.

Part 1—Minimum quality standard relating to medicinal cannabis products

Regulation 7 sets out maximum limits that certain things must not exceed when medicinal cannabis products, or related material or ingredients, are tested in accordance with the *European Pharmacopoeia*.

Regulation 8 sets out other requirements that medicinal cannabis products, or related material or ingredients, must comply with. The requirements are detailed in *regulations 10 to 21*.

Part 2—Medicinal cannabis licences

A medicinal cannabis licence authorises the licence holder to carry out 1 or more of the following:

- a cultivation activity:

- a nursery activity:
- a research activity:
- a possession for manufacture activity:
- a supply activity.

But licences under other enactments may also be needed.

There are provisions about—

- eligibility for licences (*regulations 29 to 31*):
- making and assessing applications for licences (*regulations 32 to 39*):
- issuing, renewing, and changing licences (*regulations 40 to 51*):
- terms and conditions relating to activities authorised by licences (*regulations 52 to 61*):
- record-keeping and reporting under licences (*regulations 62 to 70*):
- suspending and cancelling licences (*regulations 71 to 77*):
- offences relating to licences (*regulations 78 to 81*):
- giving notices (*regulation 82*).

Part 3—Amendments to other regulations

Part 3 makes related amendments to other regulations.

Regulatory impact assessment

The Ministry of Health produced a regulatory impact assessment on 1 October 2019 to help inform the decisions taken by the Government relating to the contents of this instrument.

A copy of the regulatory impact assessment can be found at—

- https://www.health.govt.nz/about-ministry/information-releases/regulatory-impact-statements
- http://www.treasury.govt.nz/publications/informationreleases/ria

Issued under the authority of the Legislation Act 2012.
Date of notification in *Gazette*:
These regulations are administered by the Ministry of Health.