

Psychoactive Substances

Licensing Scheme Guideline

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1 Background

The Psychoactive Substances Act 2013 (the Act) came into force on 18 July 2013. The purpose of the Act is to regulate the availability of psychoactive substances in New Zealand to protect the health of, and minimise harm to, the individuals who use these substances. The Act sets up a system of pre-market approval for psychoactive products by requiring them to demonstrate that they pose no more than a low risk of harm to the individuals who use them, and by placing restrictions on how and to whom they can be sold.

The Act establishes the Psychoactive Substances Regulatory Authority (the Authority) within the Ministry of Health. The Authority is responsible for ensuring products meet adequate safety requirements before they can be distributed in New Zealand, and also licenses importers, researchers, manufacturers, wholesalers, retailers and sellers of unapproved psychoactive substances.

The Psychoactive Substances Regulations 2014 (the Regulations) further define the full regulatory requirements for psychoactive substances. There are two other sets of regulations under the Act: The Psychoactive Substances (Fees and Levies) Regulations 2014, which specify the fees and levies associated with each type of licence under the Act; and the Psychoactive Substances (Infringement Fees and Form Notices) Regulations 2014, which outline the penalties for infringements under the Act.

The Licensing Scheme Guideline (the guideline) provides detail relating to the implementation of the regulatory licensing scheme. This includes advice on when and how to prepare applications for the different licences under the Act and what supporting information needs to be provided. The guideline gives an overview of the application process, the fee structure and the guidance documents recognised by the Authority for the purpose of supporting an application. In addition, the guideline also covers the obligations that successful applicants must meet post-approval.

2 The legislative framework

Copies of all relevant legislation can be downloaded for free from www.legislation.govt.nz.

2.1 The psychoactive substances legislation and guidelines

Psychoactive substances are regulated in New Zealand in accordance with the following.

- The Psychoactive Substances Act 2013 (the Act).
- The Psychoactive Substances Regulations, including:
 - The Psychoactive Substances Regulations 2014 (the Regulations)
 - The Psychoactive Substances (Fees and Levies) Regulations 2014 (the Fees Regulations)
 - The Psychoactive Substances (Infringement Fees and Form of Notices) Regulations 2014 (the Infringement Regulations).
- The Psychoactive Substances Licensing Scheme Guideline.
- The Psychoactive Substances Product Approval Guideline.

2.2 Legislation to read in conjunction with the guidelines

The following is a list of legislation to be read in conjunction with the psychoactive substances guidelines indicated above. Areas that are of particular importance or likely to be of particular interest are further specified; however prospective applicants should make themselves familiar with the complete documents.

- The Psychoactive Substances Act 2013.
- The Psychoactive Substances Regulations 2014.
- The Misuse of Drugs Act 1975:
 - Schedules 1, 2 and 3 – list controlled drugs
 - Schedule 4 – lists precursor substances.
- The Medicines Act 1981:
 - Section 3 – defines a medicine
 - Section 2(1) – defines a herbal remedy.
- The Medicines Regulations 1984:
 - Schedule 1 – lists all prescription, restricted and pharmacy-only medicines.
- The Dietary Supplements Regulations 1985:
 - Regulation 2(a) – defines a dietary supplement.
- The Food Act 2014 and its associated Standards:
 - Section 9 – defines a food.
- The Smoke-free Environments Act 1990:
 - Section 2(1) – defines a tobacco product.

2.3 Requirement to comply with other legislation

2.3.1 Consumer legislation

Manufacturers, wholesalers and retailers should be aware that, as psychoactive products are articles of commerce, they also need to comply with any relevant consumer legislation (such as the Fair Trading Act 1986 and the Consumer Guarantees Act 1993) administered by the Ministry of Business, Innovation and Employment. In particular, claims of psychoactivity (including use of words such as euphoria or high, etc) must only be made for products that actually produce a psychoactive effect.

2.3.2 Hazardous substances and new organisms legislation

Manufacturers are required to ensure that all ingredients comply with the requirements of the Hazardous Substances and New Organisms Act 1996 (HSNO) and its associated regulations. The Environmental Protection Authority (EPA) administers the HSNO legislation. Manufacturers will need to assess whether the ingredients cross the HSNO thresholds for hazardous properties. The website dedicated to the HSNO legislation and its application is <http://www.hsno.govt.nz>.

The website <http://www.epa.govt.nz> includes information on EPA procedures together with a searchable register of applications and approvals under the HSNO Act.

For further information about the HSNO and EPA requirements for obtaining consent to import and/or release products controlled under the HSNO legislation, contact:

General Manager, Applications and Assessments
Environmental Protection Authority
Level 10, 215 Lambton Quay, Wellington 6011
Private Bag 63002, Wellington 6140
Telephone: (04) 473 8426
Fax: (04) 473 8433
Website: <http://www.epa.govt.nz>

3 Principles of the Act

The three key principles in the Act are that:

- (i) any psychoactive product that poses no more than a low risk of harm to individuals who use the product should be approved (a product that poses no more than a low risk of harm is expected to have a risk profile similar to an over-the-counter or general sales medicine)
- (ii) conversely, any psychoactive product that poses **more** than a low risk of harm to individuals who use the product should be prohibited
- (iii) animals must not be used for the purposes of assessing whether a psychoactive product should be approved.

Assessment of the risk of harm posed by a psychoactive substance requires the Authority to consider a range of pharmaceutical, toxicological and chemical factors. In making the assessment, the Act prohibits the Authority from considering any data derived from the use of the product in animals.

4 When an application is required

4.1 Licences

Individuals or legal entities must have the Authority's consent to perform each of the following activities:

- import psychoactive substances
- manufacture psychoactive substances
- research psychoactive substances
- sell psychoactive substances that are not approved products
- sell approved products by retail
- sell approved products by wholesale.

More detailed descriptions of the conditions for these activities are provided in section 6 of the guideline.

Applications for a licence may be made by an individual or by an individual on behalf of a body corporate or trust. Under section 13 of the Act, only a person who is a New Zealand resident may apply for a licence.

Licences issued to an individual are for sole trading companies only. A body corporate or trust must not operate under a licence issued to an individual.

Application forms are available for download from:

www.psychoactives.health.govt.nz.

Completed application forms and all supporting information should be emailed to:

psychoactives@moh.govt.nz.

Under section 16 of the Act, potential licence holders must be determined to be a fit and proper person, or if an application is made on behalf of a body corporate, the body corporate must be of good repute. As part of the application process, the Authority will require a NZ Police vetting check.

4.2 Products

All psychoactive substances intended for human consumption require consent from the Authority (as established by section 10 of the Act) before they can be sold in New Zealand. The Psychoactive Substances Product Approval Guideline sets out what is required for a product approval (www.psychoactives.health.govt.nz).

5 Licensing process

The key steps in the licensing process are:

- receiving and screening for completeness
- invoicing and payment
- evaluation of initial and additional information
- notification of the outcome:
 - the opportunity for the applicant to make a submission if the licence application is declined
 - the opportunity for the applicant to lodge an appeal with the Psychoactive Substances Appeals Committee (PSAC) if the licence application is declined following a submission.

If granted, licences are valid for the period stated on the licence. Licences cannot be issued for a period longer than three years from the date of issue.

5.1 Receiving and screening for completeness

Applicants should ensure that applications include all requisite information in the specified format. Applications that are found to be significantly deficient will be refused and returned, and applicants will need to resubmit their application from the beginning of the process. Please note that this step is only intended to check that information has been submitted for each of the major requirements and is not a comprehensive check that the data is appropriate.

5.2 Invoicing and payment

Once an application has been screened for completeness, the Authority will issue the applicant with a tax invoice. The invoice will be included with the acknowledgement letter. The Authority's expected timeframe for completion of screening and issuing an invoice is within 14 working days of receipt of the application. Payments are to be made on an invoice basis only – **do not send payment with the application.**

Payment can be made by electronic funds transfer or by cheque. Details on how to make a payment by these methods is listed on our invoice remittance advice.

Credit card payments with Visa or MasterCard can also be made. A 2 percent transaction fee on credit cards applies. You should also check with your card issuer for details about other fees or charges that may apply, as credit card transactions are carried out in terms of arrangement between you and your bank.

Payments are in New Zealand dollars. If payment is made using a credit card issued outside New Zealand, any currency conversion will be done according to the terms and conditions of the card.

From the invoice remittance advice you will require the customer number, invoice number, and invoice total to complete the payment transaction. Payments received before 10.30 pm New Zealand time will be processed overnight. Payments received after 10.30 pm will be processed on the following business day.

The schedule of fees and levies payable is shown below.

Fees including GST

Application for licence to import psychoactive substances	\$2,500
Application for licence to manufacture psychoactive substances	\$19,000
Application for licence to research psychoactive substances	\$2,000
Application for licence to sell psychoactive substances that are not approved products	\$2,000
Application for licence to sell approved products by retail	\$12,000
Application for licence to sell approved products by wholesale	\$7,000

Levies including GST

Holder of licence to import psychoactive substances	\$7,500
Holder of licence to manufacture psychoactive substances	\$42,000
Holder of licence to research psychoactive substances	\$3,000
Holder of licence to sell psychoactive substances that are not approved products	\$2,000
Holder of licence to sell approved products by retail	\$7,000
Holder of licence to sell approved products by wholesale	\$6,000

5.3 Evaluation of information

The Authority's expected timeframe to complete the evaluation of all information provided with the application is within 60 working days of receiving payment.

5.4 Notification of the outcome

If the licence application is approved, the applicant will receive the licence and an outcome letter. Applicants should carefully read both the outcome letter and the certificate as these documents will describe the approved details, requirements and conditions that must be complied with. Any incorrect details should be notified to the Authority immediately.

The licence will be granted to the individual or body corporate in whose name the application was made and this individual or body corporate will be known as the licence holder.

If the licence application is declined, the applicant will receive an outcome letter that clearly explains the grounds for the proposed refusal. The letter will also advise the applicant of their right, under section 21(1)(b) of the Act, to make a written submission to the Authority to object to the Authority's proposal to refuse licence approval.

If the applicant chooses not to make a written submission within 14 working days, the Authority will notify the applicant that their licence application has been refused.

If the applicant chooses to make a written submission and it is received within the required timeframe, the Authority will reconsider the proposal to refuse the licence based on the written submission. It is the Authority's intent to complete this process within 28 working days of receiving the written submission.

If the outcome of the submission is successful, the applicant will receive the licence and an outcome letter. Applicants should carefully read both the outcome letter and the licence as explained above.

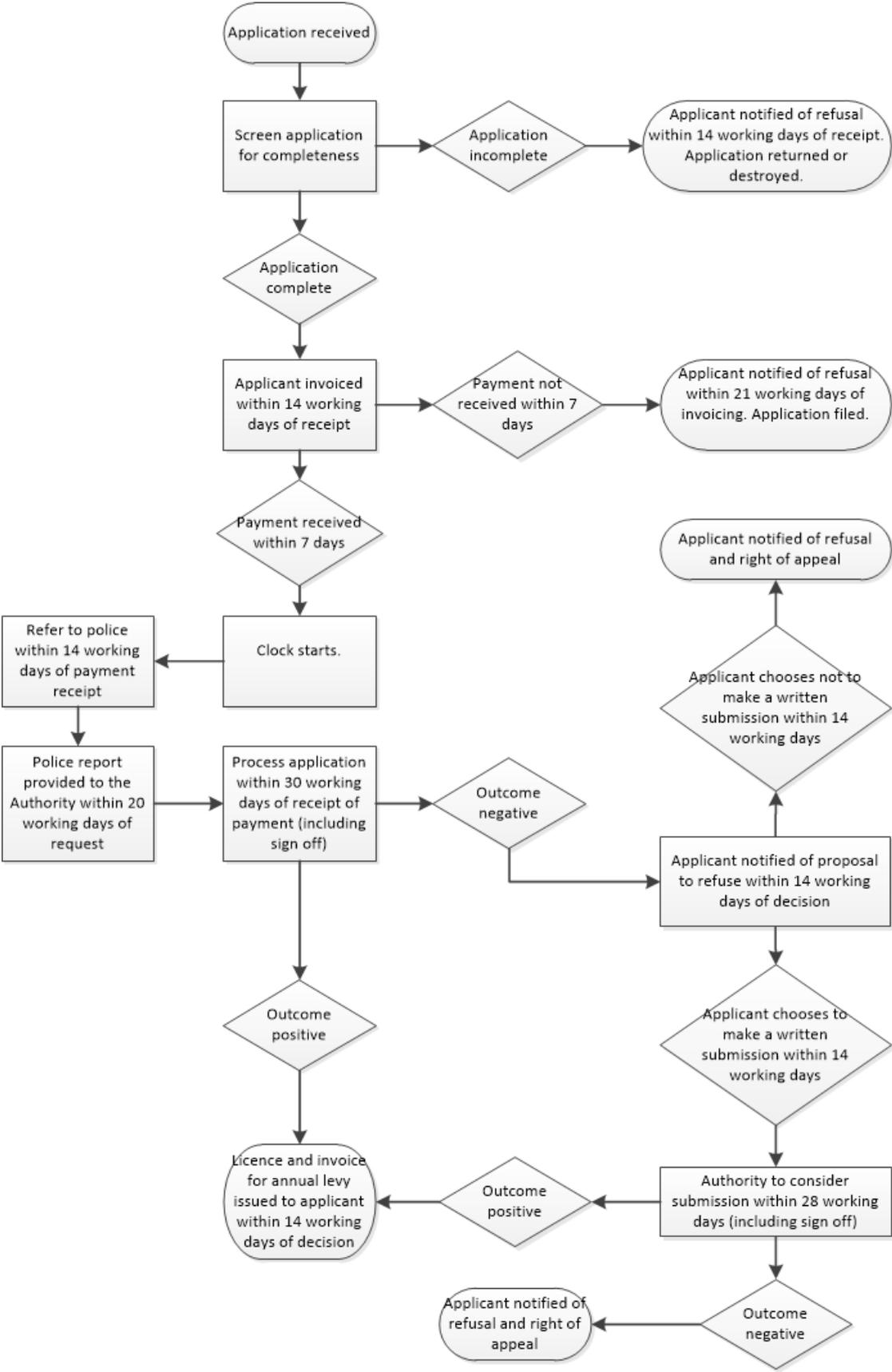
If the outcome of the submission is unsuccessful, the applicant will receive notification that the licence application has been refused, and the grounds for this refusal. Applicants will also be advised of their right, under section 45 of the Act, to lodge an appeal with the PSAC (see section 8).

Specific conditions imposed on licences can be contested by the applicant with the Authority. If the applicant is not satisfied with the outcome received from the Authority, they can appeal to the PSAC about the Authority's decision to impose specific conditions on a licence (see section 8).

5.5 Renew a licence

An application to renew a licence should be submitted at least two months, but less than three months, before the expiry date on your current licence.

Overview of the licence approval process and expected timeframes



6 Licence conditions

There are six different licences under the Act, namely: manufacture, wholesale, retail, import, research, and sale of unapproved products. You must not carry out any of these activities without holding the corresponding licence.

Where a licence is issued to an individual, it is for their use only. Section 20 of the Act states that licences cannot be transferred to another person(s) or company. This means that companies cannot operate under a licence issued to an individual without contravening section 20 of the Act.

The Act and associated regulations prescribe specific conditions and requirements, some of which are common to all licences. In addition, section 18 of the Act also enables the Authority to impose discretionary conditions on licences. Discretionary conditions include any other conditions the Authority deems necessary to be applied to a particular licence.

The licence holder is legally responsible for ensuring that all activities relating to psychoactive substances are conducted in accordance with the licence conditions and the requirements of the Act and the associated regulations.

6.1 All licences

The Regulations specify the following mandatory requirements.

- a) 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 under Regulation 12(1).
- b) Persons 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 (under Regulation 13(1)) must record the actual stock of all psychoactive substances and approved products in the person's possession on that date under Regulation 13(2).
- c) A person to whom Regulation 13 applies must, within 14 days after the date on which the stocktake was undertaken:
 - (1) prepare a stocktake report covering the period since the date of the stocktake and any previous stocktake undertaken by the person, and
 - (2) 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.
- d) The stocktake report must be provided to the Authority within 21 days after the date on which the stocktake was undertaken under Regulation 14(2).

The Regulations specify a mandatory requirement that the records required under Regulations 12 and 13 must be kept for a period of seven years after the date of the last entry made in respect of the record under Regulation 16.

In addition, the Act states the following conditions that are common to all licences.

Conditions

Section 17 of the Act states that:

- (4) It is a condition of every licence that the licence holder must—
 - (a) keep, in a secure place at the licence holder's place of business, any records required to be kept by the licence holder by the regulations; and
 - (b) retain those records for the period of time prescribed in the regulations.
- (5) It is a condition of every licence that the licence holder must, before each exportation of a psychoactive substance by the licence holder,—
 - (a) advise the Authority of the exportation; and
 - (b) provide to the Authority particulars of—
 - (i) the name and quantity of the psychoactive substance to be exported; and
 - (ii) the intended date of the exportation.

Under section 98 of the Act, a person specified in subsection (2) must, as soon as is reasonably practicable, notify the Authority if the person becomes aware of any adverse reaction arising from the use of a psychoactive substance or an approved product by any individual (whether in New Zealand or overseas).

- (2) The persons are—
 - (a) a person who holds a licence in respect of the psychoactive substance;
 - (b) the person who applied for approval of the approved product under section 33.
- (3) A notification under subsection (1) must include—
 - (a) the name of the psychoactive substance or approved product as far as it is known to the person; and
 - (b) the nature of the adverse reaction as far as it is known to the person; and
 - (c) the circumstances in which the adverse reaction arose as far as they are known to the person.

6.2 Licence to import

A licence to import allows the holder of the licence to import psychoactive substances. An importer of psychoactive substances may only sell or distribute psychoactive substances to persons who hold a licence under the Act. Despite being permitted to be in possession of a psychoactive substance or product, an importer cannot conduct research on it without a licence to research. Since licensed importers cannot do anything with the imported substances or products, prospective importers should generally apply for an additional licence at the same time as their licence to import.

Any relevant documentation requested by the Authority in relation to activities of importation of psychoactive substances must be provided to the Authority by the licence holder within a timely manner of receiving the request.

It is a requirement under Regulation 12(3) that an importer must keep a record of:

- (a) the quantity of each psychoactive substance imported by the importer
- (b) the form in which the substance was imported (for example, as a liquid or a powder).

Conditions

Section 17(1) states that it is a condition of a licence to import that the licence holder must, before each importation of a psychoactive substance:

- (a) advise the Authority of the importation; and
- (b) provide to the Authority particulars of:
 - (i) the name and quantity of the psychoactive substance to be imported
 - (ii) the intended date of the importation.

6.3 Licence to research

A licence to research psychoactive substances allows the holder of the licence to carry out research using psychoactive substances. This includes developing novel psychoactive substances from non-psychoactive starting materials, research into the characteristics or uses of psychoactive substances, and the provision of drug testing services. Anyone undertaking any type of research with psychoactive substances must hold a licence to research psychoactive substances.

The licence holder may only obtain psychoactive substances by:

- importing it themselves under a licence to import psychoactive substances
- purchasing it from a manufacturer, wholesaler, retailer, seller of unapproved products or importer licensed under the Act.

The licence holder must inform the Authority of all intended research, the timeframe for the research and the outcome.

For the purposes of developing a psychoactive product, research undertaken using animal or human studies is not permitted.

6.4 Licence to manufacture

A manufacturing licence allows the holder of the licence to manufacture approved psychoactive products for sale. Facilities must comply with the Code of Manufacturing Practice (CoMP) before manufacturing any products for use in humans.

An application for a manufacturing licence must provide an overview of the company's structure, and nominate people who are suitably qualified to maintain CoMP compliance and authorised to speak on behalf of the company. These individuals will also need to go through the vetting process.

The conditions and requirements for a licence to manufacture are set out in full detail in the CoMP (www.psychoactives.health.govt.nz) which must be complied with at all times.

6.5 Licence to sell psychoactive substances that are not approved products

A licence to sell psychoactive substances that are not approved products does **not** extend to approved products. Individuals will also need to hold a licence to import, research or manufacture psychoactive substances if they wish to import or manufacture their own unapproved products.

Conditions

Under section 17(3) of the Act, it is a condition of a licence to sell psychoactive substances that are not approved products that the licence holder may only sell psychoactive substances in New Zealand to a person who holds:

- (a) a licence to manufacture psychoactive substances; or
- (b) a licence to research psychoactive substances.

6.6 Licence to sell approved products by retail

A licence to sell psychoactive products by retail allows the holder to sell psychoactive substances to the general public that have been approved by the Authority as psychoactive products.

Note: Currently there are no approved products. Due to the prohibition on the use of animal testing for the purposes of assessing whether a psychoactive product should be approved, it is unlikely that there will be any approved products for at least the next three years. On this basis, the Authority recommends that you do not apply for a licence to sell psychoactive substances by retail at this time. For more detail, see Appendix 1 for the Psychoactive Substances Expert Advisory Committee's Position Statement on animal testing.

Approved psychoactive products must only be sold to persons aged 18 years and older, and approved products must only be sold at the location specified on your licence, which must be in line with your district's local approved product policy.

Restrictions outlined in Regulation 6 of the Regulations state that:

- (1) a retailer must not sell, or offer to sell, to any person more than two 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).

Prohibitions and restrictions on place of sale of approved products are outlined in section 52, which states that a person must not sell an approved product from any of the following:

- (a) a shop commonly thought of as a dairy
- (b) a shop commonly thought of as a convenience store
- (c) a grocery store or a supermarket

- (d) any premises where the principal business carried on is:
 - (i) the sale of automotive fuels; or
 - (ii) the repair and servicing of motor vehicles and the sale of automotive fuels
- (e) any premises where alcohol is sold or supplied under a licence issued under the Sale and Supply of Alcohol Act 2012
- (f) any premises that are not a fixed permanent structure (for example, a tent or marquee)
- (g) any vehicle or other conveyance (for example, a mobile street cart)
- (h) any other place or premises specified or described in the Regulations.

Regulation 7 outlines further prohibitions on place of sale of approved products and states that 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).

Regulation 10 sets out the requirements for storage of approved products, stating:

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.

While Regulation 11 details the restrictions around the display of approved products, outlining that 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
- (b) in a manner so that the products are not visible from outside the premises.

A retailer must also 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 (Regulation 12(2)).

Two information documents to help retailers comply with the legislation, *Retail sale of approved psychoactive products* and *Policy for the retail sale of approved psychoactive products*, can be downloaded from:

www.psychoactives.health.govt.nz.

6.7 Licence to sell approved products by wholesale

A licence to sell psychoactive products by wholesale allows the holder to sell psychoactive substances which have been approved as psychoactive products by the Authority to others who hold a licence to sell psychoactive products by retail.

Regulation 10 sets out the requirements for storage of approved products, stating:

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.

Regulation 11 details the restrictions around the display of approved products, outlining that 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
- (b) in a manner so that the products are not visible from outside the premises.

7 Suspension and cancellation of licence

Under section 22 of the Act the Authority may suspend or cancel your licence if the Authority is satisfied, at any time after the licence has been granted, that the licence holder:

- supplied information in the application for the licence that is materially false or misleading
- has breached any conditions of the licence
- is failing, or has failed, to comply with any relevant requirement of the Act or the Regulations
- has ceased to be, in the case of an individual, a fit and proper person to hold the licence, or in the case of a body corporate, a body corporate of good repute.

However, the Authority may cancel a licence only after:

- giving you a reasonable opportunity to be heard
- considering any evidence provided by you
- considering submissions made by you.

7.1 Suspension of licence

The Authority may suspend a licence for a period of time that is reasonable in the circumstances, to enable the Authority to consider whether to cancel the licence.

The Authority will inform you of the suspension and the reason(s) for that suspension in writing. The Authority may require you to undertake necessary actions in order to demonstrate compliance with the Act for the licence suspension to be lifted.

If your licence is suspended you must immediately cease any activity with psychoactive substances or products. You may be visited by a Ministry of Health enforcement officer who will check whether you have ceased all activities related to psychoactive substances or products.

You will have the opportunity to respond to the licence suspension. A date, usually 10 days from the date of the suspension letter, will be given in which to respond. Failure to respond by that time will result in your licence being cancelled.

Your evidence and/or submission will be assessed as to whether it is sufficient to change the Authority's decision to suspend your licence. If needed, the Authority may seek further information from you or another party, such as a Ministry of Health enforcement officer or NZ Police.

7.2 Cancellation of licence

Upon consideration of your submission, the Authority will write to you with the outcome as to whether the licence suspension will be lifted or your licence cancelled.

If the Authority proposes cancelling your licence, you will have a further opportunity to provide evidence and/or a written submission on the proposed cancellation. Your evidence and/or submission will be assessed as to whether it is sufficient to change the Authority's proposal to cancel your licence.

If you disagree with the Authority's final decision to cancel your licence, you can lodge an appeal with the PSAC (see section 8).

If you lodge an appeal with the PSAC against the cancellation of your licence, the licence will remain cancelled unless the appeals committee orders otherwise. Despite lodging an appeal, you must not resume dealing in psychoactive substances until you receive notification from the PSAC that the licence has been reinstated.

If your licence is cancelled, you will be required to return your physical licence to the Authority.

8 Lodging an appeal with the PSAC

The PSAC is a committee made up of three members, at least one of whom must be a lawyer with at least seven years' experience. The function of the committee is to independently review any decision made by the Authority:

- to refuse to grant the person a licence
- to impose a condition on the person's licence
- to suspend or cancel the person's licence.

The committee cannot review any decision or part of a decision that is not appealed against. On hearing the appeal, the committee may:

- confirm, reverse or modify the decision appealed against
- make any other decision that the Authority could have made
- refer appeals back to the Authority to reconsider.

Appeals against an Authority decision should be accompanied by a detailed letter stating the decision to be appealed and the grounds on which it is to be appealed.

Appeals should be sent to:

psychoactiveappeals@moh.govt.nz

Appeals must be received no later than 60 days after the decision appealed against is given unless the committee allows a longer period. The decision being appealed remains in force throughout the appeal unless the committee orders otherwise. The committee will meet as and when required.

For further information on the appeals process, please direct queries to:

psychoactiveappeals@moh.govt.nz

Appendix 1: PSEAC position statement on animal testing

6 December 2014



Office of the Psychoactive Substances Regulatory Authority

Position Statement on Alternatives to Animal Testing

This position statement has been prepared by the Office of the Psychoactive Substances Regulator and is endorsed by the Psychoactive Substances Expert Advisory Committee.

The Amendment to the Psychoactive Substances Act on 8 May 2014 removed the ability of the Psychoactive Substances Expert Advisory Committee (the Committee) to have regard to the results of animal testing when considering whether a psychoactive product should be approved for use by individuals.

The Committee has therefore considered whether suitable alternatives to animal testing are available for all aspects of the assessment that is needed to determine whether a product poses no more than a low risk of harm to the individual using it.

The Committee is required, under section 11(3) of the Psychoactive Substances Act 2013, to have regard to the following when evaluating psychoactive products to assess whether they should be approved for use by individuals:

- the specific effects of the product, including pharmacological, psychoactive, and toxicological effects; and
- the risks, if any, to public health; and
- the potential use of the product to cause death; and
- the potential for the product to create physical or psychological dependence; and
- the likelihood of misuse of the product; and
- the potential appeal of the product to vulnerable populations; and
- any other matters that the Authority considers relevant.

The “avoidance of doubt” provision in section 37(2) of the Act makes it clear that the Authority **must refuse** to approve a psychoactive **product if it is unable to satisfy itself** that the degree of harm that the product poses to individuals using the product is no more than a low risk of harm.

The Committee has considered the type of scientific evidence it would need to see in order to provide robust and evidence-based advice on whether a product posed no more than a low level of harm to the individuals who may use it. It has agreed to refer to technical guidance developed in the context of global harmonisation of requirements for the approval of pharmaceuticals. These guidance documents address the same elements that the Committee is required to consider for psychoactive substances and have been developed through a process of scientific consensus involving technical experts from a number of countries. They are known as the *International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) Guidelines*.

After considering the ICH guidance and cognisant also of the consensus views of international toxicology experts in relation to risk assessments of chemicals in food,¹ the Committee has concluded that the tests required to address the following aspects of safety are currently only satisfactorily determined in animal models:

- teratogenicity
- toxicokinetics
- immunotoxicity
- carcinogenicity
- addiction modelling.

The Committee’s position is therefore that until suitable and internationally recognised non-animal study alternatives exist for assessing these aspects of product safety, it would be unable to recommend approval of any psychoactive products.

¹ International Programme on Chemical Safety Environmental Health Criteria 240 “Principles and Methods for the Risk Assessment of Chemicals in Food”, WHO, 2009.
http://www.inchem.org/documents/ehc/ehc/ehc240_chapter4.pdf