Psychoactive Substances Amendment Bill

Government Bill

Explanatory note

General policy statement

The Psychoactive Substances Amendment Bill gives effect to the Government's decision to introduce legislation ending interim product approvals under the Psychoactive Substances Act 2013 (the **principal Act**).

The principal Act addressed the Government's concerns about the availability of potentially harmful psychoactive substances with little or no control over their ingredients, potency, place of sale, or purchase age.

The specific objectives of the Bill are—

- to revoke all interim product approvals:
- to revoke all interim retail and wholesale licences:
- to require the recall and disposal of all products for which interim product approval has been revoked:
- to suspend, until regulations come into effect, the requirement that Psychoactive Substances Regulatory Authority must consider product approvals:
- to provide that the results of trials that involve the use of animals cannot be used in the assessment of a psychoactive product. However, results of trials undertaken overseas can be used

in the assessment of psychoactive products if the trial shows that a psychoactive product would pose more than a low risk of harm to individuals using the product:

- to provide that no compensation is payable by the Crown for any loss or damages as a result of the amendments.

Departmental disclosure statement

The Ministry of Health is required to prepare a disclosure statement to assist with the scrutiny of this Bill. It provides access to information about the policy development of the Bill and identifies any significant or unusual legislative features of the Bill.

A copy of the statement can be found at http://legislation.govt.nz/disclosure.aspx?type=bill&subtype=government&year=2014&no=206&.

Regulatory impact statement

The Ministry of Health produced a regulatory impact statement on 2 May 2014 to help inform the main policy decisions taken by the Government relating to the contents of this Bill.

A copy of this regulatory impact statement can be found at—

- http://www.health.govt.nz/about-ministry/legislation-and-regulation/regulatory-impact-statements
- http://www.treasury.govt.nz/publications/informationreleases/ris

Clause by clause analysis

Clause 1 is the Title clause.

Clause 2 is the commencement clause. It provides that the Bill comes into force on the day after the date on which it receives the Royal assent.

Clause 3 provides that the Bill amends the Psychoactive Substances Act 2013 (the **principal Act**).

Clause 4 amends section 4, which sets out principles that are to be taken into account in the performance of functions or duties or the exercise of powers under the principal Act. *Clause 4* adds, as a principle, that animals must not be used in trials for the purposes of assessing whether a psychoactive product should be approved.

Clause 5 amends section 6, which sets out an overview of the principal Act, by repealing the subparagraph that refers to the sale of psychoactive products on an interim basis.

Clause 6 replaces section 12, which currently restricts the type of trials involving animals to which the Psychoactive Substances Expert Advisory Committee (the **advisory committee**) may have regard in evaluating psychoactive products and giving advice on the products to the Psychoactive Substances Regulatory Authority (the **Authority**).

New section 12(1) provides that the advisory committee must not have regard to the results of any trial that involves the use of an animal.

New section 12(2) provides that the advisory committee may have regard to the results of a trial undertaken overseas if the committee considers that the trial shows that a psychoactive product would pose more than a low risk of harm to individuals using the product. This is to ensure that, if information from trials undertaken overseas involving animals is available and the information shows a product would pose more than a low risk of harm to individuals, the advisory committee can use that information to protect the health of individuals by recommending that a product not be approved.

Section 33(3) of the principal Act provides that applications for approval of psychoactive products must not include particulars, information, documents, or other material that the advisory committee must not have regard to under *new section 12*.

The effect of section 33(3), after the commencement of *new section 12*, is that the results of any trial involving animals must not form part of the information provided to the Authority in support of an application for approval of a psychoactive product. The exception is information from a trial undertaken overseas where the trial shows that a product poses more than a low risk of harm to individuals.

Clause 7 amends section 37 of the principal Act to impose a similar restriction on the information that the Authority may have regard to in deciding whether to approve a product. *New subsection (3)* provides that the Authority must not, in deciding whether to approve a product, have regard to any particulars, information, documents, or other material that the advisory committee must not have regard to under *new section 12*.

The effect of *new section 37(3)* is that the Authority must not have regard to the results of any trial involving animals when deciding whether or not to approve a psychoactive product. The exception is information from a trial undertaken overseas where the trial shows that a product poses more than a low risk of harm to individuals.

In summary, the principal Act, once amended, will effectively provide that a trial involving animals cannot be used to support an application for approval of a psychoactive product. If a person intended to carry out such a trial in New Zealand regardless, it is expected that the trial would require approval under the Animal Welfare Act 1999. In the absence of such approval, carrying out the trial would be in breach of that Act and the penalties provided in that Act would apply.

Clause 7 also amends section 37 to provide, for the avoidance of doubt, that if the Authority is unable to satisfy itself that a psychoactive product poses no more than a low risk of harm, the Authority must refuse to approve the product.

Clause 8 provides that Schedule 1 of the principal Act, which deals with interim approval of products and the issue of interim licences, is amended as set out in the *Schedule* of the Bill. The amendments to Schedule 1 are as follows:

- some references to interim approvals of psychoactive products, and to such products approved on an interim basis, are removed:
- clauses 3 to 6, which provided for applications for and grants and duration of interim approvals, are repealed:
- clause 8 is amended to clarify that the provisions of subparts 1 and 3 of Part 2 of the principal Act apply to interim licences granted under Schedule 1:
- *new clause 11* revokes every interim approval of a psychoactive product:
- *new clause 12* provides that the Authority must, before the close of the day after the date of the commencement of that clause, issue a recall order under section 88 in respect of the products:
- *new clause 13* revokes every interim licence to sell psychoactive products with interim approval:
- *new clause 14* confirms that interim licences to sell psychoactive products granted interim approval (by retail or wholesale)

and interim approvals of products may not be granted, regardless of the outcome of any extant appeal under subpart 3 of Part 2:

- *new clause 15* preserves, until the close of the 14th day after the date of the commencement of the Bill and for the purpose of the recall under *clause 12*, the powers of entry and search under section 78 in relation to the holders of interim licences for the sale of psychoactive products with interim approval (despite the revocation of those interim licences under *clause 13*):
- *new clauses 16 and 17* impose a moratorium on the Authority processing—
  - applications for licences under section 13 until regulations relating to licence applications come into force:
  - applications for approvals of psychoactive products under section 33 until regulations relating to applications for product approval come into force:
- *new clause 18* provides that no compensation or damages are payable by the Crown for any loss or damage arising from the enactment of the Bill.

Hon Peter Dunne

Psychoactive Substances Amendment Bill

Government Bill

Contents

The Parliament of New Zealand enacts as follows:

1 Title

This Act is the Psychoactive Substances Amendment Act **2014**.

2 Commencement

This Act comes into force on the day after the date on which it receives the Royal assent.

3 Principal Act

This Act amends the Psychoactive Substances Act 2013 (the **principal Act**).

4 Section 4 amended (Principles)

After section 4(e), insert:

"(f) animals must not be used in trials for the purposes of assessing whether a psychoactive product should be approved."

5 Section 6 amended (Overview)

Repeal section 6(1)(c)(ix).

6 Section 12 replaced (Duty of advisory committee relating to use of animals when evaluating psychoactive products)

Replace section 12 with:

"**12 Advisory committee not to have regard to results of trials involving animals**

"(1) In performing the function set out in section 11(2)(a), the advisory committee must not have regard to the results of a trial that involves the use of an animal.

"(2) However, the advisory committee may have regard to the results of a trial undertaken overseas that involves the use of an animal if the advisory committee considers that the trial shows that the psychoactive product would pose more than a low risk of harm to individuals using the product."

7 Section 37 amended (Grounds for approving product)

In section 37, insert as subsections (2) and (3):

"(2) To avoid doubt, if the Authority is unable to satisfy itself of the matter in subsection (1)(b), the Authority must refuse to approve a psychoactive product as an approved product.

"(3) In deciding whether or not to approve a psychoactive product as an approved product, the Authority must not have regard

to any particulars, information, documents, or other material relating to any trial that the advisory committee must not have regard to under **section 12**."

8 Schedule 1 amended

Amend Schedule 1 as set out in the **Schedule** of this Act.

Schedule s 8

Amendments to Schedule 1 of principal Act

Clause 1

In clause 1, replace the definition of **full application** with:

> "**full application** means, in respect of an activity to which an interim licence relates, an application made under section 13 by the person who was granted the interim licence".

In clause 1, replace the definition of **interim approval** with:

> "**interim approval** means an approval of a psychoactive product granted by the Authority under clause 4 before that clause was repealed by **section 8** of the **Psychoactive Substances Amendment Act 2014**".

Clause 2

In clause 2(1), replace "This schedule applies" with "Clauses 1 to 15 of this schedule apply".

Replace clause 2(2) with:

"(2) A psychoactive substance to which this schedule applies may continue to be imported, manufactured, researched, or sold after the commencement of this Act, but only by a person who holds an interim licence and while that licence remains in force."

Cross-heading above clause 3

Repeal the cross-heading above clause 3.

Clauses 3 to 6

Repeal clauses 3 to 6.

Clause 7

Repeal clause 7(1)(e) and (f).

Clause 8

Replace clause 8 with:

"**8 Application of subparts 1 and 3 of Part 2 to interim licence**

Subparts 1 and 3 of Part 2 (except sections 13 and 16(1)(a)) apply, with any necessary modifications,—

"(a) to an application for an interim licence as if it were an application made under section 13; and

"(b) to an interim licence granted in accordance with **paragraph (a)**."

Clause 10

In the heading to clause 10, delete "**interim approval or**".

In clause 10,—

(a) delete "an application for interim approval or":

(b) replace "approval or licence" with "licence".

In clause 10, in the table, replace the heading to the first column with "**Interim licence**".

In clause 10, in the table, repeal the items relating to—

(a) interim approval of psychoactive product:

(b) interim licence to sell psychoactive products granted interim approval by retail:

(c) interim licence to sell psychoactive products granted interim approval by wholesale.

New cross-headings and clauses 11 to 18

After clause 10, insert:

"*Interim approvals of psychoactive products and interim licences to sell psychoactive products granted interim approval revoked*

"**11 Revocation of interim approvals of psychoactive products**

Every interim approval granted in respect of a psychoactive product under clause 4 (before that clause was repealed by **section 8** of the **Psychoactive Substances Amendment Act 2014**) is revoked.

"**12 Recall of interim approved products**

"(1) The Authority must, before the close of the day after the date of the commencement of this clause, issue a recall order under

New cross-headings and clauses 11 to 18—*continued*

section 88 for every psychoactive product described in **clause 11** (the **product**).

"(2) The Authority must—

"(a) display the date of the recall order prominently on the recall order; and

"(b) notify the recall order on an Internet site maintained by or on behalf of the Authority.

"(3) For the purposes of section 88(2), the recall order is deemed to have been received by every importer, manufacturer, wholesaler, or retailer of the product on the close of the day after the date displayed on the recall order.

"(4) The recall order may—

"(a) require every importer, manufacturer, wholesaler, and retailer (or any combination of them) to—

"(i) provide information to the Authority in relation to the amount and type of the product in their possession:

"(ii) dispose of or destroy, or arrange for the disposal (including by return to a manufacturer or an importer) or the destruction of, the product in their possession:

"(iii) provide information to the Authority on the disposal of or destruction or arrangements for the disposal or destruction of the product in their possession:

"(b) specify locations where the product can be delivered for disposal or destruction:

"(c) specify a time limit for compliance with the recall order:

"(d) specify any ancillary or incidental requirement.

"(5) For the avoidance of doubt, section 88(2) and (3) applies to the recall order issued in accordance with this clause.

"(6) It is a defence to a charge of an offence specified in **subclause (7)** that the action or omission that constitutes the offence was done—

"(a) in good faith in the course of complying with the recall order; and

New cross-headings and clauses 11 to 18—*continued*

"(b) within 14 days after the date of the commencement of this clause.

"(7) The offences to which the defence in **subclause (6)** may apply are—

"(a) an offence under section 28:

"(b) an offence under section 70:

"(c) an offence under section 71.

"**13 Revocation of interim licences to sell psychoactive products granted interim approval**

"(1) Every interim licence granted under clause 7(1)(e) and (f) (before those paragraphs were repealed by **section 8** of the **Psychoactive Substances Amendment Act 2014**) is revoked.

"(2) Despite the revocation of interim licences under **subclause (1)**, a wholesaler or retailer who held an interim licence immediately before this clause came into force—

"(a) must comply with the recall order issued in accordance with **clause 12** as if the wholesaler or retailer continued to hold the licence; and

"(b) is, for the purposes of section 88, to be treated as if it continued to hold the licence until the close of the 14th day after the commencement of this clause.

"**14 Appeals under subpart 3 of Part 2**

For the avoidance of doubt, and regardless of the outcome of any appeal under subpart 3 of Part 2, the following may not be granted after the commencement of the **Psychoactive Substances Amendment Act 2014**:

"(a) an interim licence to sell psychoactive products granted interim approval by retail:

"(b) an interim licence to sell psychoactive products granted interim approval by wholesale:

"(c) an interim approval.

New cross-headings and clauses 11 to 18—*continued*

"*Enforcement powers*

"**15 Power to enter and search retail premises**

"(1) This clause applies in relation to the retail premises of every holder of an interim licence granted under clause 7(1)(e) (before that paragraph was repealed by **section 8** of the **Psychoactive Substances Amendment Act 2014**) and revoked by **clause 13**.

"(2) An enforcement officer or a constable may, for the purpose of ensuring or enforcing compliance with the recall order issued in accordance with **clause 12**, exercise any powers under section 78 in relation to those retail premises until the close of the 14th day after the date of the commencement of this clause as if the interim licence concerned had not been revoked.

"(3) Section 78, as modified by **subclause (2)**, applies in relation to those retail premises.

"*Moratorium on processing applications under section 13 or 33 until regulations in force*

"**16 Moratorium on processing applications for licences under section 13**

"(1) The Authority must not process any application for a licence of a kind described in section 13(1)(a) to (d) (whether the application is made before or after the commencement of this clause) until regulations under section 95 prescribing the fees or charges for applications for licences of that kind come into force.

"(2) The Authority must not process any application for a licence of a kind described in section 13(1)(e) or (f) (whether the application is made before or after the commencement of this clause) until both of the following have come into force:

"(a) regulations under section 95 prescribing the fees or charges for applications for licences of that kind; and

"(b) regulations under section 101(1)(a) prescribing the particulars, information, documents, samples, or other material that must accompany or be contained in applications for licences of that kind.

New cross-headings and clauses 11 to 18—*continued*

"**17 Moratorium on processing applications for approval of psychoactive product under section 33**

The Authority must not process any application for approval of a psychoactive product under section 33 (whether the application is made before or after the commencement of this clause) until both of the following have come into force:

"(a) regulations under section 95 prescribing the fees or charges for applications for approval of psychoactive products; and

"(b) regulations under section 101(1)(a) prescribing the particulars, information, documents, samples, or other material that must accompany or be contained in applications for approval of psychoactive products.

"*No compensation or damages*

"**18 No compensation or damages**

No compensation or damages are payable by the Crown for any loss or damage arising from the enactment of the **Psychoactive Substances Amendment Act 2014**."

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