SUBMISSION ON THE PSYCHOACTIVE SUBSTANCES REGULATIONS

To: Ministry of Health

Details of Submitter: The Southern District Health Board

Address for Service: Public Health Service
Southern District Health Board
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Contact Person:

Our Reference:

Date: 18/03/2014

Introduction

Southern District Health Board (Southern DHB) presents this submission via its Public Health Service. This Service is the principal source of expert advice within Southern DHB on matters concerning Public Health. Southern DHB has a responsibility under the New Zealand Public Health and Disability Act 2000 to improve, promote and protect the health of people and communities. Additionally there is a responsibility to promote the reduction of adverse social and environmental effects on the health of people and communities. With 4,500 staff, we are located in the lower South Island (South of the Waitaki River) and deliver health services to a population of 304,000.

Public health services are offered to populations rather than individuals and are considered a "public good". They fall into two broad categories – health protection and health promotion. They aim to create or advocate for healthy social, physical and cultural environments.

This submission provides feedback on the consultation document for the Psychoactive Substances Regulations. Our submission follows the format of answering the questions posed in the consultation 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?

   In addition to the proposed requirements, we would suggest that applicants be required to provide a telephone number. Not only would this provide an additional method of contacting the applicant, it would allow more immediate contact than email/post if there was an urgent issue or enquiry, both during the application phase as well as after the license is issued. We would however recommend that telephone numbers should not be made publically available.

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?

   Yes, they should. In most circumstances it would be unusual for the Authority to not comply with local policy when making decisions regarding retail licences. By providing evidence of compliance with a LAPP at the time of application, the Authority will be able to process applications more efficiently.

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?

   Although this would likely be beneficial from a Public Health point of view (in terms of limiting the availability of psychoactive products), we feel that the content of a LAPP is meant to reflect a community’s attitudes towards sales of psychoactive products within their local area. We would not want to see communities bound by a generic LAPP that they were not consulted on.

   We propose that the Ministry of Health could develop a generic template LAPP for councils, which they could put out to their community for local consultation before being adopted, if a council did not have the time or expertise to develop a LAPP independently. However, if a community chooses not to establish an LAPP they should be free to make this choice.

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.

We feel that the application form should more clearly spell out relevant offences, with yes and no tick boxes to clearly identify if an applicant has been convicted of particular crimes, rather than just having them sign a statutory declaration of being a fit and proper person that has not been convicted of a relevant offence. It is possible an applicant with a conviction may not be aware of the Act that they were convicted under.

We suggest that there are some additional relevant offences that the Authority should be aware of before deciding whether or not to grant a licence, such as convictions for homicide, sexual assault or other violent crimes.

We further suggest that applicants should have to divulge instances where they have been involved in disciplinary proceedings brought by a professional body, to be able to identify those individuals who may have a history of 'behaviour' but who have managed to evade criminal conviction.

E.g. Question to include on the application form:

- Have you ever been convicted of a drug-related (including medicines) or alcohol-related offence? Yes □ No □
- Have you ever been convicted of burglary, theft, vehicle-related offences, fraud or receiving? Yes □ No □
- Have you ever been convicted of a violent crime (homicide, assault, sexual assault, firearms offence)? Yes □ No □
- Have you ever been convicted of selling tobacco, alcohol or psychoactive substances to a person younger than 18 years of age? Yes □ No □

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

Yes, because this relates to the point in Q4 about grounds for considering that the applicant is likely to fail to comply with requirements of the Act — if they have a proven inability to comply with one set of regulatory requirements it could suggest that the applicant may be less likely to comply with psychoactive substances regulations. We suggest that where an applicant has either had a licence to sell alcohol suspended or cancelled or a duty manager's certificate suspended or cancelled; or been refused a licence for the sale of alcohol on grounds of suitability they should be required to declare this.
6 What records should the regulations require licence holders to keep?

We agree with the proposal to require all sales transactions (except retail sales to the public) to be recorded and linked to a licence, to enable accurate tracking of product at every stage from import/manufacture to distribution to retailers.

Although they should not be required to record sales to individual customers, retailers should be required to record batch numbers/suppliers for all incoming product and do regular (weekly) stocktake to keep track of sales volumes.

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

For all licences records should be kept for 7 years, to be consistent with the requirements for financial record keeping for IRD.

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

We agree that retailers should be required to display their licence at their premises. Websites for internet sales should also have a link where customers can click to see a copy of the licence, so customers can be sure that they are dealing with an approved retailer.

Retail premises should have no internal access to other retail premises that are not licensed to sell psychoactive products (such as a dairy or DVD shop).

We feel that the regulations should prescribe maximum permitted trading hours for all retailers (similar to the Sale and Supply of Alcohol Act), so that licensees are not able to sell approved products 24-hours a day. We feel the Authority should also be able to specify reduced trading hours on any individual retail licence where it sees fit.

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?

The Regulatory Authority should be required, except under very extraordinary circumstances, to abide by the conditions set out in an LAPP.

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?

Yes, we agree with this proposal.
11 Do you think any further particulars, information, documents or other material should be prescribed in the regulations? If yes, what should these be?

We feel it would be relevant to ask applicants to provide credentials for key staff involved in the product development/manufacturing, so that there can be some level of assurance that the proposed manufacturing methods are possible and will result in production of the intended product.

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?

Yes, we agree with this proposal. We also feel that this requirement should be on-going, not just a one-off at the time of initial application. The licensee should be required to submit updated safety data with each renewal of their licence, so that the long-term effects of product use can be monitored. Manufacturers should have to be responsible for the monitoring of the effects of their substance in the community including supporting the investigation of any adverse events, as is standard for the pharmaceutical industry.

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?

Yes, we agree with this proposal.

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

Yes, we feel the proposed labelling requirements are very comprehensive, particularly in consideration of the small package size of psychoactive products.

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).

Yes, we feel the proposed health warning requirements are sufficient.
16 Are the proposed packaging requirements and restrictions sufficient? If not, please make specific suggestions for further requirements.

We propose that if plain packaging is approved for tobacco products, that it also be implemented for approved psychoactive products.

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

Yes, we agree with this proposal. New Zealand research shows that many users of approved psychoactive products take higher than recommended doses.\(^1\) By limiting a packet to a single dose, it will be clear to users what the recommended dose is, which may encourage safer use of approved products.

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

We agree that within a single-dose packet, the dose should be split into several portions where possible. We feel there could be several benefits from this format—it will reduce harm resulting from accidental ingestion by children or others, it will allow new users of the product to try a smaller amount and ascertain its effects before ingestion of a whole dose, and also allow established users to more easily elect to use a lower dose.

We recognise that smaller portions would also make it easier for users to have “one and a bit” doses, but feel that restricting packets to a single dose will highlight to users that extra “top-ups” are in excess of the recommended dose.

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?

Yes. We recommend that products cannot be in the form of liquids or powders, to discourage injection or snorting of products, as well as the “lacing” of other people’s food or drink. Products should not be in the form of tabs of paper that have been soaked in psychoactive substances (similar to the format of LSD). We also recommend that tablets not be in a shape or form that appeals particularly to minors (like skateboard-shaped tablets) or that resembles food or confectionary (psychoactive gummy bears).

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

We do not feel there is a need to restrict the quantity of psychoactive substance that can be stored at a premise, but we would recommend that psychoactive substances be required to be stored securely on site after hours. In case of a break in at a premise, it should be very difficult to gain access to psychoactive substances — they should be stored within a secure, lockable containment unit.

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

We do not feel there is a need to restrict the quantity of approved product that can be stored at a premise, but we would recommend that products be required to be stored securely on site after hours. Similar to Q20, in case of a break in at a premise, it should be difficult to gain access to approved products — for example, by storing products in a safe or other secure containment unit, or installing lockable roll-down barriers on display shelves etc.

Rather than a requirement to store products at or below a certain temperature, it should be a requirement of the manufacturing licence that the products are stable within the normal range of ambient temperature (e.g. -5°C to +35°C).

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

We recommend display restrictions similar to those in the Smoke-free Environments Act 1990. Neither the products nor their advertising should be visible from outside a premise. If premises are not restricted to patrons over the age of 18 (such as a DVD shop), psychoactive products should be kept out of sight (similar to tobacco) until requested at time of purchase.

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

There should be a requirement for any expired or damaged approved products to be disposed of in a way that is comparable with the requirements for the disposal of other pharmaceutical products. Accurate records regarding the amount of disposed product and the reason for disposal should be kept.

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

Yes, there should be signage regulations. Again, we propose something similar to tobacco regulations, where a sign no larger than A3 size is displayed and there should be a limit of three signs if the internal premises are no larger than 500m². The legal age for purchase should also be stated on the signage.
25 Do you think the regulations should specify further places where approved products may not be sold? If so, please provide specific suggestions.

We propose that approved products may only be sold from premises where entry is restricted to patrons over the age of 18.

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

Advertising should be strictly limited to the point of sale, either in a retail premises or on a dedicated website.

At a retail premises, advertising should be limited to a single printed poster per product; audio/video advertising and advertising (such as brochures) which can be taken out of the shop should not be allowed.

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

There should be very strict requirements on internet sales of approved products, to ensure products are only sold to those over 18.

Internet sites could require payment by credit card, with courier delivery requiring proof-of-age before delivery can happen. If proof-of-age is not provided, the products must be returned to the vendor, with the added cost billed to the buyer.

Another option is for the internet site to request proof-of-age (for example, by requiring a customer to scan a copy of their ID and email it to the internet retailer) prior to dispatching an order.

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

See our response to Question 26.

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

We are not in a position to comment with any expertise on the fee schedule. We do feel that the application fee ($15,000) and yearly levy ($7000) for retailers is quite high. While this could serve to discourage some applicants from seeking a licence, it may also encourage those who do obtain a licence to maximise their sales however they can, to offset these fees.
30. **Do you support a fixed fee or an hourly charge for processing applications for product approvals?**

   We have no preference on this issue, in so far as the costs of processing applications are covered provided that the fees/charges recovered are sufficient to meet the cost of processing the application.

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

   There could be a fee set for individuals/body corporate to appeal a decision by the Authority. However, we are not in a position to comment with any expertise on what would be an appropriate fee.

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

   We have no preference on this issue.

Thank you for the opportunity to provide feedback on the Psychoactive Substances Regulations.

Kind regards,

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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)*: Public Health Service, Southern District Health Board

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.
21 March 2014

The Manager
Psychoactive Substances Regulatory Authority
Ministry of Health
PO Box 5013
Wellington 6145

To The Manager

Re: Submission on Psychoactive Substances Regulations

Thank you for the opportunity to provide a written submission on this consultation document.

Regional Public Health (RPH) serves the greater Wellington region, through its three district health boards (DHBs): Capital and Coast, Hutt Valley and Wairarapa. As a service, RPH is part of the Hutt Valley District Health Board.

We work with our community to make it a healthier safer place to live. We promote good health, prevent disease, and improve the quality of life for our population, with a particular focus on children, Māori and working with primary care organisations. Our staff includes a range of occupations such as: medical officers of health, public health advisors, health protection officers, public health nurses, and public health analysts.

The sale and use of psychoactive substances in our communities is a concern, particularly amongst health organisations, community providers, parents and the police.

RPH wish to make the following comments

a) General Local Approved Product Policies

The Psychoactive Substances Act 2013 has proposed that in the event that a Territorial Authority does not adopt a Local Approved Products Policy (LAPP), a General Local Approved Products Policy will apply (GLAPP).

RPH recommends the GLAPP remain broad and confined to specifications on location. In particular RPH recommends restricting the location and proximity of premises selling approved products to 100 metres away from kindergartens, early childhood centres, schools, places of worship, youth centres, mental health and addiction services or other community facilities. This will reduce the exposure to young people and those people vulnerable to the harmful effects of these products.

b) Tax

Approved products should be taxed in order to cover potential expenses to government services including justice, social services and health.
c) **Licensing Application Process**

RPH strongly recommends that the licensing process for the sale of approved products be administered by Psychoactive Substances Officers.

d) **General Statement on the Evidence**

Psychoactive substances are relatively new products and therefore there is limited evidence and research on their effects and methods of harm prevention. For this reason the following submission has made recommendations based on what has been effective in preventing harm for other legal recreational drugs such as alcohol and tobacco.

e) **Reporting Adverse Reactions**

RPH recommends establishing a user friendly service to record information about adverse reactions to specific approved products. The Centre of Adverse Reactions Monitoring (CARM) is the agency responsible for collecting and responding to adverse reactions of approved products.

It is recommended that CARM specifically are promoted as the first agency to contact when reporting an adverse reaction to an approved product. Currently CARM is not being promoted and instead several other options are being promoted including the Psychoactive Substances Hotline, the National Poison’s Centre and the Alcohol and Drug Helpline. These are not ideal as many have long wait times and not all the staff operating these lines have knowledge of where or how to report an adverse reaction.

It is recommended that CARM establish a user friendly system to file reports about adverse reactions to approved products. It would be ideal if members of the public could make a report orally over the phone or by completing a form that is specific to psychoactive substances. CARM’s current system requires a form to be completed online or via fax. This may not be suitable for those who do not have access to the internet or a fax machine. In addition the forms are set up to be completed by medical professionals and ask for patient information, NHI numbers, and the name and dose of the ‘medicine’. It would be useful to develop forms for members of the public to report harms relating to psychoactive substances specifically.

Responses to specific questions, as listed within the Psychoactive Substances Regulations consultation document

1. **Is the list of proposed information requirements for licence applications comprehensive enough?**
   Yes, the current list of information requirements is adequate.

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?**
   Yes, by providing evidence of compliance, this will assist in determining if the application is eligible.

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?**
   Yes, by providing evidence of compliance this will assist in determining if the application is eligible. Please refer to the ‘General Comments’ section above, that discusses *Generic Local Approved Products Policies*. 

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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?
RPH recommends that the ‘fit and proper person test’ should aim to select only individuals with the highest possible ethical and moral standing. This is also a requirement to hold a liquor licence but RPH suggests that psychoactive substances licences should meet a much higher threshold. RPH recommends that the threshold should be similar to that used to obtain and keep a firearms licence. Police vetting alone would not be enough. A firearms licence requires a minimum of two character referees, including one being a spouse, health requirements and the applicant has to sit a firearms safety test.

With respect to a ‘body corporate’ RPH recommends that there should still be a named person who holds the licence and can be held accountable. Just being of ‘good repute’ would not be a high enough threshold for a psychoactive substances licence.

5 Should the regulations require applicants to provide details of their involvement in other regulatory regimes, such as alcohol licensing processes?
Yes, details of applicant’s involvement in other regulatory regimes will assist in providing evidence to assess the applicant’s ability to demonstrate if they are a fit and proper person or body corporate of good repute.

6 What records should the regulations require licence holders to keep?
RPH recommends licence holders keep a record of the following:
- The quantity of a product sold within a single transaction
- A record of incidences as similar to a Liquor Licence Incidence Record. This keeps track of specific incidences that occur when selling approved products. For example, how often minors may attempt to purchase a product.

7 How long should licence holders be required to keep records for?
RPH recommends these records be kept for a minimum of seven years; this provides a substantial time span to conduct an audit if necessary.

8 Do you think there are factors or issues that the Authority should consider when setting discretionary conditions?
RPH agrees with all the recommended discretionary conditions.
RPH recommends adding the two following discretionary conditions:
- Limit stock on premises
  This will enable licensing officers to set limits on stock when necessary. This could be due to the location of the store or previous history of theft/burglary.
- Each outlet must be set up as their own entity
  RPH has encountered examples of premises selling alcohol in the past that have split their outlet into two premises. This has resulted in several difficulties including the use of one staff member for both premises and products being visible from outside the licensed store due to shared counters or windows between stores.

9 Should the regulations prescribe other matters the Authority must take into account when deciding on an application?
RPH would like it to be stipulated in the Act, that licensed stores should apply for a second licence if they want to sell products on the internet. Products sold on the internet should be considered a second outlet as they require additional administrative processing and a
different set of requirements to be checked. As the Act is written, this particular circumstance has not been considered.

RPH recommends that all new licensees provide evidence that they have advised their Territorial Authority (TA) of their intention to open a store within their district as most TAs have an invested interest in what is occurring within their communities.

RPH recommends that a licensee has undertaken consultation with the community similar to the requirements under the Sale and Supply of Alcohol Act 2012. In all cases the licensee is required to inform the public through public notices of their intent. This allows community an opportunity to oppose any application and have their views heard by the Authority or designated group similar to District Licensing Committees before a decision is made around whether or not a licence is approved.

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 (PSCMP)?
Yes. RPH agrees manufacturing methods should comply with the PSCMP, as it is important in determining whether the product is safe for use and are of low harm.

11 Do you think any further particulars, information, documents or other material should be prescribed in the regulations?
No comment.

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?
Yes. RPH agrees it is necessary to provide data on toxicity, pharmacology and related clinical effects of psychoactive substances 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 behavioural effects of the substance, addictive potential, directions for use, previous use, including use in clinical trials and in the wider population?
Yes. RPH agrees it is necessary to provide all the recommended information behavioural effects, addictive potential, directions for use, and previous use in clinical trials and the wider population. This information is important in determining whether the product is safe for use and are of low harm. RPH staff continue to receive reports of highly adverse reactions to the interim products that are currently on the market. It is strongly recommended that ALL relevant information is provided and used to assess and make informed decisions on the safety and harm of a product before it is sold.

14 Are the proposed requirements and restrictions on labelling sufficient?
RPH strongly agrees to all the proposed labelling requirements. RPH also recommends the following additional labelling requirements:
- A full list of ingredients rather than just a requirement for ‘active’ ingredients. Non-active ingredients may still pose a risk to those with allergies.

15 Are the proposed requirements relating to health warnings sufficient?
RPH strongly agrees to all the proposed labelling requirements. RPH also recommends the following additional labelling requirements:
- Health warnings should include any known side effects that have been identified during the product testing phase
- A warning on products intended for smoking that ‘inhaling smoke will cause damage to the lungs’
- A warning that the drug will have a mind altering effect and may pose an unknown risk to mental wellbeing
- CARM’s contact details to report an adverse reaction.

Labelling requirements should be developed in consultation with health professionals and health sector agencies to determine size, colour and graphics necessary for health warnings.

16 Are the proposed packaging requirements and restrictions sufficient?
RPH recommends products are packaged in plain packaging. This is based on the strong support to introduce plain packaging to tobacco products in order to reduce their visual appeal\(^2\).

RPH recommends that products sold as pills must be packaged in ‘blister packets’. Evidence suggests blister packets have a significant effect on preventing overdose\(^3\).

17 Do you agree with the proposal to restrict a packet to one dose?
RPH agrees with the proposal to restrict packet size to one dose. There is a strong body of evidence that demonstrates restricting the quantity in packets can reduce overdose rates\(^4\).
RPH has also encountered anecdotal evidence that suggests young people have experienced adverse reactions (including seizures and stroke like symptoms) to approved products due to lack of knowledge about appropriate dose, with some people using an entire 1.3 gram packet in one session.

18 Do you agree with the proposal that a dose, in whatever form the product takes, is split wherever possible?
RPH strongly agrees with the proposal to, wherever possible, split the dose of an approved product. There is a strong body of evidence that demonstrates restricting the quantity in packets can reduce overdose rates\(^5\).

19 Do you think there should be restrictions on the form products can take?
RPH recommends the following restrictions:
- Approved products should not be pre-mixed with food and beverages
- Approved products should not be sold as a pre made cigarette (i.e. joint or mixed with tobacco).

20 Do you think there should be restrictions or requirements on the storage of psychoactive substances?
RPH recommends restrictions on the storage of psychoactive substances be allowed for under discretionary conditions of a licence application (please refer to our comments in Question 8).

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\(^4\) Chan TYK. Improvements in the packaging of drugs and chemicals may reduce the likelihood of severe intentional poisonings in adults. Human and Experimental Toxicology. 2000;19(7):387-91.

\(^5\) Chan TYK. Improvements in the packaging of drugs and chemicals may reduce the likelihood of severe intentional poisonings in adults. Human and Experimental Toxicology. 2000;19(7):387-91.
21 Do you think restrictions or requirements should be set for the storage of approved products?
RPH recommends restrictions on the storage of approved products be allowed for under discretionary conditions of a licence application (please refer to our comments in Question 8).

22 Do you think restrictions or requirements should be set regarding the display of approved products?
RPH recommends the display of approved products should follow the same requirements as tobacco products as outlined in the Guidelines for Implementing the Prohibition on the Display of Tobacco Products 2012. This includes ensuring all products are not visible including, their branding and promotional imagery. Evidence from the sale and promotion of tobacco indicates product display is an effective form of marketing and promotion. 

RPH recommends removing the visibility of products as done with tobacco and instead allowing retailers to provide customers with a product list that provides information on the product name, price, a FULL list of ingredients, the anticipated effect and the known potential side effects. This will allow customers to make informed decisions without being influenced by marketing, branding and graphics.

23 Do you think restrictions or requirements should be set regarding the disposal of approved products?
RPH supports the use of the Hazardous Substances and New Organisms Act 1996 as clear guidelines for the disposal of approved products.

24 Do you think there should be signage requirements in the regulations?
RPH recommends that products are not visible, however if this recommendation is not taken and products remain visible, health warnings should be displayed next to them.

25 Do you think the regulations should specify further places where approved products may not be sold?
RPH recommends that, as a condition of the licence, the sale of approved products be restricted to people over the age of 18. Allowing R18 products to be purchased in stores that minors can enter has the potential to normalise the product to those under the age of 18. Therefore we would recommend that the regulations should specify that, where practicable, approved products should only be sold in R18 stores.

26 Do you think the regulations should prescribe restrictions or requirements for advertisements of approved products?
RPH supports the restrictions on advertisements as the Act is currently written.

In addition to the current restrictions, RPH strongly recommends further prohibiting the use of sponsorship. Sponsorship accounts for a large proportion of brand and product marketing that targets youth. For example alcohol brands sold in New Zealand are increasingly being marketed via sponsorship of music, clubs and sporting events. Sponsorship is used as a vehicle to embed brands and products into subcultures and the everyday lives of young people.

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RPH would recommend harmonising this Act with the *Smoke-free Environments Act 1990* in regards to section 23 and 25A. This will effectively nullify the use of events as sponsorship opportunities. An example of this would be the following:

53 (3). An approved product brand cannot be used to provide sponsorship in any form. 
Sponsorship includes the organisation, promotion, financial contribution or other type of contribution to any of the following 
(a) events
(b) a person, team or group
(c) an object, vehicle or craft
(d) an animal or organism

It is prohibited for a brand to associate any of the above through all or any part of the company or product name, trademark, words, logos, colours, shapes sounds smells or other elements used with the purpose of advertising the product, or agreements for exclusive sale rights.

27 Do you think the regulations should prescribe restrictions or requirements on internet sales of approved products?
RPH supports the following requirements for the internet sale of approved products:
- Age verification for those entering the site
- A signature from purchasers affirming they will not on sell to minors
- Health warnings
- Full list of ingredients
- List of potential side effects
- Contact numbers for CARM, The National Poisons Centre and AOD help lines
- Payment methods should be restricted to R18 methods of payment e.g. credit cards and PayPal, no direct debit options and no cash on delivery
- Age verification needs to occur when the products are delivered.

RPH recommends that the age verification process be much more rigorous than is proposed. The process should involve a pre-approval step where the purchaser provides documentary evidence of age in advance of being permitted to purchase a product.

28 Do you think the regulations should prescribe restrictions or requirements on the advertising of approved products?
This question appears to be the same as Question 26.

29 Do you agree with the proposed fees for the different licences?
RPH agrees with the proposed fee structure. RPH advises that the fee structure covers the cost of administering the Act.

30 Do you support a fixed fee or an hourly charge for processing applications for product approvals?
No comment.

31 Should fees be set for other specific functions?
RPH has no recommendations for further fees. Instead RPH recommends that no allowance be made to permit special licenses for one off events.
Do you agree with the proposed list of items and process for setting levies?
RPH agrees with the proposed fee structure. RPH advises that the fee structure covers the cost of administering the Act.

Conclusion
RPH are pleased to see the regulations of psychoactive substances are being reviewed as it has allowed those working in the sector to provide feedback on the development of the regulations at an early stage of implementation.

Psychoactive substances are still a new product to New Zealand, their short and long term harms are relatively unknown. It is important at this early stage to monitor and manage the potential risks of products being sold and to keep their use to a minimum in particular amongst vulnerable populations.

For this reason we strongly encourage setting a tax on these products and further restrictions to the location of premises and promotional methods. As well as the implementation of harm minimising strategies including clear information about products and their harms, reducing dose size, and careful monitoring.

Thank you for the opportunity to provide a submission on the review of the Psychoactive Substances Act. We trust that our feedback is useful and we look forward to ongoing engagement with the Ministry of Health in the development and implementation of this Act. We are happy to provide further advice or clarification on any of the points raised in our written submission. The contact point for this submission is:

Nadia Freeman
Regional Public Health
Email: nadia.freeman@huttvalleydhb.org.nz
Tel: 04 570 9633

Kind regards

Dr Stephen Palmer
Medical Officer of Health

Joanne Reid
Group Manager
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?

   Police checks should be required not just of applicants for licences but of directors/officers of applicant companies.

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?

   No. Location of other retailers and sensitive sites will be changeable. Also Council definitions of what are sensitive sites are not always clear. What will happen to a licence application if the data relied upon turns out to be incorrect, or if it changes? It is suggested that this assessment may more usefully be done by the Authority or the local Council itself.

   On this issue, it is suggested that a “point in time” approach is taken, i.e. the LAPP is considered in relation to the date of licence application. If a premise would later become non-compliant due to a sensitive site moving close by, this should not be considered further until the application next comes up for renewal (if at all – there is a strong argument for existing use rights as occurs with liquor licences and brothels). Otherwise there will be no certainty for retailers and no incentive to apply for a licence. This also would guard to some degree against organisations cynically moving close to an approved retailer’s site for the purpose of ensuring they must move – something we have anecdotal evidence of having occurred.

   The status of compliance with a LAPP is something that needs to be considered very carefully. A LAPP has no status in the legislation. It is evident that some Councils are using their LAPP to put in place prohibition or de facto prohibition. For the Authority to simply accept a Council’s LAPP with no scrutiny as to its reasonableness means that the Authority has fettered its discretion and the Councils are making licensing decisions. This exposes the Authority to legal action and appeals. It interferes with the proper running of the licensing regime. It is stressful and costly for retailers. It is not what the legislation anticipated – Councils are supposed to be saying where retailers can be located, not ensuring that they can’t be.

   The recent suspensions and closure of Hastings and Hamilton demonstrate that there needs to urgently be in place:

   1. A mechanism for LAPPs to be reviewed by the Authority as to reasonableness and legality;
   2. Withdrawal of the discretionary condition on retail licences making approved products sales subject to the terms of the relevant LAPP;

   A process whereby a holder of an interim retail licence can move premises (assuming that the LAPP allows space for a site, which there will be if #1 and #2 above are implemented), or an acceptance that they have existing use rights.

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?
Definitely not. We note:

1. It is not appropriate to have generic local approved products policies. If local councils do not wish to have a policy, one should not be imposed upon them.

2. How would the Authority determine where the approved areas should be for a given district? Generic determinations as to approved distances between licensed retailers and proximity to sensitive sites would also not suit all districts, and would take no cognisance of the particular district.

3. There is no provision in the Act for a generic policy, and to include it in the regulations to the Act would exceed the powers to pass regulations.

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?

   Yes.

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

   Sales data, adverse effects reports.

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

   For at least the period of the licence.

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

   Opening hours should be restricted to 7pm.

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?

   No.
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).

   A suggestion that users keep hydrated could usefully be added.


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.
For synthetic cannabis, a dose is very dependent on the user. It would be very hard to determine what a dose is.

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

Refer comments at 17 above.

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?

Products should not be developed to be injected.

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?

They should be stored safely in a locked area.

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

No, the Act is sufficiently restrictive.

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

Retailers should have to return product to the manufacturer for secure destruction.

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

Retailers should be required to display an R18 sign, and a sign providing that a retailer has a right not to serve customers.

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

No. Retailers are already dealing with the effects of scarcity of retailers in terms of anti-social behaviour, a second-tier (unlawful) market for products, gang interest and so on.

There needs to be a process for examination of the Council LAPPs so as to ensure that Councils are not de facto deciding licence applications. The Authority has regretfully fettered its discretion already with the discretionary condition on all interim licences. This needs to be rectified urgently.

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

4 Psychoactive Substances Regulations: Submission form
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29 Do you agree with the proposed fees for the different licences? If not, please provide specific suggestions.

It seems out of proportion that retailer fees are higher than those for wholesalers. Also they are out of alignment with licences in other relevant areas such as liquor licensing. A liquor licence costs about $1000 maximum.

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.

Possibly audits, although presumably this is covered in the annual levy.

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

The annual fee for a retailer is again out of proportion to the equivalent regime of liquor licensing where the highest annual fee is $1,250.

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:
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Ministry of Health
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Sales data, adverse effects reports.

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This submission was completed by:    (name)

Address:    (street/box number)
            (town/city)

Email:    

Organisation (if applicable):    

Position (if applicable):    

837903-v1-SEE 210314
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.)

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21 February 2014

The Manager
Psychoactive Substances Regulatory Authority
Ministry of Health
PO Box 5013
Wellington

Email: psychoactives@moh.govt.nz

Dear Sir/Madam

PSYCHOACTIVE SUBSTANCES REGULATIONS - CONSULTATION DOCUMENT

Thank you for the opportunity to provide comment on the Psychoactive Substances Regulations.

Tairawhiti District seeks to improve health outcomes in our communities through the reduction of health inequalities. In Gisborne we have worked collaboratively on the management and regulation of Psychoactive Substances across our organisation and also with external stakeholders including the Eastern Policing District, Gisborne District Council and at the community level.

There is anecdotal evidence building in our district of the negative health and social impacts impact of Psychoactive Substances on the both the user and the wider community. Our submission has been formed around these concerns given the legal permission to use these substances.

We note the regulations will play an integral role in ensuring the Psychoactive Substances Act (2013) achieves its purpose, that being to regulate psychoactive substances before they reach the consumer market by ensuring that those approved for sale pose no more than a low risk to health. That overarching objective underpins our submission to ensure the reduction of harm from the misuse of psychoactive substances particularly by young people, vulnerable adults and recovering drug users.

Yours faithfully

Kate Sykes
Operations Manager – Population Health
Consultation questions

1. Is the list of proposed information requirements for licence applications comprehensive enough?
   
   The licence holder should be required to respond to the following questions:
   - Does he/she intend to reside in the locality for which a license is applied for (i.e. do they live in a different town/city)?
   - Has any consultation with other retailers within the proposed locality taken place prior to making a license application.
   - Recommend a cradle to grave tracking process for the substances ie from manufacturer to retail premises. This would also include recording the names and addresses of the buyers of these products (requiring ID), a register kept available for periodical inspection. This would enable a check on those taking these drugs, the quantities (and possible limiting control) and record for other health professionals in case of health emergency events.

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?

   Evidence of compliance and investigation into local compliance issues must accompany an application particularly for owners not residing within the community for which they are applying for a license.
   
   If the Local Authority has implemented a LAPP, evidence should be supplied that the application meets the criteria of that policy.

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?

   Yes. Where the Local Authorities do not adopt a LAPP the regulations should set a General Approved Local Approved Products Policy. These should mirror the requirements under the act but also include schools, churches, youth centres, mental health and addiction services, or other community facilities, including children's playgrounds.

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.
Information as to the applicant's personal wellbeing should be ascertained. This would include information as to any information with regards to personal drug dependency or issues of mental health that would significantly affect the person's ability to adequately and safely conduct the business for which the license has been applied for.

For foreigners residing in New Zealand there sufficient certainty that they have no history that would affect their eligibility to hold a license.

The Fit and Proper person test should be tested as to whether or not the applicant has been convicted of a relevant offence in another piece of legislation with particular reference to the Smoke free Environments Act and the Sale and Supply of Alcohol Act.

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

Yes. Applicants should be required to declare any disciplinary actions that they have been previously subjected to under other relevant NZ Legislation (i.e. 'Controlled Purchase Operations' conducted under sale of liquor and tobacco legislation), including any infringement notices they have been issued with.

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

Records should be kept to identify persons that are regularly purchasing products in excessive amounts that would be considered more than that for personal use. In addition we also suggest:
- Records of purchase i.e. invoices
- The quantity of products sold within each transaction
- Batch number of products (to assist identification of manufacturer and wholesaler)
- Recall policy including how product is disposed when requested by the authority
- Adverse reaction reporting
- Policy regarding the sale to under age consumers
- List of employees

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

The normal period for business purposes I understand is 7 years. This would seem to be appropriate.

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

Due to the clientele that these premises tend to attract many of which are in a drug altered state of mind does not provide an environment that should be readily accessible to vulnerable sectors of the community especially children.

The suitability of proposed location of these premises should give consideration to:
- Proximity to money vending machines
- Proximity to banks delivering cash withdrawals to beneficiaries
- Proximity to other facilities used by minors
- Situated within normal passage areas used by minors

Restrictions on hours of opening should be imposed to prevent drivers of vehicles and other vulnerable users having access to these products prior to the commencement of a normal working day.

Restrictions also on the maximum amount that can be supplied in any one transaction, to prevent the possibility of on-selling through non-regulated means.
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?

Consideration should be given to the secure nature of retail premises.
All premises should be required to be fitted with continually operating security monitoring devices and that the viewing of those should be available to enforcement Authorities where breaches of the legislative controls are suspected.
Controls for on-line sales similar to Sale and Supply of Alcohol. Online licence applications should contain a different set of requirements that include processes to validate the purchaser’s age and ensure that the product is only delivered to them, to reduce the risk of under age use. There would need to be a tracking system to allow access across the country by authorities investigating the substance purchased. All deliveries to the door need to be signed for and the evidence of age document unique identification number recorded.

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?

Yes, although we don’t need to see this information it must be available and submitted with the application.

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

Linked to the code of manufacturing for Psychoactive products.

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?

Yes

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?

All of the above should be required as a minimum.
The regulations should also provide for a linkage to Community Mental Health Clinics for the disclosure/availability of emerging new trends and information relating to the use of any approved product.

14 Are the proposed requirements and restrictions on labelling sufficient? If not, please make specific suggestions for further requirements and restrictions.
The packaging of the product needs to be tamper proof and not reusable. It is suggested that the product is packaged and labelled in such a way that once opened the packaging/labels are unable to be reused and resealed to prevent the refilling and redistribution of the packages potentially containing other products. There have been suggestions that the existing re-sealable packaging of some of these products has been used for the distribution and marketing of other drugs that are illegal. We also suggest that products should be marketed as “plain packs” similar to what is currently being suggested for tobacco control. This would align the two pieces of legislation and support addicts who are trying to quit. Labels should contain the full list of ingredients from most to least. This would align it to legislation required for food stuffs.

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).

We further suggest wording such as “Do not use the product if the packaging in which it is sealed is in any way damaged or appears to have been resealed”.

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

The packaging should have printed on it details in relation to access to “quit lines” and the premises should be required to display a notice of local agencies who can support those wishing to quit.

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

Observations made in relation to consumer use indicates that sales are more often than not restricted to purchasing a single packet on a frequent basis. Single dose packaging should contribute to a reduction in regular excessive use, if coupled with a maximum permitted daily purchase.

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

The question must be asked “why do we have to consider splitting dosage to prevent overdose”?. The whole purpose of the legislative framework surrounding these products is to “only approve those that are demonstrated to have a low risk of harm”. It should be impossible to overdose on a product that meets this criterion.

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?

They should be in a form that is unique to the product and cannot be confused with any other product. Products should not be prepared in a form to mimic other unlicensed and illegal drugs which not only makes for a greater appeal to users but increases the risk of unintentional use of illegal substances. Products should not be able to be pre-mixed with food and beverages as this poses a risk of accidental or un-intended consumption of psychoactive substances by children and youth, and may also encourage the attractiveness of these products to minors and at risk groups.
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?

No less than the requirements placed on a pharmacy for the storage of similar pharmaceutical products. This may take the form of a maximum amount that could any premises can hold to reduce the likelihood of being targeted; substances being locked in a secured room at night etc.

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

As above. Also where internet sales are occurring, the products cannot be held at a residential address, but must be stored at a non-residential premises licensed under this legislation.

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

Restrictions should be no less than those applying to tobacco products.

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

The disposal process should be pre-approved by the Regulator. Good documentation needs to be kept of any disposal of approved products, which will ensure the process can be audited by enforcement officers.

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

There is overwhelming evidence that the use of these substances is a precursor to the use of more dangerous drugs and that they are in fact used with other drugs to accelerate or enhance the effects of these drugs. They are relatively "low priced" in comparison to illegal products and are therefore popular for this purpose.

There should be specific warnings on the packages that "use may lead to addiction or an altered state of physical wellbeing"

Furthermore the retail premises should have specific details indicating 'community services' that are available to assist persons to quit with the products use.

There should be required signage similar to what is required by the Sale and Supply of Alcohol Act (managers name, under 18 prohibition, display of licence and conditions etc).

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

See comments in question '8'

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.

Internet sale is a relatively uncontrollable environment to provide for the protection of sale of these products and should be totally banned for retail sale. Online purchasing of psychoactive substances increases the risk that minors and youth are able to more easily access these products as the checks and balances that apply to restriction of sale at retail outlets are far less stringent for sales over the Internet (as was recently demonstrated by TV1).

If on-line sales are to be permitted this should only be by licensed retailers who would be required to provide the appropriate security checks to verify they hold the licence.

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

See question 26

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

Fees and charges associated with administering this piece of legislation, should be fully met by the licence holder.

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

No comment.

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

No comment

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

No comment

6 Psychoactive Substances Regulations: Submission form
This submission was completed by: (name) Jim Green
Address: (streetbox number) Tairawhiti District Health, Private Bag 7001, Gisborne
(town/city) GISBORNE
Email: Jim.green@tdh.org.nz
Organisation (if applicable): Tairawhiti District Health
Position (if applicable): Chief Executive

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): enforcement agency and district health board......................

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.)

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.
Auckland Council's submission on the proposed Psychoactive Substances Regulations

21st March 2014
Introduction

1. Auckland Council welcomes this opportunity to provide input into the development of the Psychoactive Substances Regulations.

2. The Auckland Council represents nearly 1.5 million people stretching from Wellsford in the north to Franklin in the south. We are committed to making Auckland the world’s most liveable city and to deliver Aucklanders great value for money. Auckland Council will deliver on these commitments by ensuring that our ratepayers, customers, citizens and visitors have the highest quality services. An important part of being a liveable city is ensuring everyone has a safe and secure place to live, work and conduct business. We see the successful implementation of the Psychoactive Substances Act and the associated regulations as a key component of providing a safe environment for Auckland’s ratepayers, customers, citizens and visitors.

3. Auckland Council believes that while the proposals in the consultation document are a good beginning. Further work is needed to allow councils the opportunity to successfully minimise harm to their communities from the selling and using of psychoactive substances. We look forward to working with the Ministry on ensuring these are included in the final regulations.

4. Auckland Council would welcome the opportunity to discuss our submission with Psychoactive Substances Regulatory Authority. We can be contacted through Michael Sinclair, Team Leader Community Policy and Planning Region-wide Social Policy (Michael.Sinclair@aucklandcouncil.govt.nz or (09) 484 8068).
Summary

5. Auckland Council supports the general approach to the regulations presented in the consultation document from the Ministry of Health. We believe that the regulations need to be clear and unambiguous in setting out the requirements of licencing and the enforcement of noncompliance. There needs to be a certainty that no licence will be granted without the appropriate council providing notification of compliance with the LAPP. It is also vital for the on-going maintenance of the licencing regime that there is a realistic cost recovery model encompassing the administrative as well as the social costs of selling psychoactive substances.

Key points

6. Set out below is feedback from the Auckland Council on specific key points in the consultation document on the proposed regulations.

Interim licenses

7. The interim licences should be subject to an adopted Local Approved Products Policy (LAPP). Any interim licence that fails to comply with the LAPP should be revoked by the Psychoactive Regulatory Authority (the Authority). Interim licenses holders who cannot continue to operate due to noncompliance with the LAPP should be permitted to apply for a license once the regulations are in effect. This application would need to meet all the conditions of any other application.

Restrictions on holding a licence

8. Auckland council submit that there should be a restriction preventing an entity or individual from holding a licence to sell/manufacture/import psychoactive substances and a licence to sell alcohol at the same time

9. All licence applicants should be required to meet the same standard of being fit and proper required from an applicant for an alcohol licence.

Evidence of compliance with the LAPP

10. It is imperative that all retail licence applications must be required to show their compliance with the relevant LAPP in their application. Without such evidence the Regulatory Authority should not grant the licence. The regulations need to make this relationship explicit and unambiguous. Any doubt over the need for compliance with the LAPP may provide an opportunity for legal challenge, compromising the integrity of the licencing regime.
11. The regulations should set out how the evidence of compliance with the LAPP will be demonstrated. Auckland Council would prefer this to be in the form of a brief letter provided to the licensee by the council. It is proposed that a simple template be developed to allow all territorial authorities to confirm or deny compliance.

Information requirements

12. The regulations should require retailers to record purchases in a similar manner to pharmacy purchases. This process would record the purchaser’s identification, proof of age, and amount and time of purchase. This information would allow the retailer to make appropriate decisions to reduce harm to customers through limiting sales as well as providing appropriate agencies with information to determine the licensee’s compliance with harm minimisation and regulatory duties. These records should be required to be available to appropriate agencies on demand. Records should include the compulsory use of CCTV to record the internal environment including clear recordings of all customers. CCTV records should be kept for a minimum of two months and be made available to appropriate agencies on request.

13. Auckland Council believes the inclusion of address of premises should be an explicit part of the required information for any licence application. This address should be the only premises where the licensee can operate. Any change of address would need to be approved by the authority and demonstrate the appropriate compliance with the LAPP and other relevant rules.

14. The licensee should provide information to the Authority on previous licence applications and any breaches of licencing laws.

15. Auckland Council strongly considers that the regulations should make it mandatory for all licence applications to contain a social impact analysis. This document would contain an assessment of the harm the proposed premises would have on the local area and what the plans are to mitigate these harms.

16. Any evidence of an increase in social harm as a result of the operation of the licenced premises would be grounds for a council to apply to the Authority for either variation or revocation of the licence. The council could ask for any new conditions it believes would reduce the harm being caused or ask for revocation of the licence if it believe that is the best way of protecting the community and substance users.

17. Auckland Council supports the view that all licence applications should be publically notified. Once granted licences should be required to be publically displayed in the licenced premises.
Licence conditions

Setting discretionary conditions

18. Auckland Council’s preferred option is an enabling regulation to allow councils to request any discretionary condition required to maintain a safe and secure environment for the users of approved products and the local community. This approach has the advantage of being future proof and flexible allowing councils to tailor conditions to changes in their own community. These conditions would still need to be interpreted in light of the primary legislation. For example a condition could not make it impossible to operate a business within the council district.

19. The regulations should be explicit that the Authority needs to consider the view of the local council in accordance with the LAPP. If the authority chooses to ignore the council recommendation they should be required to provide a written reason within a reasonable time, such as ten working days.

Adding conditions to an existing licence

20. Auckland Council believes the regulations should set out a simple and clear process where a council can ask the Authority to set additional conditions on an existing licence. We consider this should be in the form of a written submission to the Authority followed by a hearing with both parties and the Authority then required to make a written reply within a reasonable time frame, such as 30 days.

Setting operating conditions

Hours of operation

21. The regulations should specify limitations on hours of opening, setting a national benchmark. They should also allow the LAPP to make recommendations to appropriate hours of opening required to maintain a safe and secure environment for the community. The recommendations in the LAPP would not permit operation outside of the hours set in the regulations.

Purchase limits

22. The regulations should make provision for a minimum and maximum amount that can be purchased within a set time period. This measure combined with record keeping would allow a measure of control over repeated purchasing within a short time frame resulting in over use of a substance.

6
23. Auckland council support the restriction of a package to a single dose as a method of harm minimisation.

Merchandise

24. The regulations should allow the LAPP to set a condition on a licence to prohibit selling merchandise not related to the consumption of psychoactive substances. The condition should also prohibit offering any other goods or services from the same premises.

Distribution

25. The regulations should make it clear that they include the distribution of sold items as well as the selling of items directly. This would prevent the setting up of a ‘distribution centre’ to supply substances that have been purchased through another means such as online shopping or at another physical venue. This clarification would also stop the setting up of a ‘cashless’ shop where orders are made over smart devices or computers in the shop and only ‘picked up’ from the premises. Without this clarification these methods could be possibly employed to get around the need to comply with the LAPP conditions.

Product restrictions

26. Auckland Council believes the regulations should ban the sale/manufacture/import of products in a form that can be injected or smoked.

Use of substances

27. The regulations need to be clear that the licencing applies to both areas where Psychoactive Substances are available for purchase and also areas within commercial premises set aside for the consumption of the substances. This clarification would mean any operators attempting to create an area for the use of psychoactive substances would also have to comply with the LAPP. Such a restriction would allow the harm minimisation intent of the LAPP to be extended to individuals in such areas. For clarification, this point is not intended to restrict a person’s right to use an approved substance on private property. It is intended to allow for regulation of a possible ‘on licence premises’ for psychoactive substances.

28. The regulations need to unambiguously grant the territorial authorities the power to create bylaws to limit the areas where approved substances can be consumed. This would be in line with the current powers conferred for smoking and drinking under the appropriate legislation. If this is not explicit it could lead to either a high risk situation where people are able to consume psychoactive
substances in an area where they are prevented from smoking or consuming alcohol.

**Enforcement**

29. The regulations need to be explicit that the proposed enforcement mechanisms in the regulations and associated bylaws will also apply to suppliers that are in breach of the LAPP.

30. Enforcement needs to be applicable to those who breach the LAPP by selling substances as well as those who breach any bylaws resulting from the LAPP regulating where psychoactive substances can be consumed.

31. The entire enforcement regime for the LAPP needs to be able to be applied by council enforcement officers and Police. If there is noncompliance then it should be explicit that this will be enforced by Police with an appropriate escalation of penalties.

**Requirements on labelling, packaging and displays**

32. No advertising should be visible from the street. This would require that shops were able to display a trading name and no other advertising. All advertising should include appropriate health warnings and age restrictions. This would include online advertising.

33. Labelling restrictions should be consistent with the advertising restrictions to prevent labels being used as de facto advertising. This would require that products should not be viewable from the street. All labelling should include appropriate health warnings as well as directions who to contact if there is an emergency such as an overdose.

34. Labelling, advertising and product appearance should not make a product attractive to minors.

35. Auckland Council recommends that the Ministry consider the option of employing a similar plain packaging regime as the one proposed for cigarettes. It would seem that this could be an opportunity to remove a number of contentious issues such as the use of images that may appeal to young people as well as de facto advertising.

**Cost recovery**

36. The regulations should make it clear that a licence fee and/or levy can be set to recover the full administrative cost of the application as well as the cost to the local community of expected harm from the psychoactive substances. This
charge could be varied to take into account the different cost of licencing and enforcement for each council.

37. Fees and any levy should be set to take into account central and local administration cost as well as costs to the local community services for services accessed by the users. These should be set in consultation with local authorities and if there is doubt a ‘worst case’ cost model should be adopted to ensure full cost recovery. The charge should allow for ongoing cost recovery of licence reviews and regular compliance monitoring of the premises.

38. There should be a clear mechanism for the calculation and return of an appropriate portion of the charge to the local council.

39. Auckland Council would be happy to work with the Ministry of Health to determine a cost model that would allow the setting of a reasonable fee/levy to allow for full cost recovery.

Defining a venue

40. Auckland Council believes it would be useful to clarify the definition of a venue where an approved product can be sold to make it explicit that it includes the wider structure. This will prevent the ‘shop in a shop’ situations from arising as a way of getting around selling restrictions.

Communication with the public

41. Auckland Council considers there would be a significant benefit to a centrally developed communication strategy to inform the public about the Psychoactive Substances legislation. The communication should include details of the roles and responsibilities of the different agencies. Auckland Council would be happy to work with the Ministry of Health and other agencies to develop this package.
21 March 2014

The Manager
Psychoactive Substances Regulatory Authority
Ministry of Health
PO Box 5013
Wellington 6145

Regulations Consultation Submission - Psychoactive Substances Regulations

Waikato District Council would like to thank you for the opportunity to make a submission on the development of regulations to give effect to the Psychoactive Substances Act 2013 (the Act).

Background
Waikato District Council adopted a draft Local Approved Products Policy (LAPP) for consultation on 9 December 2013. The draft policy was open for consultation between 14 January and 17 February 2014. Four hundred and eighty-four (484) submissions were received. The submissions are now being analysed with hearings to be held in early May after which a final policy will be adopted. The number of submissions received reflects the high level of concern in the community regarding psychoactive substances.

General Comment
Council generally does not support any sale of Psychoactive Substances and this view is reflected in the feedback from submitters on the draft LAPP. The community clearly does not want retail outlets selling these products in their towns but are being given no choice by government imposed legislation.

The consultation document on the regulations has a broad scope and deals with a number of matters that extend beyond the normal focus of councils, such as manufacturing, labelling and importation. Council has focused its response on the following areas:

- Information requirements
- LAPPs and Generic LAPPs
- Fit and proper person test
- Licence conditions
- Health warnings
- Place of sale
- Advertising
- Fees and levies

Thank you again for the opportunity to provide feedback on the proposed regulations.

Yours sincerely

G J Ion
Chief Executive
SUBMISSION

This submission comments on those areas identified within a response to the relevant consultation questions:

Information Requirements

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

No. The applicant should be required to declare any convictions. Similar provisions to those under the Sale and Supply of Alcohol Act 2012 should be in place whereby a report is sought from the Police, principally in respect of the applicant’s suitability. While it is noted that it is proposed to include consent to undergo a Police check on the application form, this is very different to a statutory requirement for the application to be forwarded to the Police to provide a report.

The application should also provide for:
• The property owner’s consent to utilise the property for retail sale;
• A current telephone number

Question 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?

Yes. Council considers that before applying for a retail licence, applicants must first obtain a consent from the territorial authority confirming compliance with their LAPP. An application to the Authority for a licence should be required to be accompanied by the consent. The process should be similar to that under the Gambling Act 2003 for a territorial authority consent to establish a Class 4 gambling venue in accordance with the Class 4 venue policy. This will also give the Authority confidence that the proposed site complies with the LAPP and provides Council an awareness of potential developments in its community.

Inherent in providing a consent from the territorial authority is provision for recovery of costs. While relevant fees may be set under the provisions of the Local Government Act 2002, Council considers that specific provision should be made within the regulations for recovery of costs of considering an application and providing the consent. It is not appropriate for this to be funded or subsidised by ratepayers.

Council supports the Local Government New Zealand submission point relating to the matters that are still to be determined in the legislation and that require clarification, for example:
• What are “facilities of a particular kind”?
• What does “broad areas” mean?

A matter of concern is that of the status of a LAPP that may have the effect of effectively banning sales by preventing the location of a retail outlet within a particular jurisdiction. This is particularly problematic in smaller communities where there are many places of a particular kind that may be considered to be sensitive receivers.
Question 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?

Council agrees that a generic policy is desirable where a council has not adopted a LAPP. Council is of the view that applications for retail licenses should contain evidence of compliance with generic policies on the grounds that the desired effect of restrictions in one area that has a LAPP will be reduced if a neighbouring area/s does not have a LAPP in place. Council considers a generic policy to be a good idea to avoid a retailer setting up on the boundary between a Council with a policy and one without so they can easily reach both markets. Robust processes would need to be in place to confirm that the proposal complies with the generic policy since there is no provision or confirmation from the Council as recommended for a LAPP in question 2 above.

There are some potential issues in the creation of a generic policy such as relevant distances that retail premises should be separated from premises or facilities of a particular kind (sensitive sites) and distances between retail shops. In small rural townships such as those in the Waikato District it can be difficult to establish buffer areas that will enable any retail outlets to establish while maintaining a reasonable separation from sensitive receivers. A generic policy could potentially be found to be ultra vires by effectively prohibiting establishment of outlets.

Fit and Proper Person test

Question 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?

No. The Authority should take into account any conviction, not just relevant offences. The general background of the applicant in complying with legislative requirements should also be considered (eg if a person has a history of not complying with one piece of legislation (whether convicted or not) then their suitability to hold a licence should be brought into question). The authority could seek information from the Police and local authority to ascertain any relevant experience they may have with the applicant as it is possible that applicants will have a history of contact with the territorial authority that shows them to be either good corporate citizens or, at the other extreme, serial non-compliers.

In respect of corporate applicants, there should also be mechanisms for the Authority to "look beyond the corporate veil". It is unclear what enquiries are to be conducted in respect of applications and who might carry these out. The associations of company directors need to be considered to ensure that a company applicant is not a front for undesirable groups or people. If a licence is granted to a company there should be a requirement for any change of director or shareholding to be notified to the Authority and that the Authority assess the suitability of the new company personnel using the same criteria as for a new licence application. If found to be unsuitable, the licence should be cancelled.

The financial resources of the applicant should also be considered to establish their ability to operate a reputable business.
Question 5 Should the regulations require applicants to provide details of their involvement in other regulatory regimes, such as alcohol licensing processes?

Yes. Any information regarding involvement and compliance with regulatory regimes can contribute to the assessment of the applicant's suitability to hold a licence.

Licence Conditions

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

In respect of retail sales, licensees should maintain live records detailing the inventory received into the shop and products and quantity sold.

Question 8 Do you think there are factors or issues that the Authority should consider when setting discretionary conditions?

Council supports the Local Government New Zealand view that the statutory tools in the Act may not go far enough to meet community expectations for the regulation of retail sites. Council considers that a limit on the quantity of an approved substance that may be purchased in a single sale should be imposed and that hours of operation should be considered, particularly at key sensitive times such as when school children may be passing the outlet on the way to or from school.

Labelling and Packaging

Health Warnings

Question 14 Are the proposed requirements and restrictions on labelling sufficient?

Council agrees with the proposed regulations on labelling and packaging and requests that:

a) Labelling should be consistent and clear, including listing the content, analysis and concentration of the active ingredients.

b) Regulations should require plain packaging that does not promote the use of the product.

c) It is suggested that the use of words such as "Legal", "Natural", "High" or "Cannabis" be banned due to the association of these words (that is, Legal or Natural implies that it is safe; High or Cannabis implies that it is desirable).

d) Health warnings should include the warning that prolonged use can lead to psychosis.
Place of Sale and Advertising

Place of Sale

Question 25 Do you think the regulations should specify further places where approved products may not be sold?

The consultation document suggests that the regulations could place further restrictions on the types of places where approved products can be sold. Council supports any mechanism that restricts the availability and "normalisation" of approved products, or where the provision of other goods and services may be used to mask the sale of products to otherwise prohibited persons. Council would suggest adding any premises where the preparation or sale of food takes place to those prohibited.

Advertising

Question 28 Do you think the regulations should prescribe restrictions or requirements on the advertising of approved products?

Council agrees that on-site advertising should be restricted to the inside of the premises where approved products are offered for sale and should be limited to communicating only product information such as active ingredients. Health warnings should also be required to be clearly displayed in retail outlets. Regulations should specifically prohibit any form of shop window advertising or prominent advertising within the shop that may be viewed from outside the shop.

Fees and Levies

Question 32 Do you agree with the proposed list of items and process for setting levies?

Council submits that any levies taken from the industry for the Ministry to fund its functions should be set at a level that covers the costs of doing so. This industry should not be subsidised by the taxpayer.

Council submits that each Council that develops a LAPP should be able to recover its costs in carrying out the special consultation procedure. If the Council is required to “sign off” or approve a licence application as being compliant with the Council’s LAPP then it should also be able to charge a fee. Therefore, Council submits that the examples of the costs a levy can be charged for should include all territorial authority costs in addition to all the central government costs listed.
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?
   Yes – I believe the details proposed are sufficient.

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?
   Yes – I believe that the retail applications should be accompanied with evidence to demonstrate compliance with a Local Approved Products Policy.

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?
   Yes – I believe that the retail applications should be accompanied with evidence to demonstrate compliance with a generic LAPP or with the general legislation, in absence of a generic LAPP.
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.

- Whether or not the applicant has previous history in regards to importing and their compliance records
- Whether or not the applicant has had previous history relating to alcohol licensing processes or similar

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

Yes I believe the applicant should provide these details, particularly regarding alcohol licensing and gambling.

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

- License holders should keep records of sales including quantity of products received and distributed.
- License numbers should be noted on every transaction of the seller and purchaser.
7. How long should licence holders be required to keep records for?
   - License holders should keep all transaction records for a minimum of 7 years.

8. Do you think there are factors or issues that the Authority should consider when setting discretionary conditions? If so, please provide details.
   - The license must be displayed on the premises

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?
   - Unsure

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

The on-going monitoring, inspection and enforcement of manufacturing methods as described above, with an associated fee regime. Any such regime must be enforced and the costs of doing so imposed on the manufacturer.

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?

Yes I agree.

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?

Yes I agree with the details sought, however request that this is detailed in plain English.

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

Yes I agree with the details sought, however request that this is detailed in plain English/commonly used language.
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).

I believe that the wording of the warnings are:
- too long and not plain English
- Need to include to consume them at your own risk
- There needs to be details regarding what is in the product
- The packaging of these products should be bland e.g. brown packaging and black writing. This should be along the same lines as plain packaging of cigarettes legislation
- Need to be clear that usage is not for anyone under 18 years

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

Yes – but I also submit that they should be plain/plain packaging as per plain packaging cigarette legislation.

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

Yes – as I believe that this provides the consumer with the information necessary as to what can be safely consumed (according to the Authority).
Providing multiple doses in one packet could encourage their over-use and is not seen as a way to minimise harm.

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

No – I believe that splitting the dose over a number of packets, may lead consumers to believe that it is OK to consume greater numbers of pills at a time, and this is likely to lose the meaning of the dose levels.

It also encourages the idea that taking more than one portion at a time is okay - which becomes dangerous when the person is unaware of dosage strength of other pills they might be given. In addition some consumers may not accurately recall the numbers of the ‘split’ dose they have consumed.
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?

Yes - I believe these products should be restricted to pill format only.

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?

Yes - I submit that the storage amounts should be minimal e.g. no more than 10 doses of a type, and no more than 10 types per premise’s i.e. 100 doses.

This is to minimise the likelihood of theft from the premises and minimise the harm if it does occur.

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

Yes - I submit that the storage amounts should be minimal e.g. no more than 10 doses of a type, and no more than 10 types per premise’s i.e. 100 doses.

Also, these should not be visible to the public and should be securely locked.

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

I do not believe that the products should be on visible display within the premises e.g. similar to the constraints of tobacco.
23 Do you think restrictions or requirements should be set regarding the disposal of approved products? If so, what should they be?

Yes — these should be treated in a similar manner as a hazardous substance, as if this are not disposed of carefully, they could create a significant hazard to someone who finds them e.g. child.

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

I believe that signage should not be permitted on or in these premises, to advertise the sale of these products. To minimise harm from these products, especially for those with addiction problems, we need to minimise their visibility. Word-of-mouth will mean people know where to find them. If communities are not being allowed to choose to outright ban them, it they should at least have the opportunity to minimise their impact through minimised publicity.

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

Yes — I believe that the restrictions should also extend to a premises selling these products should not be within a specified distance e.g. 100 metres of a licensed premises or a TAB, school, bus stop or residential area.

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

I agree with the proposed restrictions in the Act and would submit that whilst this includes the internet, to avoid doubt, the use of social media should also be prohibited.
27 Do you think the regulations should prescribe restrictions or requirements on internet sales of approved products? If so, please provide specific suggestions.

Yes – I submit that the restrictions should include internet sales, including those only used for the sale of such products.

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

I submit that advertising should not be permitted on-site i.e. it is stored in a manner that it cannot be seen by the customer. And no signage at all either within the premises, on the external walls/windows of the premise or sandwich board.

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

I believe the costs appear reasonable if the above caveats re-marketing restrictions, monitoring and enforcement costs etc are put in place.

If not, then the costs should go up considerably as the community will be paying far more for the downsides of allowing the sale of the psychoactive substances.

If the community has to pay those costs, the people producing and marketing the products should pay considerably higher upfront fees for the opportunity to profit at the community's costs.

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

I believe that a combination of a minimum application fee and an hourly fee on top for processing if complicated or inadequately prepared applications require this is to ensure the community is not cross subsidising potential producers.
31 Should fees be set for other specific functions? If yes, please state what they should be set for.

Fees should be set for specific functions and should reflect the work involved i.e. recover costs of the service.

Other functions that should have a specific fee prescribed include ongoing monitoring of effects, inspection of production facilities, and if necessary, enforcement costs.

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

Yes, agree

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): Individual

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:  
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Please put ‘Regulations Consultation’ in the subject line.

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✓ 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.
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?
   Yes. I do think the penalties for supplying minors should be increased, and properly policed though.

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?
   Yes, but careful limits should be placed of LAPP, so that the system isn't abused by moral minorites.

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?
   No
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.

[Yes]

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

[No]

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

Sales records (anonymous), in order that the effect of the law can be monitored.

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

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?

Yes. Manufacturing process, especially at the chemical production level, is important. Currently Chinese manufactured chemicals do not have a high enough purity, and the finished products should be also solvent free and use otherwise (apart from the active/actives) food safe ingredients.

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?

Yes

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?

Yes, but, I think that addiction, should be measured not by guess work or subjectivity (ie potential), but on actual usage statistics from human “free access” usage, and addiction animal studies. There is risk in the vagueries of guesswork here. They should also observe general or average usage patterns, rather than outliers.

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

Yes. If anything they are stricter than currently available more harmful substances. Hiding the products behind the shelves for example, if they have passed testing, seems excessive. That may actually add to a “forbidden fruit effect”. I would remove that, and allow them to be displayed behind the counter.

I would add that it should be mandatory to say “try a tiny bit, and wait ten minutes” or similar – do not use with gravity bongs, or lungs, or consume in excessive qualities, and do not over use. These things are common sense, and well known with say alcohol, but some people lack a sense of caution, and it will take time for public awareness to raise.
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).

Yes. I would add that cannabinoids for example, always lower blood pressure and raise heart rate initially, and can cause initial anxiety. These are known medical effects. Known medical side effects should be listed.

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

Yes

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

No. Nothing else is sold that way, not medicines, alcohol or tobacco. And cheaper products are more available to be abused. Would you sell one cigarette at a time? No, it maximizes harm.

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

If the product is a pill, it makes sense to have a dose that can be used by different body weights and tolerances and preferences, so a split makes sense there. But I don't think mandating dose splitting makes sense. I think instead a product should be designed so that it can be used safely, within the margins of study, by differing body weights, tolerances and preferences and that the instructions should match this.
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?

No.

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?

Bottles should probably have child safe lids. There might be a requirement to store cool, or out of sunlight, and possess a used by date if chemicals in the product can degrade.

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?

No. Restrictions here can increase the attraction. There is no evidence that it helps. This policy should be as much as possible evidence based.
23 Do you think restrictions or requirements should be set regarding the disposal of approved products? If so, what should they be?

Yes, they should be disposed of in a way that the products cannot be used.

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

It should be fine to advertise outside the store, that the store possessed the product (but no more). Inside the products should be able to have signage that tells you what each product is like.

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

No

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

I don't think TV advertising is appropriate for alcohol, or sports sponsorship, or newspaper advertising, or radio advertising. Billboards is okay. Same goes for legal highs. Signs = fine.
27. Do you think the regulations should prescribe restrictions or requirements on internet sales of approved products? If so, please provide specific suggestions.

Only age proof, and use instructions and health warnings.

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

Yes. Magazines/media only if they are drug related in topic, and signage and billboards. No sponsorship, newspapers, unrelated media, or TV. Should not be able to grossly misrepresent potency or safety.

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

Yes

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

Fixed fee
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): N/A
Position (if applicable): N/A
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): As a private citizen (I don’t use legal highs anymore either).....

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

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☐ I do not give permission for my name to be listed in the published summary of submissions.
Health Action Trust Submission
to the Psychoactive Substances Regulations

This submission was completed by: (name) Rosey Duncan
Address: (street/box number) PO Box 691
(town/city) Nelson
Email: roseyd@healthaction.org.nz
Organisation (if applicable): Health Action Trust
Position (if applicable): Health Promoter

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): Health Promoter ..................................................

Do you wish to receive updates about the development of the psychoactive substances regulations?
☐ Yes
(If yes, please make sure you provide an email address.)

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☐ 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.
License Applications:

1. Proposed Information Requirements

We recommend that license applications require applicants to:

1.1. undergo a police check.
1.2. update their contact details if they change after a license is granted.
1.3. disclose any previously declined license applications
1.4. We also recommend that the regulations clarify whether the Act requires a retail license holder to be present at the time of sale, or whether the license applies to the business. (i.e. do all staff of a retail outlet have to be retail license holders?)
1.5. We recommend that if a retail licence holder employs staff to sell on their behalf, employees should:
   - hold a retail sub-license attached to the retail license held by their employer
   - also be of “fit and proper” character
   - not have a criminal record
   - undergo training (similar to bar staff requirements)

Regarding research licenses, with respect to determining risk of harm, we recommend:

1.6. testers/researchers must gain MoH approval based on criteria such as:
   - tester / researcher must have no vested interest in the product in any way
   - tester / researcher must demonstrate no other conflict of interest
   - tester / researcher must hold a minimum pre-requisite relevant professional qualification

1.7. testing must be done in an MoH-registered laboratory

2. Evidence of Compliance with LAPP

2.1. We support that the application should be accompanied by evidence of compliance with the LAPP if one is in effect in the area.

3. Evidence of compliance with generic LAPP

3.1. Yes we support this requirement if there is no local LAPP.
4. **Fit and Proper Person Test**

4.1. We recommend that the definition of “fit and proper” clearly identify unacceptable criteria that would allow the public to get retailers shut down if the criteria are not met.

4.2. We support the proposal to ensure applicants have no criminal record of:
   - drug-related offences
   - dishonesty (including fraud)
   - failure of compliance with the Act or is likely to fail to comply

4.3. We also recommend the applicant has no criminal record of:
   - harm to other members of society (such as but not limited to violence/aggression/sexual assault), as crimes of this type would indicate the person does not hold the health and safety of other members of society in high regard.
   - non-compliance with other relevant Acts or regulations such as Sale of Liquor Act, Sale and Supply of Alcohol Act, or the Medicines Act.

5. **Applicants required to provide details of involvement in other regulatory regimes**

5.1. Yes, we support this proposal.

6. **License Conditions – records to keep**

6.1. We recommend all licence holders be required to keep:
   - Purchase records - including licence number of the seller from whom the psychoactive substances or products were received
   - Sales records, including quantity of products or substances distributed, and quantity sold in a single transaction
   - Records of disposal of any product or substance and the reason for doing so

6.2. Specific to retail licence holders, we recommend retention of the following records:
   - Incident reports, for example, attempts by a person under 18 attempting to purchase a psychoactive product; theft or burglary (or attempted theft).
   - Feedback from any purchaser relating to adverse effects of a product
7. License Conditions – how long to keep records

7.1. License holders should keep records for a minimum of 7 years in line with financial records.

8. Discretionary Conditions

8.1. We support the proposals to:
   - require display of license on the premises
   - declare if internet sales are proposed
   - restrict opening hours

8.2. Consumption of psychoactive products within a retail-licensed premise does not appear to be considered under the Act or the proposed regulations. We therefore recommend an interim requirement that licensed retail premises prohibit consumption inside their premises, at least until such time as health impacts of such supply and usage can be assessed and consulted upon, and appropriate health measures and regulations developed. For the interim, this avoids the possibility of intensive use at a party venue, where intoxicated persons may continue purchasing and taking excessive doses of psychoactive products that would be damaging to their health.

In Nelson members of the public sometimes consume smokable ‘approved products’ in public (in full view of minors) on a seat across the road from an outlet. We recommend a restriction around the use of smokable products in public places.

9. Other matters to take into account deciding on applications

9.1. No comment
Product Approval Applications

10. Information Requirements – Method of Manufacture

10.1. We support that Ministry of Health should receive information on proposed manufacturing methods for their own scrutiny, however we believe this information should be kept confidential, and not be made available for public viewing.

11. Information Requirements - Other particulars

11.1. No comment

12. Determining the Risk of Harm

12.1. We support:

- the proposed evaluation of products as per Section 11(3) of the Act as described on page 13 of the discussion document;
  - “(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.”

- the proposal that applications contain information and data on toxicity, pharmacology and related clinical effects of the substance for which approval is sought.
13. Adverse effects / Addictive potential

13.1. We support the proposed requirements as per Question 13 of the discussion document:
   o psychoactive potential/related behavioural effects of the substance
   o addictive potential
   o proposed directions for use
   o previous use

We also recommend that:

13.2. product effects should be tested both alone and in poly-drug situations, especially with alcohol, cannabis and any other substances which are commonly available in New Zealand.

13.3. the testing regime should take into account the likely effects of longer-term use, based on known pharmacological, psychoactive and toxicological effects of the ingredients, with ongoing monitoring at specified intervals, with a clear process for reassessment if problems are reported

13.4. MoH should make random tests of products to ensure retailers do not stock unapproved products.

We recommend that the regulations:

13.5. clearly identify what would constitute an “adverse effect” that would allow the PSRA to withdraw a product.

13.6. require hospital Emergency Department reports to itemise NPS use separately from other substances.

13.7. enable the implementation and promotion of an “adverse effects” 0800 hotline.
Labelling and packaging

14. Labels

14.1. In addition to supporting the proposed labelling requirements, we recommend that the regulations include a clear definition of what is unacceptable under the Act, with regard to “appeal to minors” (for example bright colours, cartoon drawings, or tagging style graphics, etc).

14.2. We support a requirement for plain packaging.

15. Health warnings

15.1. We support the proposed 4 compulsory warnings outlined in the discussion document.

We recommend:

15.2. additional health warnings:

- “Health effects of long-term, regular use of this product have not been assessed”
- “All psychoactive substances carry risk of adverse physical and psychological reactions”
- emergency response information (eg 111 number, and recovery position)

15.3. a minimum font size for health warning labels.

16. Packaging requirements

16.1. We support the proposed packaging regulations as per the discussion document.

16.2. We recommend that naming of products should be restricted to prevent use of words that may associate products with youth culture.

16.3. We recommend that inserts relating to health effects, dosage and emergency response be permitted a more attractive design than exterior packaging in order that they are not immediately discarded, and therefore more likely to be read.

17. Restricting Dose to One per Packet

17.1. We support the proposal to restrict products to one dose per packet. This may work as a psychological or price deterrent to reduce the likelihood of users purchasing larger amounts. It also makes it clear what quantifies a single dose.

18. Split Dose
18.1. We support the proposal to split the dose, in whatever form the product takes. Both the above restrictions (17 & 18) would minimise the likelihood of harm to children who may accidentally consume products.

19. Restrictions of Form of Product

We recommend that:

19.1. approved products should not be pre-mixed with food and beverages, due to risk of accidental consumption by adults and particularly children.

19.2. smokable forms should not be allowed, for 3 reasons:
   o smoking psychoactive substances could establish habitual behaviour which could encourage tobacco smoking.
   o Smoking any product is probably harmful to health
   o Smoking will subject people nearby to second-hand smoke.

20. Storage of substances

20.1. Substances should be required to be stored in storage facilities with alarm systems.

20.2. The location of storage facilities should be disclosed to MoH, but not be visible online.

21. Storage of approved products

21.1. Retail stores should only be permitted to hold a limited amount, eg up to a certain dollar value on premise, to reduce the likelihood that they would be targeted by burglars, and in the event that a burglary removes product, the quantity is minimised.

22. Display of approved products

22.1. Approved products should be displayed in locked cabinets

23. Disposal of approved products

23.1. We recommend a requirement for disposal via a public health regulatory agency such as a District Health Board or the Police. A form should be completed by the regulatory agency recording the product type and amount, identity and licence
number of the person or company it has been received from, name of regulatory representative and witness, and a confirmation that the regulatory agent and witness have seen the product as described (type, amount) and disposed of it according to requirements of the Hazardous Substances and New Organisms Act.

24. Signage

We recommend the following signage be visible in retail outlets:

24.1. Approved products cannot be sold to persons under 18 years of age.

24.2. Persons appearing to be aged under 25 will be asked for age verification.

24.3. Information on how to identify use-related health issues

24.4. Details of where to access help services

24.5. When and how to access emergency help

24.6. Reporting number to call to report adverse effects
Place of sale and advertising

25. Place of Sale - No comment.

26. Restrictions or requirements for advertisements of approved products
   26.1. We support restriction of advertising from any other media as per section 56(1)(d) of the Act, and the proposed requirement in the regulations that any advertising must be consistent with the Advertising Standards Authority's Advertising Code of Ethics.
   26.2. We recommend a restriction on product endorsement.

27. Internet sale restrictions
   We recommend:
   27.1. Online sales by NZ-based websites should be subject to purchasers using RealMe identification to verify their age.
   27.2. Clear communication of the fact that personal possession of unapproved products (for example products purchased via the internet) is a punishable offence, and the subsequent consequences of being found in possession.

28. Restrictions or requirements on the advertising of approved products
   28.1. We support that the regulations contain detail that ensure on-site advertising is restricted to objective information only.
Fees and Levies

29. No comment

30. No comment

31. Fees for other specific functions.
   31.1. Levies should be collected to enable the establishment of data collection and
         monitoring systems
   31.2. Fees should be collected from retailers to enable development, delivery and
         evaluation of standard training on safe retailing practices such as:
         o identifying under 25 year olds and appropriately seeking identification
         o signs of intoxication, drug-related health or addiction issues
         o how to initiate a conversation about health or addiction issues when
           appropriate, and effective ways to offer or guide people to resources for help

32. No comment
Other comments

33. Transparency of Information

33.1. We recommend that the following information is made publicly available:

- Names of the members of the Psychoactive Substances Regulatory Authority (PSRA)
- How the members are selected
- The length of their term
- Who receives the results from substance testing
- Who receives the fee charged for approval process
- Where the funds raised from the approval process go
- Due date for review of the regulations and the Act

34. Points to clarify

34.1. The new act says no-one under 18 is permitted to purchase or possess psychoactive products. Can MoH clarify whether is it illegal to use if you’re under 18? (ie: if you are aged under 18 and found to be under the influence, is that an offence?)

34.2. What is the government planning to do about “approved substances” that have been known to have adverse effects on people using them, eg: alcohol?
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?

Criminal History Declaration of fraudulent activity and/or involving drugs—detailing any of those crimes committed in NZ or overseas to be submitted with application.

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?

If the local approved products policy is implemented on an informed and consultative basis from all parties who have interests, and that policy represents a non-biased approach based on the who and how retailers operate, not just where, and does not result in the immediate suspension of licences until full legislation is in place, then Yes it should be.

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?

Yes. I think a generic LAPP provided by the MoH will be more balanced and based on information from all relevant parties. Non Biased and an approach that has not only central government but local council, community and the industries points of views considered in it.
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?

All information relating to the import/ amount of psychoactive ingredients applied by batch number/ amount sold by batch number and the amount wholesaled and retailed by product type & batch number should be stored using an electronic system suitable of keeping these records that allows with ease the authority to trace by batch & barcode how much, to who & where these products have been sold.

7 How long should licence holders be required to keep records for?
(As long as the authority sees fit in requirements in terms of timeframe for an audit to take place), and those records be held until at least then

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

The limiting of hours for sale of Psychoactive products. This opens up the ability for the black market to thrive more. During outside of opening hours. We believe a sensible timeframe would be from 8am until 8pm. Limiting it to inside school hours (9am -2.30pm) may seem logical, but again the black market will not be looking to age verify consumers nor what hours they will supply. It also allows for the majority of 8am-5pm workers that may want to purchase an approved product from a licensed retailer will be able to do so at the end of the day of completing work, and take the product home to consume in their own private environment, and not be forced to purchase and possess the product at work during the working day.

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?

Systems used for record keeping.
In particular, electronic record keeping systems that hold – goods received (product delivery from supplier)
Returned Goods (In the event of a product recall or return to supplier due to no sales)
Sales transactions for each product sold.

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?

Yes

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.

No.
GS1 Barcoding on all products essential in the ability for Product transactional handling and record keeping.
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.

Type of packaging material used (Limit to a standard type in relation to form of product ie:
Synthetic cannabis in smoking format to come in tamperproof sealed foil packaging in a standard size and volume. (No tins as this used to make it appealing as a branded storage device.)

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

No. We don't agree with this. If it makes the retail price point of the product due to the small volume contained inside more accessible to low income and for underagers to find adults to purchase the product for them (current market activity has some products retailing at $10 a packet. As a retail group we have identified this as being an issue at certain sites whereas the $20 plus pricepoint stores do not face the same level of underagers attempting to purchase the product. We also do not support the need for different volumes of the same approved product (ie 2g, 5g, 7g) as it creates an unnecessary extended range of the product and excessive stock holdings in a retail store. One generic packet size for the form for each approved product, and that packet size be relevant to what the authority believes is a maximum amount of doses to be sold in one unit (ie Synthetic Smoking Cannabinooids only to come in maybe a 2g packet size only, which will only turn into 2-3 rolled smoking smoking doses) We also believe this will help prevent redistribution through the black market and abuse of the products.

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

Yes, as this will help guide users into not overusing a product accidentally.
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?

No. As long as the Authority believes it poses less than Harm of a risk. Our belief is that as technology advances Manufacturers will find safer delivery mechanisms, particularly in smoking format as this directly transmits into removing the illegal activity of Cannabis smoking.

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?

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

Secure facility with surveillance monitoring outside of sales hours.
For ease of stock monitoring, product should be supplied and stored by batch number, in the event there is an issue with a certain batch the product can be easily separated and identified.

C

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

Products to be kept out of visible sight, and only presented by a folder showing range of products on request for a psychoactive product by a consumer.
23  Do you think restrictions or requirements should be set regarding the disposal of approved products? If so, what should they be?

All products that need to be disposed of should be done by the manufacturer only.
I.e: Product recall/ Not selling/ packaging issues. Return to manufacturer for disposal or repackaging.

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

Yes:
Approved products can only be sold by the licensed retailer to the consumer. It is a criminal offence to onsell any Psychoactive product to another person, and in the event this is found to have occurred, you will prosecuted.

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

No.

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

No Advertising, purely on the package itself that is guided by the authority.
Do you think the regulations should prescribe restrictions or requirements on internet sales of approved products? If so, please provide specific suggestions.

No Internet sales. This is an R18 product and should be handled appropriately with visible contact of the licensed retailer with the end consumer.

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

No Advertising.
Purely what the regulations allow to be on the packaging.
Instore retailers should be allowed to place a generic Authority guideline small sign instore at the Point Of Sale advertising the fact that Psychoactive products are available here. No branding allowed on sign.

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

Yes.

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

Fixed Fee
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):  

Psychoactive Substances Regulations: Submission form
Are you submitting this:
(Tick one box only in this section)

☐ Y as an interim licence holder
☐ Y a person or body corporate intending to apply for a licence
☐ Y other (please specify): On behalf of Interim licensed retailers

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

(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:

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Please put 'Regulations Consultation' in the subject line.

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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?
   
   The list of proposed information is comprehensive enough.

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?
   
   Retail licence applications should be accompanied by evidence of compliance with a Local Approved Products Policy. To support this, the Applicant should be required to attach a copy of the relevant Policy to the Application together with a description and details of how the applicant will comply with the Policy.

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?
   
   Retail licence applications should be accompanied by evidence of compliance with a generic Local Approved Products Policy if there is no LAPP in the area.
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.

In addition to the factors required by Section 16 (2) applicants must:

i. provide a medical certificate that a person is in good health physically and mentally

ii. provide a statement that the person is not bankrupt or has not been declared bankrupt in the last ten [10] years and has not been the director of a company that has gone into receivership in the last ten [10] years

iii. that the person has a character reference provided by an employer or a person who can establish that they are of good standing in the community

iv. any other matter an authority considers relevant which can provide information that they have the ability to run a business

v. provide information that the business is economically viable without the sale of psychoactive substances if an applicant is applying to add psychoactive substances to its existing business

vi. if the applicant is applying for a new licence and does not already have a retail business, provide a business case that indicates that the business is viable and will survive without psychoactive substances. It is understood that there used to be a similar requirement for new service stations, and they had to trade for a number of years before they were permitted to install fuel pumps.

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

1. Applicants should provide details of their involvement in other regulatory regimes such as the Sale and Supply of Alcohol or preceding legislation in this area, and disclose the regulatory environments that they have operated within.

2. They should provide details of whether they have had any failures to comply with those regulations and explain why.

What records should the regulations require licence holders to keep?
Licence holders should be required to keep sufficient records to allow for an evidence base to be built around consumers and long term impacts.

Every single sale should be recorded with a name, physical address, signature and identification verification. This is the standard expected in pharmacies for many non-prescription drugs and should be the level of expectation for these products.

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

The following discretionary conditions should be included:

I. restrictions on opening hours

II. they should be restricted to the usual hours for the shopping centre or the shopping area that the outlet is situated in and if there are no usual hours then the default hours of 9am to 6pm. Products should not be sold on Sundays.

III. that there will be no selling food from the same premises

IV. that the regulations impose a maximum amount of an approved product that can be purchased in a single sale. This regulation would help reduce the likelihood of black-market sales to underage users.

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?

No comment.

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?

No comment.

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?

Yes, there should be total transparency of information, with all effects including adverse effects being provided. It should, in essence, be treated like any other drug on the market.

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?

Yes, and this information should not be skimped on.
Are the proposed requirements and restrictions on labelling sufficient? If not, please make specific suggestions for further requirements and restrictions.

**Labelling and packaging**

I. **Labels**
   a. the proposed requirements are insufficient, they should impose minimum font size for the compulsory printing to ensure that it is legible
   b. the labels must not be similar to other product labels eg sweets.

II. **Packaging**
   a. Should be such a size that the information required for labelling and health warnings will be easily legible
   b. also ensure that packaging will be of a minimum size so it is not easy to carry or pass undetected to an underage user
   c. quantity and dose requirements.

In short, there should be extremely high visibility of the fact that these products are dangerous to your health, similar to cigarette packaging.

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).

There should be contact numbers for emergency assistance, including Healthline, Alcohol and Drug Helpine as well as depression/suicide type support numbers such as Lifeline, Samantans, Youthline.

There should also be basic first aid suggestions such as the recovery position.

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

Products must be safely packaged and unit dosed, not easy to access. Again we reference pharmaceutical drugs that have 'child proof' packaging for safety reasons. This should be no different.

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

i. agree to restrict a packet to one [1] dose

ii. this is aimed at harm reduction; it would take more effort to take multiple pills if each dose has to be unwrapped separately

iii. it is also in line for the reasoning of splitting doses if each packet only has one [1] dose it is even less likely a child may take a dangerous amount.

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

Council agrees that a dose should in whatever form the product takes be split wherever possible. This will prevent accidental use and also slow down consumption.

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?

Products should not be able to take liquid form, which would increase the risk of over consumption.

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?

Storage should be behind locked, opaque cabinets and not on display. They should be inaccessible to the general public in a shop setting.

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?

As for cigarette sales, there should be no advertising permitted.

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

There should be restrictions on disposal. Disposal should be secure so that excess product are not able to be obtained to be on-sold, especially to those who are underage.

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

Signage

- Any signage should not include other products. This is to prevent psychoactive substances being used as an enticement to people to enter the store. It also means that people will make a conscience decision to go to the place to buy psychoactive substances and they may need to make more than one stop.

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

i. private residence should be added to the list of excluded premises.

ii. support vehicles being an unlawful place of sale

iii. it should not be permitted for products to be available at stalls at events

iv. Temporary licensing should not be permitted.

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

Advertising restrictions or requirements

i. should not be allowed near schools, dairies, liquor stores etc or places where people are likely to congregate

ii. should also exclude temporary advertising for example at events

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

Products should not be available for sale over the internet. Proof of age is too difficult to obtain accurately, as can currently be evidenced with the sale of alcohol.

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

See question 26

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?

No comment

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

No comment.

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

No comment
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) Andrea Curtis  
Address: (streetobox number) Private Bag 907 (town/city) Upper Hutt  
Email: Andrea.curtis@uhcc.govt.nz  
Organisation (if applicable): Upper Hutt City Council  
Position (if applicable): Director of Community Services

Are you submitting this:  
(Tick one box only in this section)  
☐ other (please specify): As a local authority

Do you wish to receive updates about the development of the psychoactive substances regulations?  
☐ Yes  
(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:  
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Psychoactive Substances Regulatory Authority  
Ministry of Health  
PO Box 5013  
WELLINGTON  
Email: psychoactives@moh.govt.nz

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☐ I do not give permission for my name to be listed in the published summary of submissions.
I don't have a lot of time to write a compelling email as I have four children to look after as well as having leukemia and a husband addicted to legal highs. I have a lot of knowledge and experience in the field of addiction and I honestly believe my husband wouldn't be where he's at right now if these drugs weren't legal and sold in local dairies and sex shops. It is destroying our family and our youngest is only 12 weeks old. I am currently on my own with our children due to his addiction and behavior and have to resume oral chemo next week. Needless to say this is a very difficult time for us. Please ban all these legal highs!!! It has become a extremely widespread problem all over New Zealand. We have enough problems with illegal drugs, we are now seeing a major increase in addictions because of legal highs. Please!!!! Get them out of our country!!!!

Sent from my phone on the smartphonetwork
Making a submission

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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?

   Business telephone contact number should be required. This makes it easier to make enquiries with the applicant and schedule appointment times.

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?

   Yes. This will then alert applicant to research and find out about Local Approved Products Policies (LAPPs) early on in their planning. Also if council's do not have a LAPP and they get a number of people asking about it, then this may prompt the council to look at writing such a policy.

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?

   Any local policy which places restrictions on licensees' proximity to sensitive sites should address the potential for new sensitive sites being established after a license is granted. For example, what will a territorial authority do if they decide that schools are sensitive sites, and a new school is proposed near an existing licensed premise?

   The conditions set out in a generic LAPP should be open for consultation prior to being implemented.
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.

Anyone engaged in the sale of psychoactive substances should be able to engage the purchaser in English in order to determine they are over 18 or intoxicated.

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

Yes, Toi Te Ora – Public Health Service believes that the authority should cross-check an applicant's involvement in other regimes such as Sale and Supply of Alcohol. This would enable the authority to check an applicant's compliance in other regimes and would provide further evidence of the suitability of the applicant.

The authority should clarify 'involvement'. License holders, duty managers, and bar staff are all involved in the sale of alcohol, but have varying degrees of responsibility and training.

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

Toi Te Ora – Public Health Service supports the proposed requirements for the different license types, as described in the discussion document.
7 How long should licence holders be required to keep records for?

No comment.

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

Toi Te Ora – Public Health Service supports the requirement to have the licence displayed.

Retail licensees should provide basic training in the purpose of the Act and Regulations to all employees, and satisfy themselves of the employees' understanding.

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?

No comment.

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?

Yes.

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?

Yes.

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?

Yes.

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

Toi Te Ora – Public Health Service is opposed to the sale of psychoactive substances being available in the form of smoking products. However, should they continue to be permitted, any psychoactive substances that are also smoking products should be packaged in plain packaging and displayed in line with the requirements of the Smokefree Environments Act and its regulations.
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).

Any approved product that is a smoking product should carry a second health warning advising that inhaling the product is harmful.

Other non-tobacco smoking products can contain levels of harmful substances such as carbon monoxide and tar similar to tobacco products. These may contribute to cancer and respiratory diseases.

It should be noted that Toi Te Ora – Public Health Service recommends that no approved products should be smoking products.

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

See question 14.

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

Yes. Restricting the product to one dose per pack reduces the risk of a person overdosing on a 'party-pack' of product.

If a packet contains more than one dose there is an increased risk of separation of the product from written warning material i.e. sharing product with friends and not passing on health warnings.

Limiting a packet to one dose reduces the risk of unlawful on-sale.

The maximum amount of product that can be sold in one transaction should be determined in reference to the toxicity data provided when the product is approved.

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

Yes.
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?

Approved products should not be smoking products. New Zealand has a goal of being smoke-free by 2025. To achieve this goal a number of things need to change, particularly the de-normalising of smoking. By making it acceptable to smoke a psychoactive substance does not help achieve this goal. As long as there are people in the community who can be seen smoking ‘something’, smoking will appear acceptable.

Approved products should not resemble smoking products, foods (particularly confectionary) or drinks. Products should not be injectable. Every effort should be made to ensure that approved products do not look attractive to children.

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?

Storage should comply with the Hazardous Substances and New Organisms regime.

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

Storage should be as per the manufacturer’s recommendations e.g. refrigeration, out of direct sunlight.

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

Display requirements for approved products that are also smoking products should match the requirements of the Smokefree Environments Act. In particular these products should not be on display and not advertised.

Care should be taken to ensure that the display of other approved products is not attractive to minors.
23 Do you think restrictions or requirements should be set regarding the disposal of approved products? If so, what should they be?

Yes, customers should return products to the retailer and retailers should return products to the manufacturer.

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

All retailers should be required to display signage which states it is an offence to sell to people under 18, and that proof of age may be requested. This should be observable at the point of sale. The sign should also state that all products pose a low risk of harm, not any risk.

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

The Regulations should restrict the sale from domestic residences. Such a restriction would reduce the number of 'legitimate tinny houses' in neighbourhoods, and reduce the exposure of persons (particularly children) to approved products.

Sales should also be restricted at:
- sports and recreation facilities such as aquatic centres;
- cinemas;
- airports, aircraft and aerodromes.

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

Advertising must be consistent with Advertising Standard Authority's Advertising Code of Ethics. Advertising must not appeal to minors.
27 Do you think the regulations should prescribe restrictions or requirements on internet sales of approved products? If so, please provide specific suggestions.

Internet sites must contain health warnings and be restricted to over 18 years – via an entry page.

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

See question 26.

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

No comment.

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

No comment.
31 Should fees be set for other specific functions? If yes, please state what they should be set for.

No comment.

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

No comment.

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) Dr. Jim Miller
Address: (street/box number) PO Box 2120
(town/city) Tauranga
Email: Jim.Miller@bcpdhb.govt.nz
Organisation (if applicable): Toi Te Ora – Public Health Service
Position (if applicable): Medical Officer of Health

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): Toi Te Ora – Public Health Service

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.)

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Consultation questions

1. Is the list of proposed information requirements for licence applications comprehensive enough?
   If not, what else should be required, and why?

   1. Information on difference between licencing a product and licencing a substance seems unclear.
   2. Will a licence be required to import a chemical entity, or is a chemical entity considered to be a 'substance'?
   3. For manufacture, how will the quality of plant materials be tested and assured? How will intra and inter batch variation be dealt with?

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?

   Yes and also if they have previously held other related licences (for example, Liquor licence, gambling related licence, licence in relation to delivery of alternative medicines/healthcare), and any violations / breaches of those licences.

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?

   As above
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.

NZ resident – does this mean has permanent residence status, or just that they live in NZ?
Clarification around what is meant by “relevant offence” — in the context of what legislation/regulations?
Medicines Act? Misuse of Drugs Act? Liquor licensing, fraud?

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

Yes, including any breaches

What records should the regulations require licence holders to keep?

Importers, manufacturers and researchers

- Name of substance, chemical, device
- Name and address of person who supplied or person it was supplied to
- Amount in grams or units
- Date obtained or supplied
- Batch number
- Signed and dated, and checked by someone else with authority to do so

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.

Internet sites to display link to official website which holds documentation confirming the licence details

C

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?

YES

- Ability of licence holder for retail to be able to prove age of purchaser
- Sales outside of New Zealand to be banned?
- Export only allowed for research or to places which legally allow importation?

C

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?

Yes, in detail

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?

Yes.
The regulations need to clarify and specify what is meant by “related clinical effects”
Also the regulations should include a requirement for consideration of drug – product interactions in deciding whether to licence

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?

In relation to:
- the psychoactive potential and related behavioural effects of the substance
- the addictive potential

Yes, such data should be required, although may be difficult to show. What information exactly will be required? Is it a requirement to ‘prove’ the above? Or just an indication? i.e. what does ‘contain information and data on’ actually mean in practice?

With respect to:
- previous use, including use in clinical trials and in the wider population?

What is the definition of clinical trial, in this context? Information will be required not just on the outcomes, but on study design, ethical approval, etc.

14 Are the proposed requirements and restrictions on labelling sufficient? If not, please make specific suggestions for further requirements and restrictions.
Additional suggestions:
- How to dispose of the product safely
- Quantity of product – dosage units
- Information on how to report to CARM - carm.otago.ac.nz/
- AOD helpline
- In an emergency call 111
- Contact details for manufacturers/licence holders must include phone number in NZ/email address/website/physical address
- How much time must elapse before a repeat dose (assuming only one full dose per pack, would need to clarify that if starting a new pack need to wait...)
- More detailed info on package insert

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).

Yes see question 14 in relation to CARM, 111, repeat dosing, AOD helpline

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

Package insert – see above

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

Yes.
Limits risks of people buying larger packs and then sharing with others. In such a scenario, those ‘others’ would not have access to the health and safety warnings or any package insert. Also no batch number for tracing problems later, CARM reporting etc

18 Do you agree with the proposal that a dose, in whatever form the product takes, is split wherever possible?
Yes. And there needs to be clarification that taking all the split doses at once constitutes a maximum recommended dose within an X time period (X to be explicitly defined).

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?

Dosage forms which speed up the delivery of the active ingredients to the brain should be avoided. Rapid onset of effect can be a reinforcer for abuse, for example inhalation via the nasal passage or through the lungs, including E-cigarette type delivery devices. Furthermore, the Government is trying to get NZ Smoke Free, so licensing smokeable products sends out the wrong message. Also health implications of inhaling combusted plant material.

Oral formulations should not be easy to inject. For example, liquid filled capsules allow for needle to be inserted and liquid easily injected. However, if people are likely to inject these dosage forms sometimes these ‘harm reduction’ measures may end up being more harmful (e.g. blocking veins)

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?

In wholesale and manufacturer environments should be locked away, and a requirement to sign substances in and out with detailed records kept.

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?
In retail environments they should not self selection.

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

For manufacturers, wholesalers, retailers: Disposal should be by an approved method in the same way of medicines. For example not in general garbage, not into waterways or drinking water systems. Disposal by the public – maybe have something on the packaging

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

Signage should be standardised by regulation. All retailers should use the same sign. That way it is easy to recognise a retailer. The sign should also include the licence holder name and licence number and expiry date of licence.

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

Petrol stations. Healthfood stores. Healthcare settings (e.g. clinics, pharmacies)

26 Do you think the regulations should prescribe restrictions or requirements for advertisements of approved products? If so, please provide specific suggestions.
Attention needs to be paid to the role of social media and how this can be managed.

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

Site must not be designed to appeal to under 18 year olds.
Site must not be able to sell outside NZ
Site must have a reasonable means of checking the age of the purchaser (is just ticking a box to say "I confirm I am 18 years old or over" enough?). If not, and details are required for verification, how will the data be managed?
For example, in a physical store the person can ask to see documentation. Online this is slightly different. Would a purchaser need to scan a document and upload? Then someone would need to verify and destroy the scanned document.

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

As Q 26
Should not link the product with fun, getting high etc.

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.

Fees should also cover the cost of managing CARM reporting and analysis, for example.

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)  
☑ other (please specify): individual  

Do you wish to receive updates about the development of the psychoactive substances regulations?  
☑ Yes  
(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.
Hi,

The Winton Community Support Committee want to make a submission with regard to the Psychoactive Substances Regulations.

I have copied out the submission pages from the document you send out and I can return them to you if you really need them. However, we don't want to answer the questions individually so I hope the following is acceptable. Our submission is:

"We do not want any psychoactive substances to be sold in Winton or the surrounding districts".

The reason is that we have enough social distress and antisocial behaviour without adding another cause. It is these antisocial elements in our community that make our Community Worker's role difficult.

We want the community to be a place children, old people and women on their own can feel safe and freely enjoy walking and playing outside.

regards

Cherry Thompson

Chairperson of Winton Community Support Committee

Winton 9720
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?
   
   No. Should also include residency status/work visa and any classification under any relevant Act. Applicant need to meet "Fit and Proper" person test criteria. Past history also important in terms of other matters that may affect eligibility.

   Gender identification is not considered necessary.

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?
   
   Yes definitely

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?
   
   Yes definitely
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.

Yes sufficient.

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

Yes, it provides an indication of the applicants experience and knowledge of retailing other potentially dangerous drugs.

What records should the regulations require licence holders to keep?

Records of bulk sales to individual persons. Also: amount of product stored on the premises and confirmation that it is in cool storage.

How long should licence holders be required to keep records for?
For the entire duration of the licence i.e. 5 years.

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

Council supports all the discretionary conditions suggested by the Authority and in particular the restrictions on opening hours of sales.

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?

Any general past history of the person/s relating to all laws eg regular traffic law offending, in line with the Sale and Supply of Liquor Act 2012.

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?

Yes most definitely

11 Do you think any further particulars, information, documents or other material should be prescribed in the regulations? If yes, what should these be?
Council supports a description of proposed manufacturing methods and demonstration how they will comply with the Code of Manufacturing Practice.

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?

Yes most definitely in terms of the manufacture of approved products.

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?

Yes to all the above.

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

Yes
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).

Include a statement that the consumption of any amount of the approved product may be injurious to one's health. Provide take out brochures and literature to customers that is readily displayed and valuable from the Ministry of Health on the health risks of consuming psychoactive substances.

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

Packaging should be plain and not glamorous the product e.g. no graphic positive imagery. Could include imagery of the results of overdosing and negative imagery. Display a “use by” date?

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

Yes. One dose to be limited to 3 grams. Need for definition for "dose"? Reason is to assist in reducing the risk of overdosing.

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

Product should be sold in the form to comes from the manufacturer and packaged in safe doses to limit ability for tampering and mixing with other lethal chemicals thereby increasing the risk of harm. Who would be doing the splitting? Support protection of children not consuming product inadvertently as non-prescription/prescription medication -clear labelling therefore to state not suitable for persons under 18 years and contains substances harmful to minors.
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?

Yes follow a similar line to tobacco policies.

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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?

Yes. A restriction on the amount able to be stored on a premise may deter burglaries. All shops to be fitted with CCTV camera surveillance and security alarms.

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

Yes ensure a minimum amount of product is available for sale and the remainder is stored in a secure cabinet on the premises.

---

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

No maximum purchase limit but buyer to meet safe storage requirements including cool storage. No visible product from either a public place or to the customer (as per tobacco sales). Storage to be in accordance with the Act.
23 Do you think restrictions or requirements should be set regarding the disposal of approved products? If so, what should they be?

Yes regular and secure disposal to an approved site for disposal. With regards any banned hazardous substance there needs to be an immediate ban and not time lapsed with regards disposal. Support inclusion in regulations rather than reliance on Hazardous Substances and New Organisms Act.

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

Yes most definitely. Council agrees with the suggestion made by the Authority

External advertising to be restricted to one small fascia sign stating "Approved Psychoactive Substances Shop"

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

No

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

Yes. Regulations should also include restriction for advertising on buses and other public transport, bus and other transport shelters and depots, before film screening and at public audio-visual events.
27. Do you think the regulations should prescribe restrictions or requirements on internet sales of approved products? If so, please provide specific suggestions.

Yes. Council supports age verification, age declaration, licence publication and health warnings. Internet sales from NZ licensees would be prohibited.

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

Yes. Approved product promotion/advertising should be restricted to plain packaging.

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

Agree with the price differentials but would support even higher fees ie 50% higher. What is meant by "Non approved Products" in Table 1?.

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

Hourly rate charge. Who pays for monitoring of product health impacts after approval?
31 Should fees be set for other specific functions? If yes, please state what they should be set for.

Yes. Monitoring and compliance costs for regular checking.

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

Yes. Again the annual levies could be even higher ie 50% higher.

Additional Comments

- There should be more local government involvement in the granting of licences for the manufacture and sale of psychoactive substances. Council submits that it desires "to have a greater say" in matters that affect the health and wellbeing of the inhabitants and communities in its district. There are numerous examples of this in other legislation eg Sale and Supply of Alcohol Act, Resource Management Act and the Gambling Act. The Gambling Act empowers territorial authorities to develop Class 4 (pokie machines) policies which control the number of venues and machines in their district. Without the approval (site approval/certificate) from the T.A., the Department of Internal Affairs will not grant a Class 4 venue licence. There should be additional provisions/powers provided to councils within the legislation more so than merely a simple planning instrument on the locations of sales points ie social impacts, harm to communities or inhabitants must be extended to councils.
- Who better than a territorial authority to determine what is best for its residents.
- The licensee has no real control over the management of retail outlets. There is a need for general manager certification similar to the Sale and Supply of liquor licences and requirements for managers to be physically present onsite during the retail opening times.
- Manager's certificates should follow a Fit and Proper Person test same as for licensees.
- Social concerns on impact to families and communities is greater than individual consumers health concerns.
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) Alan Moss on behalf of the South Waikato District Council
(street/box number) Private Bag 7, Tokoroa 3444
(town/city) Tokoroa

Email: alan.moss@southwaikato.govt.nz
Organisation (if applicable): South Waikato District Council
Position (if applicable): Planning Manager

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): Territorial Authority

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

☐ Yes - alan.moss@southwaikato.govt.nz
(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

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Dear The Manager, Psychoactive Substances Regulatory Authority, Ministry of Health (please acknowledge receipt of this submission)

I am a public health physician in British Columbia, Canada, and I have been closely following the recent NZ initiative to regulate psychoactive substances.

This submission is consequent to a personal interest in this topic and work I have done with a group of public health physicians in BC, the Health Officers Council of BC (HOC); and work I am doing with the Canadian Public Health Association on public health approaches to illegal and pharmaceutical drugs (especially opioids).

The recent publication by HOC (see http://healthofficerscouncil.net/positions-and-advocacy/regulation-of-psychoactive-substances/) forms the basis of most of my suggestions and contains additional information that you might find useful.

In addition I have recently presented and participated at a NZ industry sponsored event on March 20, Pathway to Reform, for which my travel and hotel were covered by Star Trust, but no compensation was requested or given.

I have had the opportunity to review documents on the NZ Ministry of Health website, including "Psychoactive Substances Regulations: A consultation document" and the following comments are provided corresponding to the numbered consultation questions in and at the end of the regulation consultation document.

These comments are given in the spirit of assisting to develop regulations that protect and promote public health and support the intent of the new Act. These comments are my personal comments as a practicing public health physician and DO NOT represent the opinions or position of the Government of BC.

Overall NZ is to be congratulated on this innovative and world leading approach!

No where else has there been developed such an explicit, well thought out initiative to regulate rather than prohibit psychoactive substances in the interest in protecting public health and minimising harm.

The importance of this in avoiding the harms of prohibition that arise from criminalizing such substances cannot be overstated, so kudos to you!

The following are my specific comments. Please note that I have not commented on all the questions:

Licence Applications
In general it is likely that guidelines for preparing local authority products policies would be helpful.

3. A generic local policy would seem to defeat the purpose of having specific local policies and would seem to add another level of central regulation that may not be necessary. Perhaps development of a local policy should be entirely left to the discretion of the local council.

Fit and proper person test
4. It is not clear whether "other grounds" includes just convictions, or additional information. If information in addition to convictions are to be considered does the applicant have the right to know what is that information, and have the right to appeal an adverse decision based on that information.

Licence conditions
8. A history of complaints, non-compliance and contraventions could provide a basis for additional conditions, based on the specifics of the history.

I am not sure if it would apply here but considerations should be given to requiring retail shop owners, managers, and staff to complete an approved course (could be internet based) regarding the basics of psychoactive substances, obligations under the Act and regulations, how to deal with difficult customers or how to deal with/refer if concerned about health/behaviour of certain customers, working with community health and social services and local government, and perhaps other issues. Consultation with retailers and health and social services would assist in refining these requirements.

Determining the risk of harm
13. "addictive potential" is a difficult term to define due to conflicting views of the concept of "addiction", and imprecise definition of this concept. The Act already refers to "physical or psychological dependence", so it is probably adequate to stick to these terms as they are better understood.

Labels
14. The label should clearly indicate that approval by government does not mean that the product is "safe" as that may be the impression created by government approval. This message should also be included in any public information put out by government on this topic.

I suggest avoiding the concept of "recommended dose" and instead refer to maximum doses, with advice to generally take less than maximum, especially for first time users.

Labels should not be allowed to imply an association with sports, entertainment industry, sex, performance enhancement, celebrities, relaxation, being energized, or pleasure.

Limiting labels to black (or an alternative color) and white would also assist in reducing the creation of attractive labels that could result in product promotion.

15. Health Warnings - Consider requiring that the warning state that people who experience adverse reactions should report the event by phone to an appropriate centre e.g. the National Poisons Centre.

The warning should clearly indicate that approval by government does not mean that the product is "safe" as that may be the impression created by government approval.

16. Packaging - The regulations, or accompanying guidelines that must be followed, will need to be clear on what "packaging that associates approved products with youth culture" means.

The regulations should also allow the authority to refuse packaging that associates products with sports, entertainment industry, sex, performance enhancement, celebrities, relaxation, being energized, or pleasure.

The package should clearly indicate that approval by government does not mean that the product is "safe" as that may be the impression created by government approval.

Quantity and dose requirements -
17. Restricting packets to one dose initially is a reasonably conservative approach, however once experience is gained it might be reasonable to allow more than one dose so the Authority should be given the discretion to allow increased doses for specific products based on evidence that the product is not causing problems.

18. Splitting the dose initially is also reasonable, but again the Authority should have discretion to vary the application of this requirement based on the specifics of and experience with the product.

Restrictions on form of product
19. I would agree that prohibiting injectable forms is reasonable for the reasons mentioned in the document. Restricting to oral products may be too restrictive as the effects may best be achieved by inhalation, oromucosal spray, or sublingual absorption. Also delayed effects due to ingestion may lead to overdosing as the person may not think the product is working and take an excessive amount. The frequency of inhalation is unlikely to be similar to tobacco, but the actual practice could be a subject of research. If the product is to be inhaled then encouraging vaporized preparations may be preferable to forms that require ignition, but it may be premature to be too restrictive on this point until more evidence and experience is gained.

Storage, disposal and display
23. Approved products should be restricted from display to the general public, and should be restricted from display to persons under 18 if being sold from a shop to which the general public has access.

Signage
24. To limit product promotion there should be signage requirements. This could be achieved by having requirements that standardize sign size and shape to be bland in nature, limiting colors and not allowing lighted signs, and including restrictions such as mentioned above for labels and packages about not allowing associations with sports, entertainment industry, sex, performance enhancement, celebrities, relaxation, being energized, or pleasure.

Signs could also indicate that approval by government does not mean that the product is "safe" as that may be the impression created by government approval.

Place of Sale
25. The co-use of inhaled products with tobacco is a potential concern (as has been identified with respect to co-use with alcohol), and consideration should be given to restricting sales to shops that do not sell tobacco. This would reinforce the message to not co-use.

Advertising
26. Product promotion or promotion of companies that produce products is a major concern from a public health perspective, as it is a significant driver of population levels of use and consequent harms. Product promotion includes advertising, sponsorship, product placement in entertainment, give aways, and associations with sports, entertainment industry, sex, performance enhancement, celebrities, relaxation, being energized, or pleasure.

All activities that are designed to promote products or promote producing/distributing companies though such strategies as above should be prohibited by regulation. Relying on voluntary codes of conduct have been demonstrated to be ineffective in limiting alcohol promotion, so enforceable regulations are needed. One exception for company sponsorship could be allowing sponsorship of industry events.

27. The comments above should apply to internet product promotion.

28. The comments above should apply to on-site product promotion.
Levies
Although not directly related to the questions in this section I wish to point out that price is an important determinant of consumption levels for tobacco and alcohol, so some considerations should include establishing minimum product pricing schemes that discourage excess consumption or diversion to the youth market.

Lastly I would like to comment on the importance of resources, research and evaluation.

On the resources question I anticipate that this initiative will initially be resource intensive, so ensuring that there are adequate numbers of well trained personnel will be crucial. In particular district and ministry health department staff and police who are expected to implement this new regime will need to be well supported.

With regards to research and evaluation, this initiative is actually an experiment on a large scale with many unknown and unanticipated consequences - both potentially positive and negative. The implications will be very important not only to New Zealand, but also to the rest of the world as they consider this new paradigm.

Therefore I suggest that this initiative be accompanied by a robust research program to generate and translate knowledge about this initiative, and that a comprehensive evaluation plan be designed and implemented now so that information can be generated to assist in monitoring progress, detecting unanticipated consequences, and supporting decisions to change course if necessary.

I sincerely wish you well in this exciting endeavor and would be pleased to elaborate on or discuss any of these points further.

All the best and I look forward to hearing more about your progress.

Sincerely,
Brian Emerson

Dr. Brian P. Emerson, Medical Consultant, Population and Public Health Division
BC Ministry of Health  4-2 1515 Blanshard St. Victoria, BC, V8W 3C8
T 250.952.1701  C 250.514.2219
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?
   The Rotorua District Council suggests that the details required on the application form should be similar to that of an application for a liquor licence. The staff employed at the retail premises should also be required to undergo a vetting process that includes the police conducting a suitability check to ensure that they are a fit and proper person.

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?
   If a Local Approved Products Policy has been adopted in the Council district then the Regulatory Authority must ensure that the application is accompanied by how the applicant demonstrates they are complying with the Council Policy.
   Council must be required to be involved with the process of checking the application against the relevant Council Policy and there should be a provision included that allows Council to charge a fee for this service.

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?
   Council supports that there should be a generic policy for those Councils that do not develop their own policy.
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.

Council supports the submission from LGNZ. The Authority should take into account whether the licensee has had any past breaches or committed any other offences. Included in this check should be any warnings issued by any regulatory agency for breaches of their current licence.

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

Yes, applicants should disclose details of where they are involved in other regulatory regimes such as alcohol, gambling and prostitution.

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

Records that licence holders could keep are the names of staff employed at the premises, and the list of products sold and to whom, including photo identification of the person sold to. This could use a similar process as used for the sale of alcohol. Ie Drivers licence, passport or the Hospitality 18+ card.
7 How long should licence holders be required to keep records for?

Similar to other requirements under the law for financial records, i.e. 7 years

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

The Authority must take into consideration any LAPP in force in the district. The LAPP may also include the days and hours that a retailer may be permitted to sell approved products. The timeframes should be set to reduce social impacts in the community, of having these products available when vulnerable people like school children would/could be in the area.

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?

Council supports the use of the LAPP to add further matters of consideration plus any matter that would raise the bar higher for granting of licences.

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?

Yes agree with the proposal
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?

   Agree with this proposal

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?

   Agree with this proposal

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

   Agree with the proposed labelling requirements
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).

Agree with the health warnings proposed. Ensure that health warnings include the risks associated with the consumption of alcohol and the product.

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

Agree with the proposal on packaging and restrictions

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

Agree with the proposal to restrict the dosage to one

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

Agree with the proposal that the dose is split
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?

No products should take the form that is appealing to children or youth, i.e. block colours, no artistry on the products and no shapes that appeal to youth. The term 'legal high' should not be used as this implies that the product is legal and it is safe.

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

Suggest that the products are stored out of sight in a locked cabinet, similar to tobacco products.

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

Licensees should only be permitted to possess a set amount of product with the product being secured at the end of each day in a safe or similar storage device.

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

Ideally the products should be locked away in a cabinet, unable to be seen. Products should not be easily visible from the street.
23. Do you think restrictions or requirements should be set regarding the disposal of approved products? If so, what should they be?

These products should only be allowable to be disposed of in such a manner similar to the disposal of prescription medicines.

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

Signage should be restricted to the internal confines of the premises, no colours that appeal to youth and a maximum size of the sign. Should external signage be allowed then it must be approved by Council. Signage must be displayed at the point of sale, stating issues like but not contained to; no product will be sold to anyone over 18 years of age, similar to that required for Alcohol sales. Window displays should not display approved products.

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

Approved products should not be able to be sold in premises that hold a gambling licence.

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

Yes, no exterior signage allowed for approved products and signage only to be confined to the interior of the retail premises place of sale. Again, reinforcing that the products are not attractive to young people, as previously mentioned.
27 Do you think the regulations should prescribe restrictions or requirements on internet sales of approved products? If so, please provide specific suggestions.

Internet sales should be subject to the restrictions in regards to obtaining a person's age of being over 18 and the use of a Realme login to verify a person's credentials. Must ensure at all steps, that the problems currently being faced by internet sales of Alcohol are not repeated.

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

Yes, advertising should be contained within the interior of the premises only, no physical hawking or leaflet distributions should be permitted.

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

Agree with the proposed fees. They should be charged per licence per premise and ensure that it is non-refundable even if the licence is not granted. A new licence application and fee should be charged if the licensee moves premises. Must ensure all the full costs of the Authority are recovered from licensees.

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

Support for a fixed fee base and the ability to then charge hourly for anything over the fixed fee.
31 Should fees be set for other specific functions? If yes, please state what they should be set for.

Council must have the ability to charge to get full cost recovery and have the ability to review charges in the future similar to functions like approval for prostitution and Class 4 gambling.

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

Agree with the principle that all costs can be recoverable from the industry

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) Councillors Merepeka Raukawa - Tait and Karen Hunt

Address: (street/box number) Private Bag 3023, Rotorua Mail Centre, (town/city) Rotorua 3046

Email: mail@rdc.govt.nz

Organisation (if applicable): Rotorua District Council
Position (if applicable): Chairperson and Deputy Chairperson, Strategy, Policy and Finance Committee
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): Local Council

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.
18 March 2014

The Manager
Psychoactive Substances Regulatory Authority
Ministry of Health
PO Box 5013
Wellington 6145

By email: psychoactives@moh.govt.nz

Dear Sirs,

Re: Psychoactive Substances Regulations: A consultation document
Community Action on youth and Drugs (CAYAD) Whanganui welcomes the release of this consultation document as the issue of psychoactive substances is one of much interest and concern within our community. We thank the Ministry of Health for providing this opportunity to comment on and provide input into the development of the psychoactive substances regulations.

Introduction
This submission begins with several important additional considerations to protection of health under the purpose of the Psychoactive Substances Act ("the Act") that are not covered in detail in the consultation questions. This is followed by our responses to the specific consultation questions.

Internet retail: We recommend that to achieve the intentions of controlling and limiting supply through LAPPs that internet sale is prohibited. Internet sale makes products available anywhere, and with very limited oversight or connection made with purchasers of products who may be highly vulnerable individuals.

Research into substance or product risk levels: We are concerned that the trial and assessment of new products should be conducted in a reliable and independent manner. We therefore recommend that the Ministry of Health identifies a list of approved testers or researchers who are the only groups able to provide the trial data that the Psychoactive Substances Expert Advisory Committee (PSEAC) and Psychoactive Substances Regulatory Authority (PSRA) require to assess products for approval. We recommend that approved testers/researchers:

- demonstrably have no vested interest in the wholesale, manufacture or retail of psychoactive substances/products
- have no other conflict of interest the Authority (or the Psychoactive Substances Expert Advisory Committee) considers relevant.
- work to the same international standards required for approval of medicines.

Monitoring and reporting adverse reactions: It will be challenging to monitor the health effects of products after they are approved. Wilkins\(^1\) cites the difficulties of identifying the effects of specific drugs, such as the way that recreational drugs are often used in combination, effects that are similar across substances or similar to health conditions, the rarity of some effects, and long timeframes between use and effects. In addition, product manufacturers and retailers have a financial disincentive to monitor the safety and impact of their products. For these reasons, we recommend:

- Independent monitoring is well resourced by levies, and carried out under the oversight of the PSRA. Manufacturers should be required to develop and include a detailed plan for monitoring of their product in their product application.
- Monitoring plans should include:

\(^1\) Wilkins, C. A critical first assessment of the new pre-market approval regime for new psychoactive substances (NPS) in New Zealand. February 2014. Addiction. DOI: 10.1111/add.12484
- Regular collection of baseline data on emerging patterns of use and effects of the product.

- Detailed analysis and review by the PSRA every three years after approval of a product.

- Enable thorough medical case events to be developed — including provision of resources for medical staff to undertake detailed testing and analysis to case events (individuals suffering acute or chronic symptoms from use of a product).

- We suggest a suggestion to use the Centre of Adverse Reactions Monitoring (CARM) as the first agency to contact to report an adverse reaction to a product. We recommend investment in a user-friendly process for reporting adverse effects of psychoactive products, with relevant forms.

- We suggest exploring a simple national system for collecting and providing such data to CARM through all medical facilities in New Zealand, particularly emergency departments.

- Funding for independent, university or other non-government research into the appeal of psychoactive products to vulnerable populations and assessment of trends in product use.

**Product Recall:** The Psychoactive Substances Act provides for recall of a product if “the product poses more than a low risk of harm to individuals using the product”. We are concerned that this definition may not allow for recall of a new product that could be causing serious harms when used in combination with another product or drug. We suggest the regulations or the Act include a power for the authority to recall a product if evidence shows it poses more than a low level of risk in combination with products legally available before the date of its approval. New Zealand research has shown that recreational drugs are very often used in combination here, most commonly with alcohol.

**Tax:** We recommend a tax is applied to approved products in order to:

- Cover potential expenses for government services including justice, social services, health and particularly ongoing independent monitoring and analysis of longer term effects of products. Because no psychoactive product can be entirely safe for all individuals, health interventions and social support will be required for some users.

- In addition, tax is an efficient way to make products more expensive and therefore discouraging heavy, dependency-oriented patterns of use and making it more difficult for young people under the age of 18 to access substances.

**Drug-Driving:** We recommend for each product that is to be approved, that prior to approval assessment is carried out of its impact on risky tasks such as driving and the operation of machinery, and safe levels or limits for diving established. In addition, reliable and simple roadside tests for the presence of such drugs will be required.

**Total product cap:** We recommend a cap on the number of products that will be approved. Beyond ten additional products, for example, various difficulties and expenses will be incurred:

- Monitoring and oversight of health impacts by the PSRA will be very difficult.

- Assessment of risks of using products in combination will also be highly difficult as the number of possible combinations increases.

- Testing of users by Police to confirm intoxication while driving will become very difficult

- Testing by regulatory bodies such as Police and Customs to confirm a product or substance is approved/unapproved will be more expensive and difficult.

**SUBMISSION**

- **Identification**

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CAYAD Whanganui supports the proposed requirements for identification and favours the introduction of a requirement that licence holder's keep the Psychoactive Substances Regulatory Authority (Authority) informed of any changes with respect to their contact details.

CAYAD Whanganui support the proposal that all applicants undergo a NZ Police check. However, as part of this police check CAYAD Whanganui believe that all prospective licence holders should be required to advise the NZ Police of any other licences they may currently hold, or have held in the past along with details of how long they held such licences, infringements, suspensions etc. Additionally, with respect to the proposed NZ Police check CAYAD Whanganui, believe that rigour applied to the NZ Police check should be an exception to the ‘clean slate’ rule i.e. that all convictions be visible and considered. Where a licence application is made in the name of a business CAYAD Whanganui believe that both the NZ Police check and the ‘fit and proper’ person test should be undertaken with respect to each named director of the Company. CAYAD Whanganui would also like to see an extension to the proposed regulations making it mandatory for a retail licensee of psychoactive products to undertake NZ Police checks with respect to all their staff.

- **Fit and proper person test**

CAYAD Whanganui believes that as part of the ‘fit and proper’ person test and as an extension of the NZ Police check there is also a need for the Authority or its Agent to consult with both the local District Health Board (DHB) and local council to ascertain what information the DHB and council may have with respect to those individuals who have previously held licences which were regulated and monitored by the DHB and/or local council.

- **Inspection of premises**

As part of the application process for retail premises CAYAD Whanganui support the proposal that a Ministry of Health official should inspect proposed retail premises before a licence is granted. Furthermore, we believe that in addition to this pre-licence inspection there should also be provision within the regulations for annual or six monthly unannounced inspections by a Ministry of Health official or its agent.

- **Compliance with Local Approved Products Policy**

CAYAD Whanganui believe it is essential that with respect to retail licence applications the applicant must provide the Authority with evidence confirming that the location of their proposed retail premises complies with the local authority Local Approved Products Policy (LAPP). Such evidence to be in the form of a letter of confirmation provided by the local DHB medical officer of health or health protection officer. Additionally, as not all local authorities will develop a LAPP, Safer Whanganui strongly supports the development by the Authority of a generic/default policy which can be applied to all retail licence applications in connection with communities who do not have a LAPP.

- **Changing premises**

The consultation document states that one of the key criteria for the Authority when drafting the regulations is that they must be clear and unambiguous. Currently, there is much uncertainty about
what happens when a local council adopts a LAPP which results in some or all premises retailing psychoactive products locally being outside the LAPP designated retail zone; urgent guidance from the Authority is needed on this issue. Safer Whanganui supports the development of a mechanism to deal with the potential relocation of licenced retail premises in the event that such premises no longer comply with a LAPP.

- **Record keeping**

  We believe that all retailers of psychoactive products should keep sufficiently detailed records so that it can be readily identified that the amount of product brought by the retailer is equal to the amount of product sold. Such data should be collected by the Authority to assist in identifying areas where use is high so that appropriate health and community programmes targeted to such communities can be developed and implemented. Records should be kept by the licence holder for a minimum of seven years.

- **Display of licence**

  CAYAD Whanganui supports the proposal that all licences with respect to psychoactive products must be displayed in a prominent place within the premises, additionally, if the retailer is intending to also sell psychoactive products over the internet this too should be clearly stated on the licence.

- **Restricted trading hours / products**

  CAYAD Whanganui strongly supports restricting the hours in which retailers can legally sell psychoactive products to school hours (9am – 3pm) so that school student’s exposure to such products is restricted.

  In addition to restricted trading hours CAYAD Whanganui believe that retailers of psychoactive products should be restricted to only selling such products i.e. be a specialty store and not be permitted to sell anything else.

- **Labelling and packaging**

  CAYAD Whanganui considers the proposed requirements and restrictions with respect to the labelling of psychoactive products need to be strengthened. Included within the health warning on packaging should be wording advising consumers not to mix the use of psychoactive products. Additionally, CAYAD Whanganui believe that included within the regulations should be a requirement that all occurrences of adverse effects reported to health officials must also be forwarded to the Authority so that accurate numbers of such occurrences and where such occurrences are happening can be recorded. Going forward, such information will be invaluable when developing and implementing health and/or social programmes to combat adverse individual, family, whanau and community impacts derived from the availability and use of such products; and also in the event that it becomes necessary to seek the removal of an approved product from the market.
CAYAD Whanganui believe that it is important that the packaging of psychoactive products be kept plain and non-descript, be child proof and tamper proof, and not designed using images/words associated with youth culture.

While it is important that all packaging contain a generic health warning CAYAD Whanganui believe it is essential that within the packaging of each product is included a separate insert detailing the number of doses included within the package (if more than one), the maximum amount of product to use at any one time and over a 24 hour period, the toxicity of the product, a list of the active ingredients and the amount of each ingredient, the name of the manufacturer and the phone number of the National Poisons Centre.

- **Quantity**

CAYAD Whanganui believe that there should be a limit imposed on a retailer as to the amount of psychoactive products allowed to be stored on the retail premises at any one time, and that there should be a limit imposed as to the maximum amount of psychoactive product(s) (cumulatively) an individual can buy at any one time. Due to safety concerns about mixing products, and/or exceeding the recommended dose of such products CAYAD Whanganui strongly recommends to the Authority that each retail packet of psychoactive product only contain a single dose.

- **Storage**

We believe that all psychoactive products sold via a retail outlet should be stored behind the counter of the premises in an opaque or solid cupboard/drawers and that there should be a limit to the amount of psychoactive product a retail licence holder can purchase from a wholesaler at any one time. Accordingly, there should also be a corresponding limit on the amount of psychoactive products permitted to be stored on a retail premises at any one time.

- **Generally**

Just as there is with tobacco, we believe that the retail price of such products should be mandated by central government. This could be achieved either by way of price setting or through setting minimum retail prices. Furthermore, we strongly support the introduction of some form of sales tax on psychoactive products (both wholesale and retail), the proceeds of which to be utilised for community and health programmes within affected communities to ensure that the social and health impacts of the use of psychoactive products are mitigated, through comprehensive data collection on sales and adverse effects such programmes will be able to be targeted at communities most impacted by the availability of such products and the resourcing of ongoing monitoring of compliance with the LAPP by the Ministry of Health or its agents.
On behalf of Community Action Youth and Drugs (CAYAD) Whanganui
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?

Please see attachment

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?

Please see attachment

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?

Please see attachment
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.

Please see attachment

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

Please see attachment

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

Please see attachment

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.

Please see attachment

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?

Please see attachment

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?

Please see attachment

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

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?

Please see attachment

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?

Please see attachment

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

Please see attachment
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).

Please see attachment

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Please see attachment

C

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Please see attachment

C

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Please see attachment
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Please see attachment

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Please see attachment

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Please see attachment

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Please see attachment
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Please see attachment

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

Please see attachment

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

Please see attachment

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

Please see attachment

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

Please see attachment

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) Community Action on Youth and Drugs (CAYAD) Whanganui

Address: (street/address) 142 Guyton Street
(street/box number) Whanganui
(town/city) Whanganui

Email: julie@ntota.co.nz

Organisation (if applicable): Nga Tai o Te Awa Trust

Position (if applicable): CAYAD coordinator
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): CAYAD COORDINATOR

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

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☐ I do not give permission for my name to be listed in the published summary of submissions.