

Psychoactive Substances Regulations

A consultation document

Citation: Ministry of Health. 2014. *Psychoactive Substances Regulations: A consultation document*. Wellington: Ministry of Health.

Published in February 2014
by the Ministry of Health
PO Box 5013, Wellington 6145, New Zealand

ISBN 978-0-478-42783-7 (online)
HP 5810

This document is available at www.health.govt.nz



MANATŪ HAUORA



This work is licensed under the Creative Commons Attribution 4.0 International licence. In essence, you are free to: share ie, copy and redistribute the material in any medium or format; adapt ie, remix, transform and build upon the material. You must give appropriate credit, provide a link to the licence and indicate if changes were made.

Foreword

I am pleased to release this document consulting on regulations under the Psychoactive Substances Act 2013.

The rise of psychoactive substances both in New Zealand and internationally over the last decade has been rapid and almost entirely uncontrolled. The resulting widespread availability of these substances and products has led to significant health and social issues and, in some overseas cases, deaths.

New Zealand's approach to the issue has been typically pragmatic. This is a market that with modern technology will only continue to evolve, rendering a prohibitionist response largely ineffectual. By regulating the market and only allowing products posing no more than a low risk of harm, it is my expectation that the detrimental health impacts upon those who choose to take such products will be minimised.

These regulations will play an integral part in ensuring that the Act is fit for purpose, future-proofed and achieves its purpose. I encourage all with an interest in this area to make a submission.

Hon Peter Dunne
Associate Minister of Health

Contents

Foreword	iii
Introduction	1
How to have your say	1
1 Psychoactive Substances Regulations	2
Introduction	2
Overview of consultation topics	4
Proposed two-phase implementation process	5
Assessment criteria	5
2 Licence applications	6
Background	6
Information requirements	6
Fit and proper person test	8
Licence conditions	9
Process for considering applications	10
Any other matter the Authority may consider	11
3 Product approval applications	12
Information requirements	12
Grounds for approval	12
Determining the risk of harm	13
Process for considering applications	14
Additional products	14
4 Labelling and packaging	15
Labels	15
Health warnings	16
Packaging	17
Quantity and dose requirements	18
Restrictions on form of product	18
Storage, disposal and display	19
Signage	20
5 Place of sale and advertising	21
Proposed two-phase implementation	21
Place of sale	21
Local government policies for approved products	21
Advertising	22

6	Fees and levies	24
	Introduction – the Act’s framework	24
	Licence applications – a set fee	25
	Product approvals	26
	Levies	27
	Appendix: Example of interim application form	29
	Application form for an interim licence to manufacture psychoactive substances	29
	Making a submission	31
	Consultation questions	31
	List of Tables	
	Table 1: Proposed licence application fees	26
	Table 2: Proposed product approval application fees	27
	Table 3: Proposed annual levies	28
	List of Figures	
	Figure 1: The psychoactive substances regime	3
	Figure 2: Overview of implementation dates for Psychoactive Substances Code of Manufacturing Practice	4

Introduction

This consultation document is divided into six chapters. It covers:

- introductory matters
- the licence application process
- the product approval process
- labelling and packaging
- place of sale and advertising
- fees and levies.

How to have your say

Your feedback is important because it will help shape the final regulatory proposals, ensuring they are workable and contribute to achieving the purpose of the Psychoactive Substances Act 2013. Please take the time to make a submission.

There are two ways you can make a submission.

- Forward your comments, with the detachable submission form at the back of this document, to:
The Manager
Psychoactive Substances Regulatory Authority
Ministry of Health
PO Box 5013
Wellington.
- Electronically complete the submission form available at the back of this document, add your comments and email to:
psychoactives@moh.govt.nz
Please put 'Regulations Consultation' in the subject line.

All submissions are due by **5 pm on Friday 21 March 2014**.

Your submission may be requested under the Official Information Act 1982. If this happens, the Ministry will normally release your submission to the person who requested it. If you think there are good reasons that your submission should not be released, please indicate those reasons in your submission.

1 Psychoactive Substances Regulations

Introduction

Purpose of the Psychoactive Substances Act

The Psychoactive Substances Act 2013 (the Act) came into force on 18 July 2013. The Act regulates the importation, manufacture and supply of psychoactive substances.¹

The purpose of the Act is to regulate psychoactive substances in order to help protect the health of, and minimise harm to, individuals who use these substances. This is approached in two main ways – first, by ensuring only low-risk products are on the market, and second, by placing a range of controls on how and to whom psychoactive products may be sold.

The Act established 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. It also licenses importers, researchers, manufacturers, wholesalers and retailers.

The Authority is operating an interim regime while the Psychoactive Substances Regulations are developed. As regulations come into force, the part of the regime that they apply to will shift from the interim to the full regime.

These are the key features of the regime.

- It is illegal to sell unapproved psychoactive products.
- Only products that present no more than a low risk of harm to the user can be approved.
- Licences are required to import, manufacture, research or sell psychoactive substances.
- The sale of psychoactive substances is prohibited from dairies, convenience and grocery stores, supermarkets, service stations and liquor outlets.
- The sale of approved products to people under 18 years of age is prohibited, and no one under 18 years of age is permitted to purchase or possess psychoactive products.
- Advertising of approved products is strictly controlled and only permitted at the point of sale, and must not appeal to minors.
- All approved products must be labelled with appropriate health warnings, a list of the active ingredients, contact details for the manufacturer or distributor, and the telephone number of the National Poisons Centre.

¹ A psychoactive substance is anything that can be used to induce a psychoactive effect in humans. An 'approved product' is a psychoactive substance that has been packaged and approved for sale.

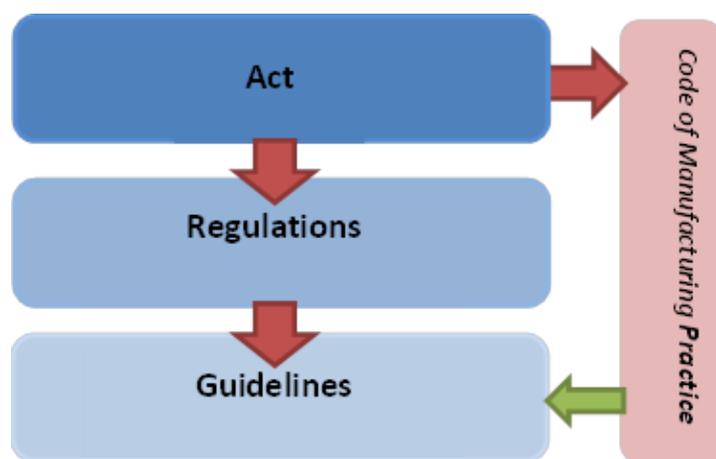
The aims of the regime are to:

- provide a way to effectively regulate psychoactive substances before they reach the market – only products with no more than a low risk of harm will be approved
- place controls on the availability of psychoactive products, including purchase age and place of sale
- provide information for consumers on product contents, dose and potency.

Elements of the psychoactive substances regime

The Act is supported by other elements which make up the regime, as shown in Figure 1.

Figure 1: The psychoactive substances regime



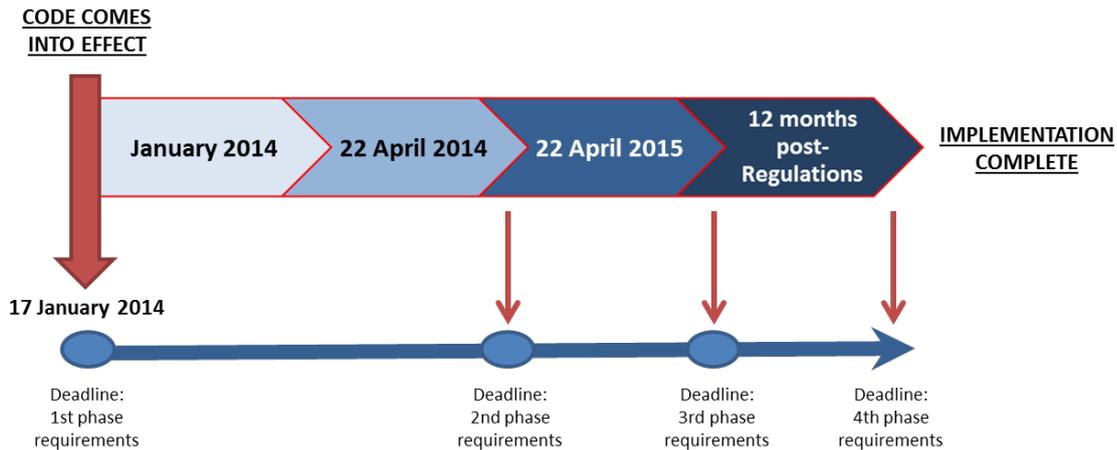
The Code of Manufacturing Practice

The Psychoactive Substances Code of Manufacturing Practice has been in place since 17 January 2014. The Code focuses on making sure all psychoactive products on the market in New Zealand are made to a consistently high standard in clean, controlled environments, and details the quality control requirements for psychoactive substances and products. The Code outlines the processes and information that must be submitted to the Authority for assessment.

The Code and its implementation plan can be found at <http://www.health.govt.nz/publication/psychoactive-substances-code-manufacturing-practice>

The dates for compliance with the Code are shown in Figure 2.

Figure 2: Overview of implementation dates for Psychoactive Substances Code of Manufacturing Practice



The Code applies to manufacturers only, but together the regulations and Code will focus on product quality and safety.

Regulations

This consultation is on proposals for the Psychoactive Substances Regulations. The Act allows for regulations to apply to:

- psychoactive substances or approved products generally
- particular substances or products
- classes of substances or products.

Once regulations are in force, the part of the regime that they apply to will move from the interim to the full regime.

Regulatory Guidelines

As part of the regulations development, Regulatory Guidelines will be published. These guidelines will provide detail on how to comply with the regulations, and in particular, how to comply with the Code of Manufacturing Practice.

Overview of consultation topics

This consultation covers the regulatory detail relating to:

- the licence application process
- the product approval process
- labelling and packaging of approved products
- advertising and place of sale matters
- fees and levies.

Proposed two-phase implementation process

Implementation of the regulations is proposed to take place in two phases. Phase one will cover licence applications for all licences except retail licences. For example, phase one will cover licences for importing, researching, manufacturing and wholesaling of psychoactive substances and products. Phase one will also cover product approvals, and labelling and packaging issues because these issues affect importers and manufacturers. Manufacturers and importers will also have to comply with the Psychoactive Substances Code of Manufacturing Practice throughout this period.

The timeframe for having phase one in place is up to Cabinet. Therefore, is it not possible to say exactly when the regulations will be in force; however, it is likely to be around July or August 2014.

The second implementation phase will cover retail licence applications and other matters relating to marketing and retailing products, such as advertising. The difference in timing is to ensure local authorities have time to prepare local approved products policies, if they wish to do so.

The Act is designed to allow local authorities, in consultation with their communities, to determine where psychoactive products can be sold within a council district. The two-phase implementation will allow a managed approach and an integrated licensing system.

Again, it is not possible to say exactly when phase two will take effect because this depends on local authority progress, but it is likely to be by the middle of 2015.

One consultation

This consultation covers details relating to both phases of the implementation of the regulations. There will not be a second consultation on the retail aspects in phase two because these proposals are being consulted on now.

Assessment criteria

The regulatory proposals will be assessed under the following criteria.

- **Health protection** – in line with the purpose of the Act, the regulations will aim to protect the health of, and minimise harm to, individuals who use psychoactive substances.
- **Proportionality** – any burden created by regulations (for example, a cost to a licence applicant) should be in proportion to its corresponding benefit.
- **Certainty** – the regulations must be unambiguous so that anyone needing to comply with them is clear about what is required. Any criteria and processes in the regulations should be clear.
- **Durability** – the regulations must be flexible enough to respond to change.

2 Licence applications

Background

A person who is a New Zealand resident may apply to the Psychoactive Substances Regulatory Authority (the Authority) for a licence to do one or more of the following:

- import psychoactive substances
- manufacture psychoactive substances
- research psychoactive substances (research might be necessary to establish an evidence base for a substance that goes into a product for which approval is later sought)
- sell psychoactive substances that are not approved products (the Act sets out that such substances can only be sold to researchers or wholesalers who are licensed under the Act)
- sell approved products by retail
- sell approved products by wholesale.

Substances and products

The Act distinguishes between a psychoactive substance and a product. A substance is any mixture, preparation, article, device or thing capable of inducing a psychoactive effect. A psychoactive product is the finished product packaged for retail containing one or more psychoactive substances, but it is also a psychoactive substance. Under the Act, products go through an approval process to become approved products.

The Act sets out the requirements for granting a licence. The Authority must grant a licence if it is satisfied that:

- the application has been made in the correct manner and form
- the application does not contain materially false or misleading information
- the applicant is a fit and proper person (or a body corporate of good repute).

Information requirements

The Act requires licence applications to be made in a form and manner approved by the Authority. Applications must also be accompanied by any particulars, information, documents or other material required by the Authority and prescribed in the regulations.

Broadly, the applicants will be required to identify themselves and confirm they meet requirements for the particular class of licence. It is proposed to use the government's RealMe service to verify the identity of applicants, where possible, and to develop other verification processes where it is not possible. This may include supplying a verified copy of a document, such as a passport.

Interim application requirements

In order to meet the identity information requirements, under the interim licence process applicants had to provide details such as their name and address.

A sample interim application (for a licence to manufacture psychoactive substances) is included at Appendix 1.

Proposed requirements

Identification information

Based on experience with the interim application process, it is proposed that the Authority seeks the following information from individual applicants (not corporate applicants):

- residential address (not a PO Box number); mailing address; email address
- date of birth
- gender
- any other names the applicant is known by.

It is also proposed to include consent to undergo a Police check on the application form.

Under the interim application process, applicants must make a statutory declaration (that is, make a signed statement that the information provided is true, witnessed by a Justice of the Peace or other judicial officer). A similar requirement for a statutory declaration is proposed under the regulations.

Keeping information up to date

The Authority needs information to be kept up to date so that it is able to contact licence holders whenever necessary. In order to achieve this, it is proposed that the regulations place an onus on licence holders to advise the Authority of any changes to their contact details.

For retail licences only

Compliance with local approved products policy

Retail licence regulations will be implemented in phase two to allow councils to have their local policies in place. It is proposed to require retail licence applications to be accompanied by information showing compliance with council policy. Doing this early in the process will save both applicants and the Authority time and money checking for compliance later on in the licence application process.

The development of a generic local policy as a fall-back option for applicants from areas where no local policy exists is being considered.

A mechanism for reviewing the on-going operation of a retail licence when a change of premises is required is also under consideration (for example, where a change to a local policy means that a retailer can no longer sell from the address that the licence was issued for).

Consultation questions

- 1 Is the list of proposed information requirements for licence applications comprehensive enough?
If not, what else should be required, and why?
- 2 Should retail licence applications be accompanied by evidence of compliance with a local approved products policy if one is in effect in the applicant's area?
- 3 Should retail licence applications be accompanied by evidence of compliance with a generic local approved products policy if no policy is in effect in the applicant's area?

Fit and proper person test

The fit and proper person test is one of the application criteria in the Act. As long as the other requirements are met, the Authority must grant a licence if it is satisfied that an individual applicant is a fit and proper person, or a body corporate (for example, a company) is of good repute.

In determining whether the applicant is a fit and proper person, the Authority must consider the factors set out in section 16(2) of the Act:

- whether the applicant has been convicted of a relevant offence (defined as an offence against the Act, the Misuse of Drugs Act, Medicines Act or a crime of dishonesty under the Crimes Act)
- whether there has been a serious or repeated failure by the applicant to comply with any requirement of the Act
- whether there are other grounds for considering that the applicant is likely to fail to comply with the Act
- any other matter the Authority considers relevant.

It is proposed that the New Zealand Customs Service and New Zealand Police be involved in the fit and proper person check. This is because these agencies may hold relevant information about an applicant, for example, a person's previous compliance record in regard to importing. Information about previous involvement in other regimes, such as alcohol licensing processes is also being considered.

Your views are sought on what information should be required to adequately demonstrate that a person is fit and proper or that a body corporate is of good repute.

Consultation questions

- 4 Are the factors the Authority should take into account when determining whether a licence applicant is a fit and proper person or whether a body corporate is of good repute in section 16(2) enough?
The section 16(2) factors are:
 - whether the applicant has been convicted of a relevant offence
 - whether there has been a serious or repeated failure by the applicant to comply with any requirement of the Act

- whether there are other grounds for considering that the applicant is likely to fail to comply with any requirement of the Act
- any other matter that the Authority considers relevant.

If you think these factors are not enough, please give examples of additional factors the Authority should consider.

- 5 Should the regulations require applicants to provide details of their involvement in other regulatory regimes, such as alcohol licensing processes?

Licence conditions

Compulsory conditions

For all licences

Export

All licence holders must advise the Authority of any export of a psychoactive substance before it is exported, including the name and quantity of the psychoactive substance, and the intended date of export.

It is proposed that regulations require any person advising the Authority of the export of any psychoactive substance to state the country that the substance is being exported to along with the name and contact details of the importer in that country.

Record keeping – requirements under the Act and regulations

In addition, licence holders must keep records required by regulations. These records must be held in a secure place at the licence holder's place of business.

The regulations can set out what records are required and the length of time they should be kept. Feedback is sought on what records should be kept and for how long.

Proposed additional sales record keeping under the regulations

It is proposed that licence holders should keep sales records – that is, records of the quantity of products received and distributed. If this is required at every step, each sale should be able to link to a licence. For this reason, it is proposed that regulations require the licence number of both the seller and the purchaser, to be noted on every sales transaction (except for retail sales to the public). These records will help determine whether any product leakage is occurring – that is, whether products are being diverted to the illegal market.

For this reason, it is proposed that anyone with a licence to research psychoactive substances must keep records with sufficient detail to trace imported substances.

For specific licence types

Compulsory licence conditions are set out in section 17 of the Act, and include the following conditions relating to specific licences.

- **Licence to import** – Licence holders must advise the Authority of the importation before it takes place, and provide details of the name, quantity and date of importation of the substance.

- **Licence to manufacture** – Manufacturers must comply with the Psychoactive Substances Manufacturing Code of Practice.
- **Licence to sell psychoactive substances that are not approved products** – If granted this licence, the licence holder can sell the substance only to a holder of a licence to manufacture or a licence to research psychoactive substances.

Consultation questions

- 6 What records should the regulations require licence holders to keep?
- 7 How long should licence holders be required to keep records for?

Discretionary conditions

The Authority also has the ability to set discretionary conditions on a licence as it thinks fit. The Authority must provide reasons for these conditions to the licence holder on request.

Discretionary conditions may apply generally to a particular class of licence, or may apply only to an individual licence. The following conditions are proposed for retail licences:

- a requirement to display the licence on the premises
- a declaration if internet sales are proposed.

Other issues being considered include:

- how regulations can achieve the required degree of physical separation, for example, in licensed premises with an adjoining doorway to a dairy
- restrictions on opening hours
- prohibiting the sale of food (with some limited exceptions), confectionery, soft drinks and other household goods at the licence location. This is to ensure the purpose of the Act is met and was included in interim retail licences.

Consultation questions

- 8 Do you think there are factors or issues that the Authority should consider when setting discretionary conditions?
If so, please provide details.

Process for considering applications

It is important that the rules for processing applications are clear, so it is proposed to process licence applications by applying the standard practice used in similar regulatory schemes. It is proposed the regulations set out that applications will be processed in the order in which they are received, with complete applications being processed before those requiring further information (which will be requested).

Any other matter the Authority may consider

Regulations can prescribe any other matter that the Authority must take into account when deciding on a licence application. Your views are sought on what matters the Authority might consider.

Consultation questions

- 9 Should the regulations prescribe other matters the Authority must take into account when deciding on an application?
If yes, what should these matters be?

3 Product approval applications

Information requirements

A person who is a New Zealand resident may apply to the Authority for approval of a psychoactive product as an approved product. 'Person' in this context includes natural persons and bodies corporate.

The application must be made in a form and manner approved by the Authority.

The Authority may also require the applicant to provide further particulars, information, documents or any other material prescribed in the regulations.

One example of further information to be required in the proposed regulations is a description of proposed manufacturing methods and how they will comply with the Psychoactive Substances Code of Manufacturing Practice, which came into effect on 17 January 2014.

This Code focuses on making sure all psychoactive products are made to a consistently high standard in clean, controlled environments, and details the quality control requirements for psychoactive substances and products. The Code outlines the processes and information that must be submitted to the Authority for assessment.

It is proposed that product approval applications will have to explain how the manufacturing processes will comply with the Code. This will focus applicants on what is required early on in the application process, and will save time later.

Consultation questions

- 10 Do you agree that a product approval application should include information on proposed manufacturing methods and how they will comply with the Psychoactive Substances Code of Manufacturing Practice?
- 11 Do you think any further particulars, information, documents or other material should be prescribed in the regulations?
If yes, what should these be?

Grounds for approval

The Authority must approve a psychoactive product as an approved product if all of the following criteria are met.

- The Authority is satisfied that the application requirements are met.
- The application does not contain any materially false or misleading information.
- There is no more than a low risk of harm to individuals using the product.

Determining the risk of harm

The Act deliberately leaves open the question of how to determine a low risk of harm to the individual, because this is a subjective question, and it is a threshold that may shift over time.

Section 11 of the Act sets out a role for experts, convened as the Psychoactive Substances Expert Advisory Committee (PSEAC). PSEAC evaluates trial results to assess whether psychoactive products should be approved for use by individuals, then recommending to the Authority whether a product should be approved or not (the final decision rests with the Authority).

Section 11(3) of the Act states that when evaluating psychoactive products, PSEAC must have regard to:

- “(a) the specific effects of the product, including pharmacological, psychoactive, and toxicological effects; and
- (b) the risks, if any, to public health; and
- (c) the potential for use of the product to cause death; and
- (d) the potential for the product to create physical or psychological dependence; and
- (e) the likelihood of misuse of the product; and
- (f) the potential appeal of the product to vulnerable populations; and
- (g) any other matters that the Authority considers relevant.”

PSEAC also has a role to increase public awareness about its work.

Proposed approach

To support PSEAC and the Authority, it is proposed that the regulations require applications to contain information and data on the toxicity, pharmacology and related clinical effects of a substance.

In addition, it is proposed that the regulations require applications to contain information and data on:

- the psychoactive potential and related behavioural effects of the substance
- the addictive potential
- the proposed directions for use
- previous use, including use in clinical trials and in the wider population.

The regulations will enable the Authority to prepare detailed guidance, including guidance on the test procedures that may be used to generate this data.

Comments received on the issue of assessing the risk of harm from this consultation will be presented to PSEAC in order to inform its approach.

Consultation questions

- 12 Do you agree with the proposal that the regulations require applications to contain information and data on the toxicity, pharmacology and related clinical effects of the psychoactive substance they are seeking approval for?
- 13 Do you agree with the proposal that the regulations require product approval applications to contain information and data on:
 - the psychoactive potential and related behavioural effects of the substance
 - the addictive potential
 - the proposed directions for use
 - previous use, including use in clinical trials and in the wider population?

Process for considering applications

The number of licence applications the Authority might receive is unknown. It is likely that for some application types there will be an intensive demand for Authority decision-making, especially initially. There will be limits to the number of product approval applications that can be assessed by PSEAC and considered by the Authority. This may become important because new products will not be able to be sold until approved; therefore there is a significant commercial value (including potential market advantage) in gaining approval as quickly as possible.

It is important that the rules for processing applications are clear, so it is proposed to process product approval applications by applying the standard practice used in similar regulatory schemes. It is proposed the regulations set out that applications will be processed in the order in which they are received, with complete applications being processed before those requiring further information (which will be requested).

Additional products

It is proposed that products containing the same mix of active ingredients marketed in different size packages or with different flavours will require approval as additional products.

For information about proposed fees for additional product approvals, please refer to chapter 6.

4 Labelling and packaging

Part 3 of the Act places controls on approved products. These controls involve a set of restrictions and requirements that limit how and when approved products can be marketed and sold, and whom they can be sold to. While some details relating to these issues are covered in the Act, further detail in the regulations will refine the operation of these controls.

All importers, manufacturers and wholesalers of approved products must comply with regulations. Manufacturers also have to comply with the Psychoactive Substances Code of Manufacturing Practice, which came into effect on 17 January 2014. Guidelines that contain detail on how to comply with the Code and the regulations will also be published in due course. The Code and the guidelines will together provide detail (beyond that supplied in the regulations) on how to comply with many aspects of the regime, including the labelling and packaging of approved products.

Labels

The Act sets out some rules on labelling. A label must not appeal to minors. Labels must also list the following information in a prominent position:

- active ingredients and their quantity
- an appropriate health warning
- contact details for the importer, manufacturer, wholesaler or retailer of the product
- the National Poisons Centre telephone number and any other number prescribed in the regulations (for example, the regulations could prescribe the number of the Alcohol and Drug Helpline)
- any other information prescribed by the regulations.

Regulations may prescribe additional labelling restrictions or requirements. For example, the Act sets out that a label must contain an appropriate health warning, but the regulations could elaborate on what an appropriate health warning should include. Some proposed health warnings are given later in this chapter.

The Act sets out examples of the type of matters that regulations might cover:

- restrictions relating to labelling designed to be particularly appealing to minors
- prescribed requirements, such as plain packaging
- a requirement that labels appear on both inner and outer packages, containing certain prescribed information.

Labelling matters proposed for the regulations include requirements that labels must clearly show:

- a bar code
- a batch number
- an expiry date
- the recommended dose
- contact details for the importer, manufacturer, wholesaler or retailer of the product that include a physical New Zealand street address (not a PO Box number).

These requirements offer a measure of consumer protection, and the bar code in particular, will assist with record keeping, and with tracing of products.

It is also proposed that the regulations require the label to be:

- clearly visible and legible
- in English
- durable
- placed in a prominent position on the product, where it won't be damaged or removed when the container is opened
- designed to maximise safe use of the product.

The proposed regulations will allow the Authority to waive particular labelling requirements if the safe use of the product is not compromised by doing so.

All of these requirements are similar to those in the now revoked Misuse of Drugs (Restricted Substances) Regulations 2008.

Guidelines may set out further labelling details that will operate as best practice guidelines. The guidelines are likely to include recommendations over and above the minimum requirements in the Act and regulations.

Consultation questions

- 14 Are the proposed requirements and restrictions on labelling sufficient?
If not, please make specific suggestions for further requirements and restrictions.

Health warnings

The Act requires each label to contain an appropriate health warning.

Examples of matters relating to health warnings that may be prescribed in regulations are provided in the Act. These relate to labels and advertisements, and cover both the information that might appear in a warning and its form, such as prescribing:

- the information that should appear in a health warning
- requirements relating to the manner, way, medium or form in which health warnings should appear in labels and advertisements.

Four compulsory warnings are proposed in the regulations to satisfy the Act's requirement for appropriate health warnings.

- 1 Do not drive a vehicle or operate machinery after consuming.
- 2 Do not consume with other drugs, alcohol or medicines.
- 3 Do not consume if you are breastfeeding, pregnant or think you could be pregnant.
- 4 Do not exceed the stated dose.

It is proposed that the regulations should require health warnings to be displayed on the packaging and on any inserted material.

Consultation questions

- 15 Are the proposed requirements relating to health warnings sufficient?
If not, please make specific suggestions for further requirements (for example, advice on what to do in the case of an overdose).

Packaging

The Act does not specify packaging requirements or restrictions, but allows for these to be prescribed in regulations. Section 101(1) (f) and (g) of the Act provides examples of requirements or restrictions that may appear in the regulations:

- requirements or restrictions relating to the size and type of packaging, for example, tamper-proof or child-proof packaging
- the type of material and the medium or form of material that may be inserted in packages. for example a restriction against material that may associate approved products with youth culture
- the content of material to be inserted, such as information leaflets about contraindications for use of the approved product
- the material and the medium or form of material to be inserted in packages, such as a requirement for material to be presented in a certain size or manner.

Proposals being considered for inclusion in regulations are:

- requiring packaging to be tamper proof and child proof
- enabling the Authority to refuse packaging that associates approved products with youth culture
- prohibiting the use of swear words and other words with inappropriate connotations, especially as product names
- prescribing detail for the content of inserted material, such as repeating the health warnings that are required on labels and setting out any contraindications
- detailed prescription of material, and medium and form of material to be inserted.

As these products are often sold in small packages, and a lot of detail will be required on labels and packages, it is likely inserts will be necessary. It is proposed that the content of inserts and their appearance and accessibility within the product must be approved by the Authority.

Consultation questions

- 16 Are the proposed packaging requirements and restrictions sufficient?
If not, please make specific suggestions for further requirements.

Quantity and dose requirements

Regulations can prescribe the quantity, or maximum dosage or serving of an approved product that can be sold at any one time.

Dose restriction

It could be useful for products to be restricted to a dose size, to help protect consumers of approved products, which is in line with the purpose of the Act. This might mean limiting pack sizes (whether tablet, capsule or smokeable product) to one dose. The proposed labelling requirements will specify a dose, and the label will include a warning not to exceed this stated dose.

Requirement to split the dose wherever possible

For products in tablet or capsule form, it is also proposed to require that one dose is split into several units wherever possible, for example split into four tablets, rather than consumed in one tablet. This approach is used elsewhere to reduce the risk of overdose, and in particular, to minimise harm to children who accidentally consume products. As with medicines, a number of earlier steps in the process will help avoid consumption by children – such as restrictions on sale to anyone under 18 and the requirement for child-proof packaging, but this dose-splitting restriction could strengthen protection for children.

While comments from any submitter are welcome, the views of health professionals about restrictions on the quantity of product that can be sold at any one time, and on any dose restrictions or requirements, are particularly welcome.

Consultation questions

- 17 Do you agree with the proposal to restrict a packet to one dose?
(Please give reasons for your answer.)
- 18 Do you agree with the proposal that a dose, in whatever form the product takes, is split wherever possible?

Restrictions on form of product

Regulations can restrict the form that an approved product can take. Some restrictions already appear in the Act. For example, a psychoactive product is not allowed to resemble food.

Your views on whether there should be further restrictions in regulations are sought, for example, products might be restricted to tablet or similar forms. It may also be helpful to prohibit certain forms. For example, products intended to be injected will not be permitted, as they would not meet the standard of 'low risk' simply because of the mode of delivery, and it may be useful to specify that in regulations.

Your views on smokeable products are also sought, given that the majority of products on the market are prepared as smokeable products. This raises an issue about whether the regulations should be consistent with New Zealand's policies on smoking tobacco, taking into account the particular health risks arising from the smoking of psychoactive products.

Consultation questions

- 19 Do you think there should be restrictions on the form products can take?
If so, what forms do you think should and shouldn't be allowed?

Storage, disposal and display

Regulations can set restrictions or requirements relating to storage, display or disposal of both psychoactive substances and approved products.

Psychoactive substances

For psychoactive substances, the Act says that restrictions or requirements in regulations may relate to:

- the storage of psychoactive substances, such as:
 - setting a maximum amount of a psychoactive substance that can be stored at premises at any one time
 - a requirement to store a psychoactive substance at or below a certain temperature
- the way to dispose of a psychoactive substance.

Storage

There is no proposal to restrict the amount of a psychoactive substance that can be stored at premises at any one time.

Disposal

Disposal of psychoactive substances (except for finished products), like other chemicals, is governed by the provisions of the Hazardous Substances and New Organisms Act (see section 104 of the Psychoactive Substances Act). Accordingly, it is not proposed to include anything about the disposal of psychoactive substances in regulations.

Consultation questions

- 20 Do you think there should be restrictions or requirements on the storage of psychoactive substances?
If so, what should the restrictions or requirements be?

Approved products

Stipulations can also be made in regulations for approved products, for example:

- their storage for sale, such as a limit on the maximum amount that can be stored at premises at any one time
- a requirement to store an approved product at or below a certain temperature
- the display of approved products for sale inside retail premises, for example regarding a particular place or that the products not be visible from the street.

No restrictions or requirements of this nature are proposed. If a particular product requires storage within a certain temperature range, a condition to that effect can be put on the product approval.

Consultation questions

- 21 Do you think restrictions or requirements should be set for the storage of approved products?
If so, what should they be?
- 22 Do you think restrictions or requirements should be set regarding the display of approved products?
If so, what should they be?
- 23 Do you think restrictions or requirements should be set regarding the disposal of approved products?
If so, what should they be?

Signage

Regulations can prescribe requirements for signs that have to be displayed where approved products are sold. Prescribed requirements can include those relating to the manner, way, medium and form in which any required signage must be displayed. This could extend to a requirement in the regulations that a sign must be of a certain size and state certain information, for example, that the approved product cannot be sold to a person under the age of 18 years, or what the recommended maximum dose is.

Consultation questions

- 24 Do you think there should be signage requirements in the regulations?
If so, please give specific suggestions.

5 Place of sale and advertising

Proposed two-phase implementation

This chapter covers issues relating to retail of approved products. It is proposed that retail matters are implemented after local councils have passed their own policies. This is likely to be during 2015.

Evidence that an application for a retail licence complies with a local approved products policy is proposed as part of the licence application (see chapter 2).

Place of sale

The Act restricts where approved products can be sold. For example, they cannot be sold in dairies, convenience stores, grocery stores or supermarkets. Nor can they be sold where alcohol is sold, in automotive service or repair facilities, or in tents or mobile street carts (see section 52 of the Act).

Regulations can specify further places where approved products may not be sold.

Consultation questions

- 25 Do you think the regulations should specify further places where approved products may not be sold?
If so, please provide specific suggestions.

Local government policies for approved products

The place of sale restrictions under the Act link to another part of the Act which allows (but does not require) a territorial authority (that is, a city or district council) to have a policy relating to the sale of approved products in its district (called a local approved products policy – see section 66 of the Act).

Local authorities must use a special consultative procedure (see section 83 of the Local Government Act 2002) to adopt a policy and it must be reviewed within five years of its adoption.

A local approved products policy can state where products can be sold by reference to:

- broad areas
- proximity to other premises from which approved products are sold
- proximity to facilities of a particular kind (for example, not within a certain distance from a school or other community facility).

Regulations relating to retail licences are proposed to be brought in after territorial authorities have their local policies in place. This is so that the licencing process is well integrated with these local policies. These regulations will form phase two of the proposed implementation process.

Advertising

The Act controls where approved products can be advertised. Psychoactive products must not be advertised on television, radio, newspapers, magazines or the internet (unless the internet site is for the primary purpose of advertising approved products for sale).

Regulations can also prohibit advertising in any other media (section 56(1)(d)).

Regulations can prescribe restrictions or requirements relating to the manner, way, medium or form in which approved products are advertised. One proposal being considered is a requirement in regulation that any advertisement must be consistent with the Advertising Standard Authority's Advertising Code of Ethics.

Consultation questions

- 26 Do you think the regulations should prescribe restrictions or requirements for advertisements of approved products?
If so, please provide specific suggestions.

Internet sale restrictions

Only internet sites maintained for the primary purpose of advertising approved products for sale may advertise approved products.

Regulations can prescribe restrictions or requirements relating to the location, manner, way, medium or form in which approved products are offered for internet sale.

Examples given in the Act include restrictions on advertising on sites designed to appeal to minors, restricting access to the site by minors or requiring health warnings to be placed on the site.

Proposed requirements

It is proposed that the regulations require an entry page to any internet site advertising psychoactive products for sale to verify the age of the person accessing the site.

It is also proposed that the website contain a declaration by the purchaser that they will not on-sell the products to any person under the age of 18, in accordance with the requirement in the Act.

Publication of the licence on the website is another proposed requirement.

Requirements for internet sale sites to contain health warnings are also proposed, as are regular audits so that sales can be tracked.

Consultation questions

- 27 Do you think the regulations should prescribe restrictions or requirements on internet sales of approved products?
If so, please provide specific suggestions.

Advertising restrictions or requirements

On-site advertising is restricted to the inside of premises where the approved product is offered for sale and to communicating objective product information such as price or active ingredients.

Regulations can prescribe restrictions or requirements relating to the manner, way, medium or form in which approved products are advertised.

It is proposed that the regulations contain detail that ensures on-site advertising is restricted to objective information only.

Consultation questions

- 28 Do you think the regulations should prescribe restrictions or requirements on the advertising of approved products?
If so, please provide specific suggestions.

6 Fees and levies

Introduction – the Act’s framework

The Act’s framework is one of cost recovery (set out in sections 90 to 97). Cabinet agreed that the industry will meet the costs of administering the Act, including the costs of running the Authority. Under the Act, the Minister must take all reasonable steps to ensure that any direct and indirect costs of administering the Act that are not provided for by money appropriated by Parliament are recovered, whether by fees, levies or otherwise.

A fee is a charge for a specific good or service. The general principle is that people or organisations directly benefiting from the specific good or service can be charged a fee for it.

In contrast, a levy is used for a defined purpose, which is not a particular good or service. Road user charges are a levy paid by owners of diesel and heavy vehicles where the money gathered is put towards the upkeep of roads. Levies can be a useful way to recover indirect costs, such as when it is not possible to directly link the cost or benefit to a specific person or group. The running of the Authority has many indirect costs.

When determining the appropriate method of cost recovery (for example, whether by fees or levies), the Minister must, as far as reasonably practicable, have regard to the following principles of cost recovery in section 91 of the Act.

- **Equity** – those who use or benefit from the function, power or service being funded should pay for it according to their level of use or benefit.
- **Efficiency** – the aim is to deliver maximum benefit at minimum cost.
- **Justifiability** – only actual and reasonable costs are recovered.
- **Transparency** – costs are identified and allocated by tangible provision.
- **Ease of administration** – the costs of collection should be kept as low as possible.

Consultation is required before costs can be recovered, although not to the point of consulting on specific levels of fees or charges (see section 91(3)). The Act allows for setting fees or charges by averaging costs and by including indirect costs relating to the service being charged for. The Act also states that strict apportionment of costs based on usage is not required. Fees and levies have to be reviewed every three years (section 94).

Section 92 of the Act allows a range of cost recovery methods:

- fixed fees or charges
- scales, formulas or rates determined on a time-unit basis
- figures based on actual and reasonable costs
- estimated costs being paid before the provision of the service and reconciled after its provision
- prepaid deposits – either refundable or non-refundable
- fees or charges imposed on all users or beneficiaries of services, or on classes or groups of them
- levies
- any combination of the above.

These cost recovery methods and amounts can be set by regulations. The regulations prescribing fees and charges may:

- prescribe fees or charges of the kinds listed above from section 92
- specify who is liable to pay
- exempt any person or class of people from payment
- provide for waivers or refunds.

With regard to levies, the Act states that regulations may:

- prescribe different levies for different classes of people (for example, the levy on importers could be set at a different amount to the levy imposed on retailers)
- specify the amount of the levy
- set out the method by which the levy will be calculated
- specify criteria for setting or resetting the levy
- provide for payment and collection
- exempt any person or class of people from paying
- provide for waivers or refunds
- provide for anything else.

Licence applications – a set fee

It is proposed that a set fee is charged for licence applications to:

- import psychoactive substances
- manufacture psychoactive substances
- research psychoactive substances (research might be necessary to establish an evidence base for a substance that goes into a product that approval is later sought for)
- sell psychoactive substances that are not approved products (the Act sets out that such substances can only be sold to researchers or wholesalers who are licensed under the Act)
- sell approved products by retail
- sell approved products by wholesale

A set fee is proposed, based on an estimate of the actual time and resources required to process the application. A fee based on actual processing costs is appropriate because it is clear who benefits (the licence applicant), and the processing costs are reasonably predictable. A set fee provides certainty about costs for applicants and it puts an onus on the Authority to process applications efficiently.

Processing licence applications will require checking for compliance with the application requirements and verifying that the statutory declarations had been carried out properly. Retail licence applications will also involve an inspection of the premises, and once in operation, at least one visit from a psychoactive substances enforcement officer.

The Authority considered charging fees based on an hourly rate for receiving, analysing and determining licence and product applications. The Authority decided against this approach because:

- it would not provide certainty for applicants of what they would be charged for an application
- it would be inefficient to invoice applicants on an hourly basis – the administrative time that it would take would be disproportionately high compared to the revenue gathered
- the cost of processing applications may change over time as expertise and experience increase, and it would be unfair to charge early applicants more for determining applications than later applicants.

Proposed fees calculated on the basis of estimated real costs are set out in table 1. The costs were derived by identifying the inputs required by the Authority to provide the service, divided by the estimated demand.

Table 1: Proposed licence application fees²

Research	Import	Manufacture	Wholesale	Retail	Sell non-approved
\$3000	\$3000	\$50,000	\$5000	\$15,000	\$3000

Proposed fees for the full licence regime are higher than those charged for the interim regime, to reflect the full cost of processing applications.

Consultation questions

- 29 Do you agree with the proposed fees for the different licences?
If not, please provide specific suggestions.

Product approvals

Product approvals are quite different to licensing decisions. They require expert assessment of technical information, and the scope of applications, for example for substances not yet invented, is unknown.

The interim approval process is a less helpful guide than it has been for licence processing, because it operated quite differently to the proposed full approval process. The full process (set out in chapter 3) will be much more detailed and thorough, and will cover new substances as well as existing ones.

A new product fee has been included (the additional products fee). This fee has been included in the fee structure to enable product owners to seek approval for the same mix of substances marketed in different size packages or with non-active flavours. These additional products will not need to be assessed to the same extent as the main product; however, some regulator consideration is necessary given the possibility of harmful impacts from different doses that might be made available. The proposed fee should cover the costs associated with processing additional product applications.

² These figures are estimates based on calculations applying the principles in the Act. Figures will be refined in the final regulations.

Table 2: Proposed product approval application fees³

Main product	Additional products
\$180,000	\$10,000

Consultation questions

- 30 Do you support a fixed fee or an hourly charge for processing applications for product approvals?
- 31 Should fees be set for other specific functions?
If yes, please state what they should be set for.

Levies

Levies allow costs to be spread over a defined group. Levies are useful for costs when it is difficult to attribute a cost to a single person or organisation. Examples of costs that a levy might be charged for include:

- establishing the Psychoactive Substances Regulatory Authority
- policy advice on the administration of the Act and administration of regulations
- stakeholder engagement, for example, between the Authority and other sectors such as local government
- the cost of setting up an infringement regime
- maintaining and deploying enforcement officers for non-licensing activities (such as routine visits to facilities or premises to check compliance with the Act, regulations or licence conditions)
- Public Health Unit officers' time assisting with the administration of the Act
- operation of the Psychoactive Substances Hotline 0800 789 652
- maintenance of dedicated databases and website.

An analysis has been undertaken of the work and resource needs generated across the psychoactive product industry for the administration of the Act. The next five financial years have been divided into an establishment phase (2013/14), initial phase (2014/15 and 2015/16) and steady state 2016/17 and 2017/18). This is to enable establishment costs to be spread evenly over the next six years and to allow upcoming operational costs to be fully budgeted.

The regulatory and administration costs to the product owners and various licence holders were calculated:

- first, on the basis of particular goods or services provided to the categories of licensee (for example, the costs of manufacture audit will be borne by licensed manufacturers)
- second, any unallocated costs (such as overheads) will be charged on a pro-rated basis.

Based on this analysis, the estimated cost of the annual levy for each licence type is as shown in Table 3.

³ These figures are estimates based on calculations applying the principles in the Act. Figures will be refined in the final regulations.

Table 3: Proposed annual levies⁴

Product	Research	Import	Manufacture	Wholesale	Retail	Sell non-approved
\$70,000	\$5000	\$5000	\$30,000	\$5000	\$7000	\$3000

Consultation questions

32 Do you agree with the proposed list of items and process for setting levies?
If not, please provide specific suggestions.

⁴ These figures are estimates based on calculations applying the principles in the Act. Figures will be refined in the final regulations.

Appendix: Example of interim application form

Application form for an interim licence to manufacture psychoactive substances

This form is to be used by a New Zealand resident when applying for an interim licence to manufacture psychoactive substances under Schedule 1, clause 7 of the Psychoactive Substances Act 2013 (the Act).

This application should be made within 28 days of the commencement of the Act.

If granted, this interim licence will continue in force until 28 days after the date on which relevant regulations are made which specify the particulars and requirements of a full licence application and the corresponding fees. After that date the interim licence will be deemed to be cancelled (see Schedule 1, clause 9).

The application must be submitted together with the prescribed fee. The prescribed fee for this application is \$500. The fee should be attached as a cheque made out to Ministry of Health.

Applications and fees should be submitted in hard copy to:
Psychoactive Substances Regulatory Authority
PO Box 5013
Wellington 6145

For further information please contact psychoactives@moh.govt.nz

Applicant details

Company name	
Postal address	
Location of manufacturing premises <i>(if different to above)</i>	
Applicant's name	
Applicant's occupation	
Applicant's email address	
Applicant's phone number	

Conditions/requirements of an interim licence to manufacture psychoactive substances

- You must only obtain psychoactive substances for manufacture from importers licensed to import under the Act, and from persons licensed to sell unapproved psychoactive substances when the import is to manufacture product for research purposes.

- You must ensure that a product’s label complies with the restrictions and requirements set out in section 58 of the Act.
- You must not advertise a psychoactive product in any way that contravenes section 56 of the Act.
- You must adhere to any other restrictions and requirements in the Act.

Statutory declarations

A statutory declaration is a written statement declaring something to be true in the presence of an authorised witness. An authorised witness is a Deputy Registrar/Registrar of the High Court or any district court, justice of the peace, or solicitors or notary public or officer authorised to take and receive statutory declarations.

It is an offence to make a false statutory declaration.

I, of ,
 (full name) (place) (occupation)

solemnly and sincerely declare that:

- I was in the business of manufacturing psychoactive substances or products during the period of not less than 28 days preceding the commencement of the Psychoactive Substances Act 2013
- I am aware of any conditions or other requirements pertaining to the licence and agree to comply with them
- I give authorisation to access personal information, including but not limited to, Police records
- I am a fit and proper person to hold a licence to manufacture a psychoactive substance and have not been convicted of a relevant offence.

I make this solemn declaration conscientiously believing the same to be true and by virtue of the Oaths and Declarations Act 1957.

.....
 Signature of declarant

Declared at
 (place) (date: day / month / year)

Before me
 (name)

.....
 (signature)

For Psychoactive Substances Regulatory Authority Office Use Only	
Interim licence number	
Total fee received	
Peer reviewed	
Customer number	
Invoice number	
Date licence issued	

Making a submission

Submissions close on Friday 21 March 2014 at 5 pm.

Please note: any submissions received after this time will not be included in the analysis of submissions.

Please detach and return this part of the document.

Consultation questions

- 1 Is the list of proposed information requirements for licence applications comprehensive enough?

If not, what else should be required, and why?

- 2 Should retail licence applications be accompanied by evidence of compliance with a local approved products policy if one is in effect in the applicant's area?

- 3 Should retail licence applications be accompanied by evidence of compliance with a generic local approved products policy if no policy is in effect in the applicant's area?

4 Are the factors the Authority should take into account when determining whether a licence applicant is a fit and proper person or whether a body corporate is of good repute in section 16(2) enough? The section 16(2) factors are:

- whether the applicant has been convicted of a relevant offence
- whether there has been a serious or repeated failure by the applicant to comply with any requirement of the Act
- whether there are other grounds for considering that the applicant is likely to fail to comply with any requirement of the Act
- any other matter that the Authority considers relevant.

If you think these factors are not enough, please give examples of additional factors the Authority should consider.

5 Should the regulations require applicants to provide details of their involvement in other regulatory regimes, such as alcohol licensing processes?

6 What records should the regulations require licence holders to keep?

7 How long should licence holders be required to keep records for?

8 Do you think there are factors or issues that the Authority should consider when setting discretionary conditions? If so, please provide details.

9 Should the regulations prescribe other matters the Authority must take into account when deciding on an application? If yes, what should these matters be?

10 Do you agree a product approval application should include information on proposed manufacturing methods and how they will comply with the Psychoactive Substances Code of Manufacturing Practice?

11 Do you think any further particulars, information, documents or other material should be prescribed in the regulations? If yes, what should these be?

12 Do you agree with the proposal that the regulations require applications to contain information and data on the toxicity, pharmacology and related clinical effects of the psychoactive substance they are seeking approval for?

13 Do you agree with the proposal that the regulations require product approval applications to contain information and data on:

- the psychoactive potential and related behavioural effects of the substance
- the addictive potential
- the proposed directions for use
- previous use, including use in clinical trials and in the wider population?

14 Are the proposed requirements and restrictions on labelling sufficient? If not, please make specific suggestions for further requirements and restrictions.

- 15 Are the proposed requirements relating to health warnings sufficient?
If not, please make specific suggestions for further requirements (for example, advice on what to do in the case of an overdose).

- 16 Are the proposed packaging requirements and restrictions sufficient? If not, please make specific suggestions for further requirements.

- 17 Do you agree with the proposal to restrict a packet to one dose? Please give reasons for your answer.

- 18 Do you agree with the proposal that a dose, in whatever form the product takes, is split wherever possible?

19 Do you think there should be restrictions on the form products can take? If so, what forms do you think should and shouldn't be allowed?

20 Do you think there should be restrictions or requirements on the storage of psychoactive substances? If so, what should the restrictions or requirements be?

21 Do you think restrictions or requirements should be set for the storage of approved products? If so, what should they be?

22 Do you think restrictions or requirements should be set regarding the display of approved products? If so, what should they be?

23 Do you think restrictions or requirements should be set regarding the disposal of approved products? If so, what should they be?

24 Do you think there should be signage requirements in the regulations? If so, please give specific suggestions.

25 Do you think the regulations should specify further places where approved products may not be sold? If so, please provide specific suggestions.

26 Do you think the regulations should prescribe restrictions or requirements for advertisements of approved products? If so, please provide specific suggestions.

27 Do you think the regulations should prescribe restrictions or requirements on internet sales of approved products? If so, please provide specific suggestions.

28 Do you think the regulations should prescribe restrictions or requirements on the advertising of approved products? If so, please provide specific suggestions.

29 Do you agree with the proposed fees for the different licences? If not, please provide specific suggestions.

30 Do you support a fixed fee or an hourly charge for processing applications for product approvals?

31 Should fees be set for other specific functions? If yes, please state what they should be set for.

32 Do you agree with the proposed list of items and process for setting levies? If not, please provide specific suggestions.

You do not have to answer all the questions or provide personal information if you do not want to.

This submission was completed by: (name) _____
Address: (street/box number) _____
(town/city) _____
Email: _____
Organisation (if applicable): _____
Position (if applicable): _____

Are you submitting this:
(Tick one box only in this section)

- as an interim licence holder
- a person or body corporate intending to apply for a licence
- other (please specify):.....

Do you wish to receive updates about the development of the psychoactive substances regulations?

- Yes
- No

(If yes, please make sure you provide an email address.)

Please return only *one* copy of your submission no later than **5 pm on Friday 21 March** to:

The Manager
Psychoactive Substances Regulatory Authority
Ministry of Health
PO Box 5013
WELLINGTON
Email: psychoactives@moh.govt.nz

Alternatively, electronically complete the submission form available at the back of this document, add your comments and email to:
psychoactives@moh.govt.nz

Please put 'Regulations Consultation' in the subject line.

Your submission may be requested under the Official Information Act 1982. If this happens, the Ministry of Health will release your submission to the person who requested it. However, if you are submitting as an individual (rather than representing an organisation), the Ministry will remove your personal details from the submission if you tick the following boxes.

- I do not give permission for my personal details to be released under the Official Information Act 1982.
- I do not give permission for my name to be listed in the published summary of submissions.