Misuse of Drugs (Medicinal Cannabis) Amendment Regulations 2024

Cindy Kiro, Governor-General

Order in Council

At Wellington this 1st day of July 2024

Present:
Her Excellency the Governor-General 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) Amendment Regulations 2024.

2 Commencement

These regulations come into force on 5 July 2024.

3 Principal regulations

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

Part 1
Amendments to principal regulations

4 Regulation 4 amended (Interpretation)

(1) In regulation 4, definition of **active ingredient**, replace paragraph (c) with:

(c) any other ingredient that is derived from cannabis and whose stated content is at least—

(i) 1.0% by weight or volume of the cannabis-based ingredient; or

(ii) 1.0% by weight or volume of the medicinal cannabis product

(2) In regulation 4, replace the definition of **cannabis-based ingredient** with:

cannabis-based ingredient—

(a) means an ingredient that—

(i) is extracted from cannabis; and

(ii) is intended to be used in, or for, a dosage product; and

(b) includes dried cannabis that is intended to be used in, or for, a dosage product

(3) In regulation 4, replace the definition of ***European Pharmacopoeia*** with:

European Pharmacopoeia means the 11th edition, version 11.0 of the *European Pharmacopoeia*, including supplement 11.3

(4) In regulation 4, replace the definition of **starting material** with:

starting material means—

(a) fresh or dried cannabis that is intended to undergo further processing and be used in, or for, a medicinal cannabis product; or

(b) initial extracts from cannabis intended to undergo further processing or extraction and be used in, or for, a cannabis-based ingredient

(5) In regulation 4, insert in their appropriate alphabetical order:

British Pharmacopoeia means the *British Pharmacopoeia* 2023

EMA Guideline on Plastic Immediate Packaging Materials means the European Medicines Agency Guideline on Plastic Immediate Packaging Materials (reference number CPMP/QWP/4359/03)

GMP means good manufacturing practice as set out in the *New Zealand Code of Good Manufacturing Practice for Manufacture and Distribution of Therapeutic Goods*

GMP-certified means having—

(a) a licence to manufacture or pack medicines issued under section 17 of the Medicines Act 1981; or

(b) evidence of GMP certification to the satisfaction of the Director-General

non-therapeutic purpose means a use for the purpose of research, testing, analysis, or product development that is not for, or does not relate to, a therapeutic purpose

United States Pharmacopeia means the *United States Pharmacopeia–National Formulary* 2023 issue 1

5 Regulation 6 amended (Minimum quality standard imposed)

(1) Revoke regulation 6(1)(a).

(2) Replace regulation 6(2)(d) with:

(d) it is imported and used by a pharmacist for a prescription to which paragraph (c) applies; or

(e) it is imported and used by a medical practitioner for the treatment of a particular patient currently under their care and with the approval of the Minister under regulation 22 of the Misuse of Drugs Regulations 1977; or

(f) it is imported and used for testing, analysis, or research for non-therapeutic purposes; or

(g) it is for export and is manufactured in compliance with GMP by a GMP-certified manufacturer.

6 Regulation 7 replaced (Requirements for testing with maximum limits)

Replace regulation 7 with:

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) cannabis-based ingredients:

(ii) 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(s) of the *British Pharmacopoeia*, *European Pharmacopoeia*, or *United States Pharmacopeia* that set out the testing method(s) that must be used; and

(d) the maximum limit that the test result must not exceed; 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	EP chapters 2.6.12, 2.6.13, and 2.6.31	The limits specified by EP chapters 5.1.4 and 5.1.8	Yes
All	Heavy metals	EP chapter 2.4.27 USP <561>	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	EP chapter 2.8.13 USP <561>	The limits specified for each pesticide specified by EP chapter 2.8.13	Yes
Cannabis-based ingredient, or medicinal cannabis product, that is not imported	Pesticides	EP chapter 2.8.13 USP <561>	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	EP chapter 2.8.18 USP <561>	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	EP chapter 2.8.22	20 µg/kg	Yes

Items tested	What is tested for	Testing method	Maximum limit	Validation of testing method
Dried cannabis as a cannabis-based ingredient or dried product	Foreign matter	EP chapter 2.8.2	2%	No
Dried cannabis as a cannabis-based ingredient or dried product	Loss on drying	EP chapter 2.2.32 USP <731>	12%	No
Dried cannabis as a cannabis-based ingredient or dried product	Total ash	EP chapter 2.4.16 USP <561> or BP Appendix XI.J	20%	No
Cannabis-based ingredient or dosage product	Residual solvents	EP chapters 2.4.24 and 5.4 USP <467>	The limits specified by EP chapter 5.4	Yes

(3) Tests for the following may be conducted on only a cannabis-based ingredient if it can be demonstrated that there is no risk that the final product will exceed the maximum limits:

(a) heavy metals:

(b) pesticides:

(c) absence of aflatoxins:

(d) ochratoxin A:

(e) foreign matter (for dried cannabis as cannabis-based ingredient):

(f) loss on drying (for dried cannabis as cannabis-based ingredient):

(g) total ash (for dried cannabis as cannabis-based ingredient):

(h) residual solvents.

(4) However, the testing referred to in subclause (3) need not be conducted on a cannabis-based ingredient if the tests are completed in the final dosage product stage and the cannabis-based ingredient is not intended for further supply.

7 Regulation 8 amended (Other requirements)

(1) Revoke regulation 8(a)(i).

(2) In regulation 8, table, replace “Starting material for export or dried product” with “Cannabis-based ingredient that is dried cannabis or dried product”.

8 Regulation 9 replaced (Testing and validation of testing method)

Replace regulation 9 with:

9 Testing and validation of testing method

(1) Any testing required by regulation 7, or by a requirement specified in regulation 8, must be carried out,—

(a) in the case of a critical test, by a GMP-certified manufacturer or laboratory:

(b) in any other case, by—

(i) a GMP-certified manufacturer or laboratory; or

(ii) an ISO/IEC 17025:2017 accredited laboratory.

(2) If regulation 7 or 8 requires the testing method to be validated, it must be validated,—

(a) for a critical test, by a GMP-certified manufacturer or laboratory; or

(b) in any other case, by a GMP-certified manufacturer or laboratory, or an ISO/IEC 17025:2017 accredited laboratory.

(3) However, this regulation does not apply to the testing of container material.

(4) In this regulation,—

critical test means a test for—

(a) assay limits for active ingredients; or

(b) dosage form requirements

ISO/IEC 17025:2017 accredited laboratory means a laboratory that is accredited as meeting ISO/IEC 17025:2017 by an accreditation body that is a signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Agreement.

9 Regulation 11 replaced (Identification of cannabis)

Replace regulation 11 with:

11 Identification of cannabis

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

(a) any dried cannabis intended to be used as a cannabis-based ingredient before further processing:

(b) any other dried product.

10 Regulation 13 amended (Assay limits for active ingredients)

(1) In regulation 13(4), delete “cannabis-based ingredient or”.

(2) After regulation 13(4), insert:

(5) Despite subclauses (3) and (4), if an active ingredient in a medicinal cannabis product is present at very low levels and difficult to control within the specified

range, the active ingredient may be assayed at a less-than limit rather than within the limits specified in the relevant subclause.

(6) For a cannabis-based ingredient, each active ingredient must assay at—

(a) no less than the lowest quantity specified by the manufacturer of each active ingredient; and

(b) no more than the highest quantity specified by the manufacturer of each active ingredient.

(7) In this regulation, **less-than limit** means a limit specified by the manufacturer below which the relevant product must assay.

11 Regulation 14 amended (No adulteration)

Revoke regulation 14(1)(a).

12 Regulation 15 amended (Container material)

(1) In regulation 15, after "*European Pharmacopoeia*", insert ", the *United States Pharmacopeia* Chapters <660>, <661.1>, and <661.2>, or the *EMA Guideline on Plastic Immediate Packaging Materials*".

(2) In regulation 15, insert as subclause (2):

(2) However, subclause (1) does not apply to cannabis-based ingredients that are not being supplied.

13 Regulation 17 amended (Restrictions on decontamination)

Revoke regulation 17(a).

14 Regulation 18 replaced (Pesticides)

Replace regulation 18 with:

18 Pesticides

(1) This regulation applies to the use of pesticides on—

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

(b) an ingredient of a medicinal cannabis product:

(c) a dried cannabis product.

(2) Pesticide active ingredients specified or described in the following table may be used:

Active ingredients permitted	Further details
Fatty acids of 8 carbons or more in their chains, and their salts	Includes ammonium salt of fatty acid (fatty acids, C8-18 and C18 unsaturated, ammonium salt) and potassium salts of fatty acids (fatty acids, C8-18 and C18-unsaturated, potassium salts)
Active ingredients that are foods or permitted food additives	Except where the food is deemed a novel food as defined in section 1.1.2 of the Australia New Zealand Food Standards Code and either the composition of the active ingredient deviates from the physicochemical range or has undergone

Active ingredients permitted	Further details
	refining to a level exceeding that accepted as common for the food
Sulphur	
Hydrogen peroxide	
Products containing paraffin oils or mineral oils as the active ingredient	Must be a product that— (a) is approved by an overseas regulatory authority for use on medicinal cannabis; or (b) has CAS 8042-47-5, CAS 72623-86-0, or CAS 97862-82-3 as the active ingredient
Extract of *Reynoutria sachalinensis*	
GS-omega/kappa-Hxtx-Hv1a	
Microbial active ingredients	*Akanthomyces lecanni* *Aureobasidium pullulans* (strains DSM 14940, DSM 14941, and YBCA5) *Autographa californica nucleopolyhedrovirus* fv11 (*baculovirus: nucleopolyhedrovirus Autographa californica* (ACMNPV)) *Bacillus amyloliquefaciens* (strains MBI600, D747, F272, QST 713, and BS1b) *Bacillus subtilis* (strain ATCC 6051, GBO3 and KTSB) *Bacillus thuringiensis* subspecies *kurstaki*, and *aizawai* *Beauveria bassiana* *Clonostachys rosea* (strain J1446) *Helicoverpa armigera nucleopolyhedrovirus* BV-0003 *Metarhizium brunneum* (strain F52) *Streptomyces lydicus* (strain WYEC 108, and ATTC55445) *Trichoderma asperellum* (strains T34 and ICC 012) *Trichoderma gamsii* strain ICC 080 *Trichoderma harzianum rifai* strain KRL-AG2 (also known as strain T-22) *Trichoderma virens* (strain G-41, LU753) *Ulocladium oudemansii* (strain U3)

(3) The following pesticide active ingredients may be used if, in its intended end use, the cannabis-based ingredient or medicinal cannabis product is not to be administered via inhalation:

(a) agricultural chemicals listed or described in Schedule 2 of the Food Notice: Maximum Residue Levels for Agricultural Compounds issued under section 405 of the Food Act 2014 for the purposes of section 383(8)(a) of that Act, and used in accordance with the Food Regulations 2015 and in accordance with use conditions:

(b) products that are registered under the Agricultural Compounds and Veterinary Medicines Act 1997 with a label claim for use on a food crop if—

(i) no registration condition prohibits off-label use of the product; and

(ii) residues of pesticide active ingredients meet the calculated maximum limit as outlined in Chapter 2.8.13 of the *European Pharmacopoeia*:

(c) for imported cannabis-based ingredients or medicinal cannabis products, pesticide active ingredients in products that are registered under the Agricultural Compound and Veterinary Medicines Act 1997 may be used if—

(i) evidence is provided to the Director-General that demonstrates that the product is authorised for use on food crops by the relevant overseas authority; and

(ii) residues of pesticide active ingredients meet the calculated maximum limit as outlined in Chapter 2.8.13 of the *European Pharmacopoeia*.

(4) Alternative pesticide active ingredients may be accepted if—

(a) evidence is provided to the Director-General that demonstrates that the pesticide product has been registered by the relevant overseas authority for use on medicinal cannabis; and

(b) the product has been used in accordance with use conditions; and

(c) a suitable safety assessment has been completed by the relevant overseas authority.

(5) The use of pesticides must comply with all other relevant legislative requirements, including the Agricultural Compounds and Veterinary Medicines Act 1997 and the Hazardous Substances and New Organisms Act 1996.

15 Regulation 19 amended (Labelling)

After regulation 19(c), insert:

(d) a controlled drug classification statement takes precedence over a classification statement required under the Medicines Regulations 1984:

(e) if a medicinal cannabis product is a controlled drug, compliance with regulation 25(1)(a) of the Misuse of Drugs Regulations 1977 is required rather than compliance with regulation 13(1)(f) of the Medicines Regulations 1984.

16 Regulation 21 amended (Excipients and other ingredients)

Replace regulation 21(1) and (2) with:

(1) A dosage product must not contain an excipient for which there is no monograph in the *British Pharmacopoeia*, the *European Pharmacopoeia*, or the *United States Pharmacopeia*.

(2) The dosage product must comply with the requirements of a monograph in one of those pharmacopoeia for each excipient that it contains.

17 Regulation 22 amended (Types of licensed activity)

Replace regulation 22(b) with:

(b) a seed supply activity:

18 Regulation 23 amended (Cultivation activity)

Replace regulation 23(2)(d) to (f) with:

(d) to produce starting material 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, seed supply, research, possession for manufacture, or supply activity:

(f) to export starting material, produced under paragraph (d) as fresh or dried cannabis, for testing, analysis, or research for non-therapeutic purposes under a licence to export controlled drugs issued under the Misuse of Drugs Regulations 1977, limited to the quantities specified in the medicinal cannabis licence:

(g) to export cannabis seed, cuttings, rootstock, tissue, and tissue culture, for the purpose of propagation, under a licence to export controlled drugs issued under the Misuse of Drugs Regulations 1977:

(h) to possess cannabis for the purposes of carrying out any of the activities described in paragraphs (a) to (g).

19 Regulation 24 replaced (Nursery activity)

Replace regulation 24 with:

24 Seed supply activity

(1) A **seed 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 cannabis seed for cultivation for therapeutic use.

(2) The activities are—

(a) to procure cannabis seed—

(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 seed 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 export cannabis seed under a licence to export controlled drugs issued under the Misuse of Drugs Regulations 1977:

(d) to possess cannabis seed for the purposes of carrying out any of the activities described in paragraphs (a) to (c).

20 Regulation 25 amended (Research activity)

(1) Revoke regulation 25(2)(b).

(2) Replace regulation 25(2)(d) with:

(d) to possess any starting material, cannabis-based ingredient, or medicinal cannabis product for the purposes of carrying out any of the activities described in paragraphs (a) and (c).

21 Regulation 26 amended (Possession for manufacture activity)

(1) Replace regulation 26(1)(b) with:

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

(2) In regulation 26(2)(b)(iii), replace "any cannabis" with "any starting material, cannabis-based ingredient,".

(3) Replace regulation 26(2)(c) with:

(c) to manufacture initial extracts for use as starting material:

(d) to possess any starting material, cannabis-based ingredient, or medicinal cannabis product for the purposes of carrying out any of the activities described in paragraphs (a) to (c).

22 Regulation 27 replaced (Supply activity)

Replace regulation 27 with:

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; or

(ii) any 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 one 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 by export from New Zealand under a licence to export controlled drugs issued under the Misuse of Drugs Regulations 1977:

(d) to supply any cannabis-based ingredient or medicinal cannabis product that has been verified to meet the minimum quality standard by export from New Zealand under a licence to export controlled drugs issued under the Misuse of Drugs Regulations 1977:

(e) to supply cannabis-based ingredients and medicinal cannabis products that have not been tested to the requirements of the minimum quality standard, by export from New Zealand under a licence to export controlled drugs issued under the Misuse of Drugs Regulations 1977, if the items have been manufactured in compliance with GMP by a GMP-certified manufacturer:

(f) to supply cannabis-based ingredients and medicinal cannabis products that have not been tested to the requirements of the minimum quality standard, for testing, analysis, or research for non-therapeutic purposes, by export from New Zealand under a licence to export controlled drugs issued under the Misuse of Drugs Regulations 1977, limited to the quantities specified on the medicinal cannabis licence:

(g) to possess any starting material, cannabis-based ingredient, or medicinal cannabis product for the purposes of carrying out any of the activities described in paragraphs (a) to (f).

23 Regulation 32 amended (Application for licence)

(1) In regulation 32(3)(c), after "operating procedures", insert "or similar procedures".

(2) Replace regulation 32(3)(f) with:

(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 seed supply, 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 seed supply, possession for manufacture, or supply activity; or (b) has an agreement to supply cannabis to the holder of a licence for a cultivation, seed supply, possession for manufacture, or supply activity, or a plan to manage the cannabis securely until an agreement is made.
Research activity	A research trial approval issued by the Director-General, or evidence that a research trial approval is not required.
Possession for manufacture activity	Details of the activities described by regulation 26(2)(b) and (c) that are to be carried out.
Supply activity	Details of each cannabis-based ingredient or medicinal cannabis product to be supplied. For each cannabis-based ingredient or medicinal cannabis product to be specified in the licence that is to be supplied in New Zealand, evidence (including the results of all required testing) to satisfy the Director-General that representative samples from each of 3 batches of the ingredient or product comply with the minimum quality standard. Each batch sampled must be at least 10% of the full production scale. 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; and (iv) must be unique and distinct from the trade name of any cannabis-based ingredient or medicinal cannabis product that is intended for export only: (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:

Type of licensed activity	Additional information	
	(g)	evidence that the facilities for its manufacture (including packing and testing) are GMP-certified or ISO/IEC 17025:2017 accredited for testing (as defined by regulation 9):
	(h)	a detailed recall plan:
	(i)	details of the recommended method of administering, applying, or using it.

24 Regulation 34 amended (Fees for applications)

In regulation 34(2), table, replace "Nursery activity" with "Seed supply activity".

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

Revoke regulation 35(1)(c).

26 Regulation 36 replaced (Other fees: licence for supply activity)

Replace regulation 36 with:

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 cannabis-based ingredient:

(b) 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 ingredient or product, under regulation 40(5):

What is assessed	Fee for assessment
Cannabis-based ingredient	$6,700
Dried product	$6,700
Dosage product	$6,700

(3) The fee for assessment of a dosage product does not cover the assessment of its cannabis-based ingredients.

27 Regulation 40 amended (Decision to issue licence or to decline licence)

Replace regulation 40(5) with:

(5) The Director-General must not approve a cannabis-based ingredient or medicinal cannabis product to be specified in a licence for supply in New Zealand unless the Director-General—

(a) has assessed the evidence in the application, of which—

(i) there must be a representative sample from each of 3 batches of the ingredient or product (3 representative samples in total); and

(ii) each batch must be at least 10% of the full production scale; and

(b) is satisfied that each of the 3 representative samples complies with the minimum quality standard.

(6) The Director-General may approve a cannabis-based ingredient or medicinal cannabis product to be specified in a licence for export for a non-therapeutic purpose without requiring compliance with the minimum quality standard or in circumstances described in regulation 6(2)(g).

28 Regulation 43 amended (Issue and form of licence)

Replace regulation 43(1)(f) with:

(f) for a licence for a supply activity, each cannabis-based ingredient or medicinal cannabis product to which the licence applies, including whether the ingredients or products are for export only:

29 Regulation 47 amended (Certain changes not to be made without approval of Director-General)

(1) In regulation 47(1)(e), replace "a consignment of starting material for export, or any cannabis-based ingredient or medicinal cannabis product, specified in the licence" with "any cannabis-based ingredient or medicinal cannabis product, specified in the licence".

(2) In regulation 47(8)(b)(i), replace "consignment, ingredient," with "ingredient".

30 Regulation 54 replaced (Cannabis, ingredients, and products to be dealt with responsibly)

Replace regulation 54 with:

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

Every licence holder and every responsible person must deal with any cannabis, starting material, 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.

31 Regulation 56 replaced (Security of cannabis, ingredients, and products)

Replace regulation 56 with:

56 Security of cannabis, starting material, ingredients, and products

(1) A licence holder must ensure that all cannabis, starting material, 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 cannabis does not spread outside the locations to which the licence applies.

32 Regulation 57 amended (Police and Director-General to be notified of unauthorised removal, loss, or activity)

In regulation 57(1)(b), after "any cannabis,", insert "starting material,".

33 Regulation 58 amended (Locations must be available for inspection)

In regulation 58(3)(c), after "samples of cannabis,", insert "starting material,".

34 Regulation 59 amended (Samples taken for testing)

Replace regulation 59(1) with:

(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) any starting material:

(c) a cannabis-based ingredient:

(d) a medicinal cannabis product:

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

35 Regulation 60 replaced (Destruction of cannabis, ingredients, and products)

Replace regulation 60 with:

60 Destruction of cannabis, starting material, 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) any starting material:

(c) a cannabis-based ingredient:

(d) a medicinal cannabis product.

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

36 Regulation 62 amended (Records for cultivation activity)

Replace regulation 62(1)(d) with:

(d) supplies within New Zealand to—

(i) the holder of a licence, including a licence specified under regulation 23(2)(e); or

(ii) a person who is authorised to receive it by any enactment; or

37 Regulation 63 replaced (Records for nursery activity)

Replace regulation 63 with:

63 Records for seed supply activity

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

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

(b) the amounts of cannabis seed that the holder possesses under the licence; and

(c) the amounts of cannabis seed that the holder destroys or disposes of.

38 Regulation 64 amended (Records for research activity)

After regulation 64(b), insert:

(c) the amounts of starting material, cannabis-based ingredients, and medicinal cannabis products that the holder destroys or disposes of.

39 Regulation 65 amended (Records for possession for manufacture activity)

After regulation 65(b), insert:

(c) the amounts of starting material and cannabis-based ingredients and medicinal cannabis products that the holder destroys or disposes of.

40 Regulation 66 amended (Records for supply activity)

After regulation 66(b), insert:

(c) the amounts of starting material, cannabis-based ingredients, and medicinal cannabis products that the holder destroys or disposes of.

41 Regulation 67 amended (Records of stocktake for any activity)

(1) Replace regulation 67(1) with:

(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) any starting material:

(c) a cannabis-based ingredient:

(d) a medicinal cannabis product.

(2) Replace regulation 67(3) with:

(3) The records and account of the stocktake must state the amount of material held on 31 December in each year and be reported to the Director-General by 31 January in the next year.

42 Regulation 79 amended (Offence to supply to unauthorised persons)

(1) In regulation 79(a), after "cannabis,", insert "starting material,".

(2) In regulation 79(b), after "cannabis,", insert "starting material,".

43 Schedule 1 amended

In Schedule 1,—

(a) insert the Part set out in the Schedule of these regulations as the last Part; and

(b) make all necessary consequential amendments.

Part 2
Amendments to other regulations

Amendments to Misuse of Drugs Regulations 1977

44 Principal regulations

Regulations 45 to 47 amend the Misuse of Drugs Regulations 1977.

45 Regulation 3B amended (Application to industrial hemp)

After regulation 3B(2), insert:

(3) Despite subclause (1), a licence may, in accordance with regulation 9, be issued to possess industrial hemp.

46 Regulation 3C amended (Application to medicinal cannabis products)

In regulation 3C, delete ", or to possess controlled drugs,".

47 Regulation 28 amended (Custody of controlled drugs)

(1) In regulation 28(1), replace "subclause (4)" with "subclauses (4) to (4AAA)".

(2) After regulation 28(4)(f), insert:

(4AAA) This regulation does not apply to any holder of a medicinal cannabis licence when carrying out any activity specified on their licence if the Director-General is satisfied that the location of the activity has adequate security arrangements in accordance with the Misuse of Drugs (Medicinal Cannabis) Regulations 2019.

Amendments to Medicines Regulations 1984

48 Principal regulations

Regulations 49 to 52 amend the Medicines Regulations 1984.

49 Regulation 4A amended (Standard for CBD products)

After regulation 4A(4), insert:

(4A) The minimum quality standard does not apply to a CBD product if—

(a) it is carried by a traveller when they enter or leave New Zealand; or

(b) it is supplied for a clinical trial under section 30 of the Medicines Act 1981; or

(c) it is used for veterinary medicine; or

(d) it is used for research, testing, analysis, or product development that is not for, or does not relate to, a therapeutic purpose; or

(e) its ingredients are not derived from a cannabis plant; or

(f) it has consent for distribution under the Medicines Act 1981.

50 New regulation 38A inserted (Prohibition relating to personal importation of CBD products)

After regulation 38, insert:

38A Prohibition relating to personal importation of CBD products

A person must not import into New Zealand any CBD product (regardless of whether the ingredients are made from cannabis) for their personal use by any method of import (such as overseas courier or post), except by physically carrying it on the person when entering New Zealand.

51 Regulation 45B amended (Licences that relate to CBD products)

Replace regulation 45B(2) with:

(2) The licence must not be issued, or amended, to expressly authorise its application to the supply of a CBD product unless—

(a) the product has been assessed as complying with the minimum quality standard under the Misuse of Drugs (Medicinal Cannabis) Regulations 2019; or

(b) the product is being manufactured and supplied for export only and the exporter provides evidence to the Director-General that the ingredients and products are accepted by the importing country; or

(c) the product has consent for distribution under the Medicines Act 1981; or

(d) the product is not intended for therapeutic use in a human; or

(e) the active ingredients and cannabinoids in the product are not made from cannabis; or

(f) the product is being imported and supplied by a pharmacist under regulation 4A(2); or

(g) the product is being supplied for a clinical trial under section 30 of the Medicines Act 1981.

52 Regulation 64 amended (Offences)

In regulation 64(1)(c), after "regulations", insert " 38A,".

Schedule
New Part 2 inserted into Schedule 1

r 43

Part 2
Provisions relating to Misuse of Drugs (Medicinal Cannabis) Amendment Regulations 2024

4 Interpretation

In this Part, **amendment regulations** means the Misuse of Drugs (Medicinal Cannabis) Amendment Regulations 2024.

5 Licences and activities affected by amendment regulations

(1) The provisions of this clause apply on and after the commencement of the amendment regulations to—

(a) licences described in this clause and in force immediately before the commencement; and

(b) activities described in this clause.

(2) A licence with cultivation activity allows the export of cannabis seed, cuttings, rootstock, and tissue for propagation.

(3) A licence with nursery activity allows the export of seed.

(4) A licence with nursery activity continues in force if an application for seed supply is made in accordance with regulation 45, as if it were a renewal of the licence.

(5) A possession for manufacture activity allows—

(a) the testing of any starting material, cannabis-based ingredient, or medicinal cannabis product:

(b) the manufacture of initial extracts for use as starting material.

(6) A licence with supply activity allows the export of starting material without meeting the minimum quality standard.

(7) For the purpose of exporting, testing, manufacturing, or doing anything else allowed by this clause, a person may possess, procure, and supply the thing to be exported, tested, manufactured, or otherwise dealt with.

Rachel Hayward,
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 (the **amendment regulations**), which come into force on 5 July 2024,—

- principally amend the Misuse of Drugs (Medicinal Cannabis) Regulations 2019 (the **principal regulations**):
- make related amendments to the Misuse of Drugs Regulations 1977:
- make related amendments to the Medicines Regulations 1984.

The purpose of the amendment regulations is—

- to broaden the medicinal cannabis category definitions so that the definitions of cannabis-based ingredient and starting material are less restrictive and do not limit innovation:
- to ensure that the current export settings for medicinal cannabis are not a barrier for New Zealand companies:
- to assist New Zealand researchers to use cannabis plant material grown or sourced from the Medicinal Cannabis Scheme (the **Scheme**) or industrial hemp framework for research outside the scope of their respective regimes:
- to improve the minimum quality standard (which is imposed by Part 1 of the principal regulations) and the operations of the Scheme.

Cannabis-based ingredients

The definition of cannabis-based ingredient in the principal regulations unintentionally prevented the use of dried cannabis as an ingredient for dosage forms such as oral capsules or tablets. The amendment regulations broaden the range of dosage forms that can be made available under the Scheme.

Starting material

Starting material describes raw material that is used in the manufacturing process and is not intended for direct patient use. The amendment regulations provide that initial extracts from cannabis plant (as starting material) are not subject to the minimum quality standard. This exemption will allow manufacturers to use a greater variety of raw material in their manufacturing process.

Changes to minimum quality standard

The amendment regulations provide that the minimum quality standard applies only to—

- medicinal cannabis intended for therapeutic end use:
- cannabidiol (**CBD**) products that are intended for human therapeutic use and whose active ingredients are derived from cannabis plant (so that CBD prod-

ucts such as veterinary medicines not derived from cannabis are exempted from the minimum quality standard).

Export settings for medicinal cannabis

The amendment regulations—

- enable a person who holds a licence for a cultivation activity to export starting material, as fresh or dried cannabis only, for the purposes of testing, analysis, or research without meeting the minimum quality standard:
- enable a person who holds a licence for a supply activity to export starting material, cannabis-based ingredients, and medicinal cannabis products for the purposes of testing, analysis, further manufacturing, or research without meeting the minimum quality standard:
- enable a person who holds both a licence to export controlled drugs under the Misuse of Drugs Regulations 1977 and a medicinal cannabis licence with seed supply activity to export medicinal cannabis seed:
- enable a person who holds both a licence to export controlled drugs under the Misuse of Drugs Regulations 1977 and a medicinal cannabis licence with a cultivation activity to export medicinal cannabis seed, cuttings, rootstock, tissue for propagation, and tissue culture:
- remove the requirement for consignments of starting material to meet the minimum quality standard before export:
- remove the requirement for cannabis-based ingredients and medicinal cannabis products to meet the minimum quality standard before export if they are manufactured in accordance with good manufacturing practice:

Changes to licensing requirements

The amendment regulations make technical changes to improve the operation of licensing requirements, including for CBD products, by—

- clarifying the intent of some requirements and the purpose of research activity:
- permitting testing of starting material and cannabis-based ingredients under a possession for manufacture activity.

Nursery activity becomes seed supply activity

The amendment regulations replace the term nursery activity with seed supply activity, to better reflect the nature of the activity.

Fees

The amendment regulations reduce the fee for dosage product assessment from $13,400 (excluding GST) to $6,700 (excluding GST). This better reflects that the assessment is of the final dosage product only.

Scientific research with cannabis in New Zealand

The amendment regulations—

- enable a licence to possess controlled drugs under the Misuse of Drugs Regulations 1977 to be issued for research activities for non-therapeutic purposes involving industrial hemp if all other requirements are met:
- enable a licence to possess controlled drugs to be issued for research activities for non-therapeutic purposes using starting material, cannabis-based ingredients, and medicinal cannabis products if all other requirements are met:
- enable the holder of a licence to possess controlled drugs to obtain starting material, cannabis-based ingredients, and medicinal cannabis products from medicinal cannabis licence holders for analytical and research purposes outside the scope of the Scheme:
- remove the requirement for imports of cannabis-based ingredients, medicinal cannabis products, and CBD products for research and testing purposes to meet the minimum quality standard.

Transition

Savings and transitional provisions are included for existing licences and related activities affected by the amendment regulations.

Amendments to Misuse of Drugs Regulations 1977

Regulation 3B of the Misuse of Drugs Regulations 1977 is amended to provide for licences that authorise persons to possess industrial hemp.

Regulation 3C of those regulations is amended to remove the prohibition on issuing licences to possess any starting material, cannabis-based ingredient, or medicinal cannabis product.

Regulation 28 of those regulations is amended to exempt all holders of medicinal cannabis licences (for any activity) from the requirements in that regulation about the custody of controlled drugs.

Amendments to Medicines Regulations 1984

Regulation 4A of the Medicines Regulations 1984 is amended to provide that the minimum quality standard does not apply to a CBD product in the circumstances set out in that provision.

New regulation 38A is inserted to prohibit persons from importing into New Zealand by overseas courier or mail any CBD products (regardless of whether the ingredients are cannabis-derived) for their personal use.

Regulation 45B is amended to prevent a licence from applying to the supply of a CBD product except in the circumstances set out in that provision.

Issued under the authority of the Legislation Act 2019.
Date of notification in *Gazette*: 4 July 2024.
These regulations are administered by the Ministry of Health.

Wellington, New Zealand:
Published under the authority of the New Zealand Government—2024