Reprint
as at 21 April 2016

Psychoactive Substances Regulations 2014

(LI 2014/243)

Rt Hon Dame Sian Elias, Administrator of the Government

Order in Council

At Wellington this 28th day of July 2014

Present:
Her Excellency the Administrator of the Government in Council

Pursuant to section 101 of the Psychoactive Substances Act 2013, Her Excellency the Administrator of the Government, acting on the advice and with the consent of the Executive Council and on the recommendation of the Minister of Health made after complying with section 101(2) of that Act, makes the following regulations.

Contents

Note

Changes authorised by subpart 2 of Part 2 of the Legislation Act 2012 have been made in this official reprint.

Note 4 at the end of this reprint provides a list of the amendments incorporated.

These regulations are administered by the Ministry of Health.

Regulations

1 Title

These regulations are the Psychoactive Substances Regulations 2014.

2 Commencement

These regulations come into force on 3 November 2014.

3 Interpretation

(1) In these regulations, unless the context otherwise requires,—

Act means the Psychoactive Substances Act 2013

automatic vending machine means a self-service machine that,—

(a) on the insertion of a coin or token or by any other means, dispenses approved products by way of sale, whether automatically or with the assistance of the buyer; and

(b) does not require replenishment between each sale

container, in relation to an approved product,—

(a) means a bottle, jar, box, packet, or other receptacle that contains or is to contain the approved product (other than any receptacle in which the container is or is to be contained); but

(b) does not include a capsule, cachet, or other article from which the approved product is or is to be administered

importer means a person who holds a licence to import psychoactive substances granted under the Act

manufacturer means the person who holds a licence to manufacture psychoactive substances granted under the Act

residential premises means any premises used or intended for occupation by any person as a place of residence

retailer means a person who holds a licence to sell approved products by retail granted under the Act

seller means a retailer, wholesaler, or person who holds a licence to sell psychoactive substances that are not approved products granted under the Act

tamper-evident, in relation to a container, means a container that can be reasonably expected to provide visual evidence that tampering has occurred

URL means a World Wide Web uniform resource locator

wholesaler means a person who holds a licence to sell approved products by wholesale granted under the Act.

(2) Terms or expressions that are defined in the Act and used, but not defined, in these regulations have the same meaning as they have in the Act.

Regulation 3(1) **URL**: inserted, on 21 April 2016, by regulation 4 of the Psychoactive Substances Amendment Regulations 2016 (LI 2016/63).

Application for licence

Heading: inserted, on 21 April 2016, by regulation 5 of the Psychoactive Substances Amendment Regulations 2016 (LI 2016/63).

3A Application for licence to sell approved products

An application for a licence to sell an approved product made under section 13(1)(e) or (f) of the Act must include the following information:

(a) the full name and date of birth of the applicant; and

(b) the address and other contact details of the applicant; and

(c) the address of all premises from which the approved products may be sold (unless products are to be sold from those premises only by Internet sale); and

(d) the URL of any Internet site from which the approved products may be offered by Internet sale; and

(e) evidence of the applicant's identity; and

(f) written consent allowing a Police vet of—

(i) the applicant (unless subparagraph (ii) or (iii) applies); or

(ii) if the application is being made by a body corporate, the directors of the body corporate; or

(iii) if the application is being made in respect of a trust, the trustees of the trust; and

(g) a statutory declaration that the applicant meets all of the requirements of the Act and these regulations.

Regulation 3A: inserted, on 21 April 2016, by regulation 5 of the Psychoactive Substances Amendment Regulations 2016 (LI 2016/63).

Approved products

4 Application for approval of psychoactive product

An application for approval of a psychoactive product made under section 33 of the Act must be accompanied by the following information:

(a) full particulars of the finished product, including—

(i) the manufacturing arrangements relating to the product; and

(ii) a statement about the formulation of the product, including its active and inactive ingredients and the quantity of those ingredients; and

(iii) a description of the packaging for the product; and

(iv) a statement of the recommended dosage of the product; and

(b) the results of all trials where the effects of the psychoactive product or any 1 or more psychoactive substances contained within the product have been specifically investigated, having regard to (without limitation)—

(i) the chemical, pharmacological, psychoactive, and toxicological effects of the product or substances; and

(ii) the potential for misuse of the product or substances; and

(iii) any related adverse behavioural effects of the product or substances; and

(c) a report on the risks to, and impact on, public health and vulnerable or at-risk populations that may arise if the psychoactive product is approved, including—

(i) information about the interaction of the product with alcohol; and

(ii) a plan to manage those risks; and

(d) a detailed plan of how the risk of harm posed by the psychoactive product will continue to be monitored and managed by the applicant if the

product is approved, including how the applicant would comply with a recall order issued under section 88 of the Act.

5 Prohibitions and restrictions on certain forms of approved product

(1) The Authority must not approve a psychoactive product that—

(a) is intended to be injected:

(b) is in the form of a liquid or a powder, except where it is contained in a capsule or tablet:

(c) is, or resembles, food.

(2) The Authority must not approve a psychoactive product that is packaged in a container if the product contained in the container would be easily subdividable.

Sale of approved products

6 Restrictions on sale of approved products

(1) A retailer must not sell, or offer to sell, to any person more than 2 approved products (whether the same or different products) at any one time.

(2) A retailer must not serve the same person consecutively more than once for the purposes of circumventing the restriction imposed by subclause (1).

7 Prohibitions on place of sale of approved products

An approved product must not be sold from—

(a) any residential premises; or

(b) an automatic vending machine; or

(c) any place that, by its nature, is likely to be frequented by minors (for example, recreational facilities or sports facilities).

7A Internet sale of approved products

Any retailer who offers approved products by Internet sale must, on the Internet site from which the offer is made,—

(a) display, in a prominent place,—

(i) the licence holder's name; and

(ii) the licence number; and

(iii) the date on which the licence expires; and

(iv) either a legible image of the licence or a clearly identified link to such an image; and

(b) require any prospective purchaser to declare, by ticking an on-screen box, that he or she is 18 years of age or over; and

(c) if the prospective purchaser is purchasing an approved product for the purpose of providing the approved product to another person (**person B**), require the prospective purchaser to declare, by ticking an on-screen box, that person B is 18 years of age or over; and

(d) require the prospective purchaser to make the declarations required by paragraphs (b) and (c)—

(i) when the prospective purchaser first enters the Internet site; and

(ii) immediately before the sale of any approved substance is completed.

Regulation 7A: inserted, on 21 April 2016, by regulation 6 of the Psychoactive Substances Amendment Regulations 2016 (LI 2016/63).

Labelling of approved products

8 Labelling of approved products

(1) In addition to the information specified in section 58(2)(a) to (d) of the Act, a label for an approved product must include the following information:

(a) the approved name of the approved product; and

(b) a description of how the approved product is intended to be used (including the recommended dosage of the product); and

(c) the words "Batch Number" or "Lot Number", or the word "Batch" or "Lot", or the letter "B" (either alone or inside a circle) followed by the batch or lot number of the product; and

(d) the words "Use by" or "Use before", or words of a similar meaning, followed by the expiry date of the product (which must be no later than 5 years after the date on which the psychoactive product was manufactured) appropriate to the stability of the product; and

(e) a bar code that meets the international GS1 standard (or any other standard as required by the Authority).

(2) A label must be—

(a) printed in English; and

(b) clearly visible and legible; and

(c) durable; and

(d) securely placed in a prominent position on the approved product so that it is not able to be damaged, defaced, destroyed, or removed when the container is opened; and

(e) designed to maximise safe use of the product.

(3) If it is satisfied that the safe use of an approved product would not be compromised, the Authority may agree to some or all of the information specified

in subclause (1) being included on a separate printed insert to be included in the container in which the approved psychoactive product is sold.

Packaging of approved products

9 Packaging requirements for approved product

An approved product must be packaged in a container that is—

(a) tamper-evident; and

(b) reasonably resistant to attempts by young children to open it.

Storage and display of approved products

10 Requirements relating to storage of approved products

A retailer or wholesaler of approved products must take all reasonable steps to ensure that all approved products are stored and displayed securely while they are in the retailer's or wholesaler's possession.

11 Restrictions on display of approved products

A retailer or wholesaler who displays approved products at any premises for the purposes of sale must ensure that the products are displayed—

(a) inside the premises; and

(b) in a manner so that the products are not visible from outside the premises.

Record keeping

12 Record-keeping requirements

(1) A person who holds a licence must keep a record of every transaction with another licence holder, including the date of the transaction and the other licence holder's licence number.

(2) A retailer must keep a record of every sale of an approved product by the retailer, including a description of the product and the price for which the product was sold.

(3) An importer must keep a record of—

(a) the quantity of each psychoactive substance imported by the importer; and

(b) the form in which the substance was imported (for example, as a liquid or a powder).

(4) A record that is required to be kept under subclause (1) must be entered on a register that complies with regulation 15.

13 Stocktake record

(1) This regulation applies to person in possession of a psychoactive substance or an approved product in accordance with a licence at the close of 30 June and 31 December in any year.

(2) The person must record the actual stock of all psychoactive substances and approved products in the person's possession on that date.

(3) For the purposes of subclause (2), the stocktake record must record the following information:

(a) for psychoactive substances in a raw state,—

(i) the actual stock of each psychoactive substance, including the name of the psychoactive substance, the quantity of the substance, and the psychoactive product or products for which the substance is intended to be used:

(ii) for psychoactive substances that are in the process of being made into psychoactive products, the quantity of each substance:

(b) for approved products,—

(i) the actual stock of each approved product in the person's possession; and

(ii) the quantity of any 1 or more psychoactive substances contained within each approved product.

(4) The information recorded under subclause (3) must be entered on a register that complies with regulation 15.

14 Stocktake report must be provided to Authority

(1) A person to whom regulation 13 applies must, within 14 days after the date on which the stocktake was undertaken,—

(a) prepare a stocktake report covering the period since the date of the stocktake and any previous stocktake undertaken by the person; and

(b) give an explanation in the report of any variation between the calculated balance of stock and the actual stock as at the date of the stocktake.

(2) The stocktake report must be provided to the Authority within 21 days after the date on which the stocktake was undertaken.

15 Forms of register

(1) A register referred to in regulation 12 or 13 must be kept in 1 or more of the following forms:

(a) a system for recording and keeping the information electronically:

(b) a book for recording and keeping the information in writing:

(c) some other system for recording and keeping the information approved by the Authority (either generally or in any particular case) for the purposes of this regulation.

(2) The Authority may, by notice in the *Gazette* or in writing the person or persons to whom it applies,—

(a) specify the form in which the register must be kept; and

(b) approve an alternative form of the register for 1 or more classes of persons.

(3) The Authority may, at any time, withdraw an approval under subclause (2)(b) by notice given in the same manner as the notice of approval.

(4) A person who is required to maintain a record in writing must—

(a) enter the record legibly and indelibly on the register; and

(b) initial each entry or otherwise indicate who made the entry.

(5) A person who is required to maintain a record must not—

(a) make, cause, or permit an entry to be recorded on the register that is false in any material particular:

(b) obliterate, cancel, or alter, or cause or permit to be obliterated, cancelled, or altered, any entry made.

(6) However, if a mistake is made in respect of any entry on the register, the mistake may be corrected by a note giving the correct particulars, which must state the date on which the note was written.

16 Retention of records

(1) The records required under regulations 12 and 13 must be kept for a period of 7 years after the date of the last entry made in respect of the record.

(2) If a person who created the record ceases to hold a licence, the person must deliver the record to the Authority.

(3) If the Authority receives any records in accordance with subclause (2), the Authority must destroy the record after 7 years after the date of the last entry made in respect of the record.

Michael Webster,
Clerk of the Executive Council.

Issued under the authority of the Legislation Act 2012.
Date of notification in *Gazette*: 31 July 2014.

Reprints notes

1 General

This is a reprint of the Psychoactive Substances Regulations 2014 that incorporates all the amendments to those regulations as at the date of the last amendment to them.

2 Legal status

Reprints are presumed to correctly state, as at the date of the reprint, the law enacted by the principal enactment and by any amendments to that enactment. Section 18 of the Legislation Act 2012 provides that this reprint, published in electronic form, has the status of an official version under section 17 of that Act. A printed version of the reprint produced directly from this official electronic version also has official status.

3 Editorial and format changes

Editorial and format changes to reprints are made using the powers under sections 24 to 26 of the Legislation Act 2012. See also http://www.pco.parliament.govt.nz/editorial-conventions/.

4 Amendments incorporated in this reprint

Psychoactive Substances Amendment Regulations 2016 (LI 2016/63)

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