Our submission

Firstly, I would like to outline my Council’s and other local authorities’ nationwide opposition against the Act.

Grey District Council strongly opposes the legalisation of the sale and supply of psychoactive products. Council duly notes the intent of the Act to restrict products for sale to products approved as not posing more than low risk of harm to users and to keep such products away from children. Council also notes the focus to remove such products from dairies and to impose hefty fines on anybody contravening the provisions of the Act and its Regulations.

Council also note the fact that the Act provides for local authorities to regulate the location of such outlets within their areas of jurisdiction. Notwithstanding, Council opposes the Act on the following basis:

- This matter relates to the very fabric of New Zealand society and represents recognition on the part of the Crown that drugs have a legitimate place in it. Is this the duty of care that Parliament owes its constituents?

- In spite of the focus in the Act on low risk ‘approved’ products only, it is strongly suggested that the sale of unapproved products and substances will continue unabated and that the ‘black market’ is a reality. The only way to deal with it is to make the sale and supply of such products illegal and impose punitive measures that will discourage such practices and also possession of such products.

- The Act naively accepts that each user will take a single tablet (or a single dose of whatever form it will be produced) which, based on the testing regime, should not cause more than low risk of harm. The reality is that users will take more than the single application, which makes a mockery of the focus on low harm. Council contends that the fundamental assumptions of the Act are wrong and that overuse will cost the country and our communities dearly. Rather ban it and deal with it as illegal drugs.

- The Act legalises the supply and sale of mind altering products which will, in spite of testing regimes, continue to pose a risk to the health of our communities, especially the more vulnerable members of society. This is confirmed by the fact that an ‘approved’ product in February 2014 was found to create hallucinations and has since been withdrawn.

- The New Zealand Police have a thankless and sometimes impossible task of managing drink driving or driving under the influence of illegal substances. These products add a new but more discreet challenge to them.

- Local Authorities, in restricting the location of outlets selling products approved in terms of the Act, will be exposed to legal challenge in terms of the anti-competition provisions of the Commerce Act and the principles of natural justice to name but a few. The Sale and Supply of Alcohol Act has similar ‘empowerment’ in favour of local authorities which is proving a real issue with open hours less than the default hours in the Act being challenged in Court.

As stated, we recognise that the Act is in place and the submission opportunity available is on the proposed Regulations only. It does not alter the fact that Council sees the Act as abhorrent and a retrograde step for New Zealand society. Council feels strongly that the ability to ban such products within geographical areas should be available to local authorities.

On that basis, Council submits as follows:

The Licence application process

Council is of the opinion that applications should only be accepted from registered medical laboratories with a proven record of quality control and testing. The full test results must accompany an application.

No applications from anybody other than a registered medical laboratory should be accepted.
The product approval process

Notwithstanding the fact that full test results must accompany an application, the Regulatory Authority must use every reasonable scientific test to ensure that products will not have anything but very low risk to users. The February 2014 incident points to a failure in the system which cannot be allowed. To Council, it simply proves that the Crown is trying to legitimise a system which is inherently uncontrollable other than through a total ban.

The process must also provide for controls that will ensure that a specific batch of product is approved rather than a blanket approval for a product by name. This will ensure that quality (if that word is appropriate in relation to such products) control is consistent.

Labelling and packaging of approved products

New Zealand justifiably insists on cigarette and other tobacco products being labelled in a manner that ‘advertises’ the health risks posed by such products. The fat, salt and other contents must equally be shown on packaging of food. Psychoactive products must be made subject to the same requirements.

It is suggested that a warning of “The use of this product may lead to hallucinations, dizziness or conversely to euphoria” would be appropriate but, at the same time, confirm why it should not be available. In order to sustain the ‘low risk of harm’ intent of the Act, it must be clearly signalled on the package that no more than one application be taken.

Advertising and display for sale

Council is of the opinion that no public advertising of the products in whatever form should be allowed. Similarly, it should not be able to be displayed near the entrance door to approved outlets.

Fees and levies

This is not a service to the public but rather a case of suppliers making money out of vulnerable people who have to use mind altering products to cope with everyday life. On that basis, fees payable for the registration of approved products and outlets must be used as a disincentive.

Paul Pretorius
Chief Executive Officer
Making a submission

Submissions close on Friday 21 March 2014 at 5 pm.

This is a submission from the Christchurch City Council

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 applications that Council staff have seen (for interim licences) do not specifically state the physical / approved address of the retail outlet. This should be made very clear on all licences.

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?

   The Council supports the requirement that retail licence applications must be accompanied by evidence of compliance with the relevant Council policy. The PSRA must not grant a licence to any applicant who does not comply.

   There is a question about the paper work that will be required to confirm whether or not an application complies with a council LAPP. This needs to be an efficient process for all involved. The Council should only be required to check or approve anything if it is also able to charge fees under the Act.

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?

   Like LGNZ, the Council supports a 'generic' policy, provided a Council can opt out of having a generic policy for their district, if they and their community do not want such a policy to apply. The 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.

   However, the Council is concerned about how the special consultative procedure will apply, or can be applied, in relation to a generic policy (given that it is a requirement of the Psychoactive Substances Act to consult with the community before adopting a policy). In light of the impending changes to the Local Government Act 2002 it would be more appropriate for the Act to be amended so that alternative forms of consultation can be carried out instead of using the special consultative procedure, and special provision made for generic policies as it is not clear the regulation making powers in the Act allow for the introduction of generic policies through regulations.
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.

A history of failures or non-compliance with a similar regulatory regime eg. under the Sale and Supply of Alcohol Act, should also be a consideration in deciding on a licence for psychoactive product retail outlets

The Council also supports:

- adding any history of violent offence charges (in addition to "relevant" offences)
- the LGNZ suggestion that the Ministry should check with Councils for any previous history with the applicant in relation to any Council business
- that where Councils are asked to vet or check anything that the regulations enable them to charge a fee. (Also see the answer to questions 31 and 32 below)

In addition, over time, evidence should be collected about which retail outlets people bought product from and then went on to commit offences as a result of using legal highs. That evidence should also be taken into account before any licence is granted.

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

Yes

What records should the regulations require licence holders to keep?

No comment

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

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

In the consultation document under the licence application heading there is discussion of a mechanism for reviewing the ongoing operation of a retail licence in circumstances such as where a Council Policy changes, meaning a retailer can no longer sell from the address the licence was issued for. There is no specific consultation question on this under the applications heading, but the Council supports this proposal and considers it should be made a condition of every retail licence.

It should also be made clear in the licence conditions for a retail premises that the licence applies to a particular premises, not just the person who is the licence holder (section 20 of the Act provides that a licence in not transferable but only relates this to the person, not the premises).

The Council also notes the suggestions in the LGNZ submission that consideration should be given to the following matters:

- The amount of an approved substance that might be purchased in a single sale;
- A sales tax on approved products to reflect the cost of consumption on the NZ health system and the local community;
- A limit on the range of non-related products, such as clothing, which is able to be sold in retail premises licensed to sell approved products;
- A limit on the hours a retail premise selling approved products may operate.

The Council also suggests that these regulations align with alcohol regulations in particular in relation to the ‘range of non-related products’ and ‘operating hours’. The Council wants the ‘limit’ and the ‘range’ clearly identified so it is obvious when the regulations are not being met.

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, as noted above in the answer to question 4, account should be taken of other licensing issues / non-compliance both within the application district and in other areas, if the applicant is operating in other Council districts.

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?

No comment

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?

No comment
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?

No comment

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

No comment

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).

The Council recommends that information on what to do in the case of an overdose should be included. It also submits that each product sold should clearly state that it contains psychoactive substances and wording confirming it is an R18 product. Such information may be useful for parents and caregivers of minors should they discover any products in the minor's possession.

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

The Council submits that all products should be in plain packaging (except for any required information), with restrictions on the colours that can be used on the packaging, to decrease the visual appeal of the products.

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

The Council does not support restricting packets to one dose, because of the concern that the same 1 dose can affect different people differently and it is difficult to be exact about what constitutes 1 dose.

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

No comment
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?

The Council submits products should only be in a tablet or similar form. A prohibition on products that must be injected or that are inhaled (including as liquid, gas or powder) is desirable as these forms of consumption are also associated with the misuse of drugs and other volatile substances that cause harm to users.

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 comment

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

No comment

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

The Council considers there should be restrictions. For example, products should not be visually displayed i.e. They should be behind doors to discourage purchase by visual stimulation. The Council supports the same rules as apply to the sale of tobacco.

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

The disposal of substances should be governed by the provisions of the Hazardous Substances and New Organisms Act. This makes it clear that there is legislation covering the disposal of psychoactive substances.

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

Yes. Council recommends the inclusion of R18 signage and a sign with health warnings to be displayed at the point of sale. (Also see answer below to question 26.)

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

The Council also suggests that areas / premises where gaming licences are in place eg. TAB, Racecourse, Casinos, should be included as places where approved products cannot be sold.

The Council considers there is a need to clearly define 'fixed permanent structures' (s 52f). Does this definition include a container or market stall that may be consented / licensed?
26 Do you think the regulations should prescribe restrictions or requirements for advertisements of approved products? If so, please provide specific suggestions.

The Council submits there should be no advertising in cinemas, bus shelters, buses (inside and out), and public conveniences. The size of an advertisement should also be restricted to exclude the use of billboards, posters etc. the Council recommends limiting the size to A4 or smaller.

Also see the answer at question 28 below

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

The restrictions suggested (entry page with DoB, and declaration not to resell) are good ideas, however the Council notes that they will only be effective if they are monitored and enforced. Unless enforcement can happen (cost effectively) then the restrictions are toothless.

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

This question relates to advertising on-site (as opposed to the wider advertising question at CQ26)

The Council agrees that on-site advertising should be limited to the provision of objective information and that the licence must be displayed in a prominent place (such as at the entrance of the premises or at the counter) where customers can readily see and read it.

The Council also recommends that any onsite advertising should include prominent health warnings.

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

It is not clear whether the fees proposed are per retail premise or per license? The Council submits it should be clear that a license holder cannot get one license (and pay only one fee) for multiple premises. A separate licence should be required for every premise and a fee paid in relation to each premise.

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

A fixed fee will make the cost transparent to the applicant.
31 Should fees be set for other specific functions? If yes, please state what they should be set for.

Yes. Council submits that fees should be set for specific functions that incur a cost to Councils:
- Verifying that an applicant meets the conditions of a local policy
- Researching and providing information on the Council's previous history with the applicant

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

The consultation document states that the framework in the Act is one of cost recovery and that the industry should meet the costs of administering the Act.

The 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, the 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.

The Council agrees with the process for setting levies but submits that the process should ensure that any levy on retailers must include a portion to be paid to those territorial authorities who have LAPPs.
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) Christchurch City Council
Address: (street/box number) 53 Hereford St (P O Box 73013) (town/city) Christchurch 8154
Email: judith.cheyne@ccc.govt.nz
Organisation (if applicable): Christchurch City Council
Position (if applicable): Senior Solicitor, Legal Services Unit (ph (03) 941-8649)

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
x other (please specify): Territorial Authority who will be developing a LAPP

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

x 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 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.
Dear Psychoactive Substances Regulatory Authority,

Thank you for the opportunity to comment on the draft Psychoactive Substances Regulations Consultation document. Officers from Wellington City Council (Policy and Community Networks Teams) have the following comments relating to questions 2, 3, and 25:

Q2. 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?

**Answer:** Yes, we are in favour of this, as the requirement to provide this evidence will help ensure that LAPPs can be implemented. We agree that provision of this evidence early will save time checking for compliance later in the licensing process.

Q3. 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?

**Answer:** Yes. We are strongly in favour of a generic LAPP. For example, a generic policy providing that licenced premises are at least 300 metres apart and at least 100 metres from schools, kindergartens, places of worship and playgrounds. There may be some territorial authorities that, due to limited resources and / or political factors, struggle to approve a LAPP for their area by mid-2015. This could then leave such territorial authorities vulnerable to a large growth of new premises selling legal highs around sensitive locations (including schools, kindergartens, and places of worship) after retail regulations take effect and the current ceiling on numbers of premises is lifted. A generic LAPP could help limit the extent of this.

Q25. Do you think the regulations should specify further places where approved products may not be sold? If so, please provide specific suggestions.

**Answer:** As previously stated in our answer to Question 3, we are in favour of a generic LAPP under these regulations to limit the extent that certain territorial authorities will be overwhelmed by large numbers of new premises selling legal highs from mid-2015.
Kind regards

Mark Jones
Senior Policy Advisor \ Wellington City Council
P 04 806 4750 | M 021 247 9750 | F
E Mark.Jones@wcc.govt.nz | W Wellington.govt.nz

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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.

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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?

   No.
   The consultation document does not provide proposed information requirements for corporate applicants. This needs to be made clear. The applicant (either individual or corporate) should have to provide details on what other businesses they own or in other ways are affiliated to. The provision of this information would inform consumers and the authority to the direct and/or indirect business activities of the applicant e.g. a brothel owner may start another business to sell Psychoactive products. Wholesale access of these products may facilitate unethical activities. The public too have a right to know who is doing what in their community.

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
   The regulations should also be explicit that if an application does not comply with the respective LAPP that it should not be lodged and cannot be granted. Not doing so devalues the local engagement conducted by Council and provides limited value to the LAPP.

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
   This could be further supported by the regulations if applicants were required to provide consent from neighbouring retailers.
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.

No
What other businesses the applicant (either individual or corporate) own or in other ways are affiliated to should be considered.

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

Yes

What records should the regulations require licence holders to keep?

The regulations should require retail licence holders to maintain records of the following for each transaction:
- The product purchased
- The quantity purchased
- The individual (Full name and date of birth)
- Proof of ID (passport, licence, 18+ card)

These should be maintained for 3 years and would assist with investigations such as, workplace health and safety, purchasing for minors, anti-social behaviour, addiction, etc.

CCTV coverage of all transactions should be maintained by all retail licence holders and be available to Police and Ministry of Health staff upon request. This would further assist with investigations if necessary and allow for auditing of record keeping.
7 How long should licence holders be required to keep records for?

3 years

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

Yes
Restricting Hours – This should only be allowed to occur during school hours (9am to 3pm). Reduces the availability to those who use heavy machinery, civil works, etc.
Availability to students over the age of 18 increases the risk of availability to minors. Restricting hours marginalises the opportunity for positive health outcomes, safe consumption, education outcomes and other negative outcomes from consumption/use by minors.
Displaying products – Products should be locked away from display, much like cigarettes.
Places of work – Worksites that provide a place of work for staff to provide services e.g. health and fitness centres, brothels, massage parlours, counselling, hairdressing, etc should not be able to hold a licence for the trade of Psychoactive Substances

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?

Compliance with the respective LAPP – no compliance no licence
Consent from neighbouring premises of the proposed venue of the applicants business – no consent no licence
Restricting Hours – The Authority could request these from the respective territorial authorities
Limitations to the quantity and frequency a retailer can sell to a customer – 1 unit per day per person.
CCTV coverage of all transactions available to Police and Ministry of Health staff upon request

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?

Yes
What other businesses the applicant (either individual or corporate) own or in other ways are affiliated to.

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.

No
Whangarei District Council also supports the use of plain packaging as a means to deter marketing to minors. Seen as a means to reducing the attraction to cigarettes Council suggests such an approach be used in the same way with Psychoactive Products.

Psychoactive Substances Regulations: Submission form
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

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

No
These should include the use of plain packaging

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

Yes
The product can be purchased by 18 year olds. This means there is a greater likelihood of these products being accessed by those under the age of 18. The provision of products being limited to one dose takes steps to mitigate the social element out of these products which in turn may lower the chance of people less than 18 years of age accessing the product.

Serving size is limited at on-licence bars and this should be the case with Psychoactive products. Limiting their serving size also mitigates the risk of consuming an excess of these products or passing on to others. Further to this point Council requests that the amount allowed to be purchased at one time be limited to 1 packet and that a consumer only be allowed to purchase 1 packet per day.

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

Yes
This is seen as another step to mitigate the risk of consuming an excess of these products.
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
Council supports the concerns raised in the Discussion Document regarding forms of the product that could be injected and request it be made explicit in the regulations that this form of psychoactive product not be allowed.
Smokeable psychoactive products should also be banned. This is a direct imitation of marijuana and uses the social cliques or cultures of marijuana smokers such as Rastafarianism, gangs and/or ‘the stoner lifestyle’ to attract users/consumers. Marijuana is a naturally derived product which these are not, this desensitises users to smoking chemical substances, perceivably making it a gateway product to Methamphetamine as well. In March 2011 the Government adopted the Smokefree 2025 goal for New Zealand. Government is committing resources into reducing the activity of smoking tobacco in NZ significantly. It seems counter productive to set up a parallel industry based on the same activity.
The only form that should be available is tablet form.

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

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

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

Yes
Products should be locked away from display in the same way cigarettes are.
23 Do you think restrictions or requirements should be set regarding the disposal of approved products? If so, what should they be?

Yes
Disposal should be done through the same processes in place for the disposal of pharmaceuticals.

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

Yes.
All stores that sell this product must have to clearly show that they do not sell their psychoactive products to those under the age of 18 and that ID will be requested upon proof of purchase.

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

Yes
Products should not be sold in premises that sell anything other than good and services to those over the age of 18, for example, cigarette shops.
Worksites that provide a place of work for staff to provide services e.g. health and fitness centres, brothels, massage parlours, counselling, hairdressing, etc should not be able to hold a licence for the trade of Psychoactive Substances or Products

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

Yes
All advertising should be prohibited, just like cigarettes.
27 Do you think the regulations should prescribe restrictions or requirements on internet sales of approved products? If so, please provide specific suggestions.

Yes
The proposed requirements in the Discussion Document are hopeless. We suggest that the regulations only allow the financial transaction to occur over the internet. Ensure the purchaser has to pick up their goods from the store to prove their age. Face to face is the only way this can be properly managed.

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

Yes
All advertising should be prohibited, just like cigarettes.

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

No
We support a full user pays system and including an annual monitoring fee as with alcohol.

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

Hourly Charge
We support a full user pays system and including an annual monitoring fee as with alcohol.
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.

Yes

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) Owen Thomas
Address: (street/box number) Private Bag 9023
         (town/city) Whangarei
Email: owent@wdc.govt.nz
Organisation (if applicable): Whangarei District Council
Position (if applicable): Community Services 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):........................................................................................................

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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WELLINGTON
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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?
   A Police Check should be mandatory and be provided as part of the licence application. It is the Applicant's responsibility to demonstrate suitability to hold a licence. The cost and onus of getting the Police Check should be on the Applicant, not the Government; the Applicant benefits from holding a licence and thus should bear the cost of providing a Police check.
   All offences, not just those committed in New Zealand should be declared and considered by the Authority.
   If the onus of keeping information on licence holders current is left with the licence holder there needs to be some sort of annual audit by the Authority to ensure the system is working. There should also be a penalty for those who do not keep records up to date.

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

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
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.

The above factors seem to be enough but what happens after a licence has been granted and then the licence holder fails one or more of the criteria above? How will continued compliance with these requirements be policed/enforced and what is the process should an approved licence holder subsequently fail the criteria?

Will relevant offences committed outside of New Zealand be considered?

In order to comply with the "Certainty" bullet point stated in the Assessment criteria on page 5 of this document there needs to be clear policy around what is considered to be serious and repeated failure to comply with Act requirements and what constitutes other relevant matters

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

Yes

What records should the regulations require licence holders to keep?

The records should be such that for each batch of substance there is a clear audit trail from point of manufacture to retail sale. The records should include batch numbers, quantities, expiry dates, storage conditions and names of licence holders responsible at each stage.
7 How long should licence holders be required to keep records for?

At least 12 months, preferably 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.

Agree with other factors outlined under discretionary conditions. In addition, there should be a restriction that no-one under the age of 18 should be allowed in the premises (including retail staff), there should be no sale of any food or drink items.

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?

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

11 Do you think any further particulars, information, documents or other material should be prescribed in the regulations? If yes, what should these be?
Once approved there needs to be a check that the manufacturing process proposed is being followed, including a check that the correct storage conditions are being adhered to.

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 that there should be data on toxicity, pharmacology and clinical effects.

The data need to be relevant for assessing the potential harm under conditions of use i.e. they need to represent the route of intended use and cover both the likely range of “therapeutic effect” plus provide adequate data for use in overdose scenarios. Robust health effect data are essential to satisfy the Health protection, Proportionality and Certainty criteria mentioned on page 5 of the consultation document. Proportionality is not purely financial costs, it could be the cost to society/friends/family who are subject to adverse effects as a result of behavioural/psychoactive effects in an individual taking a psychoactive substance.

Endpoints considered should include acute and chronic effects (including local irritation and systemic effects).

A tiered approach to testing should be undertaken starting with in vitro/in silico methods; from these data appropriate in vivo studies can be designed. However, before proceeding to in vivo studies the Authority needs to decide on their appetite to risk and whether from an ethical standpoint the cost of animal testing balances with the benefits the use of these products. Consideration should be given as to whether the Authority requires data on the particular product or whether a “read-across” type approach from data from similar substances can be used.

Not only should a tiered approach with respect to potential animal testing be undertaken but the Authority should also give consideration as to whether, in the case of Psychoactive substance, particular endpoints are more important than other e.g. it is more important to have robust data on the potential for addiction/dependence, type and duration of psychoactive and behavioural related effects verses robust data on the potential to cause local or specific organ toxicity?

Consideration also needs to be given as to the benefit of performing carcinogenicity/reproductive type studies or whether a better alternative approach would be to declare on the label that such assessments have not been undertaken. This leaves the user to decide whether to take the risk or not. If this approach is taken, then as part of their role, the PSEAC can provide public awareness around this.

When setting regulations on the data requirements for assessment of health effects it is imperative that “low risk of harm” is clearly defined. This would be consistent with the “Certainty” bullet point under “Assessment criteria” on page 5 of this document.

There should be literature available to those taking approved products which clearly communicates that “low risk of harm” does not necessarily equate to low harm i.e. it should be made clear that although the likelihood of outcomes such as death or permanent psychological damage may be 1:100, 1:1000 or 1:1000, 000 it is the probability which is “low” not the harm.

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 – see comments above.

The proposed directions of use should cover the route and dosage, and a warning not to be used in combination with other drugs or alcohol.

The application should also contain information on the suitability of the packaging, including information on the potential for the active substance to leach from the packaging and the stability of the substance in the packaging. This type of testing is a routine requirement for marketing authorisation of pharmaceuticals.

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

C

It is unclear as to how the active substance(s) will be identified e.g. common name, chemical name etc. It is important that this is clearly defined with respect to traceability, informing the user of what they are taking and efficient treatment in overdose situations.

Labels should also state not to use if the packaging has been tampered with/broken – should follow general pharmaceutical 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).

C

Health warning should include:
- information as to what to do in the case of overdose.
- Only to be used via intended route
- Not to be used in conjunction with other drugs (including prescription drugs) or alcohol
- Do not use if the expiry date has been passed
- Do not use if the packaging has been broken

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.

Will there be any restrictions on how many packages can be brought by an individual at any one time? If so will it be possible to track purchase by an individual at multiple outlets?

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

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

Form should be restricted to oral only.

Inhaled forms should only be allowed if effects on secondary inhalation, particularly in children have been assessed. Let’s learn lessons from the tobacco situation and avoid the risk of addition/psychoactive effects in bystanders, particularly children.

If smokable products are allowed policies on tobacco products should apply as a minimum.

Agree with comment on not allowing injectable forms.

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?

If it is intended not to put any restrictions on temperature/humidity during storage then the application data need to clearly show that the products are stable over a range of temperature/humidity likely to be encountered during storage.
21. Do you think restrictions or requirements should be set for the storage of approved products? If so, what should they be?

See comment above

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

They should follow the same rules for tobacco and alcohol.

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

Yes – there needs to be controls on the disposal of these products as there are potential risks to the environment including ground water and soil contamination. In addition inappropriate disposal may result in children/animals accidently ingesting the products.

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

Approved products should only be sold in places solely designated for the sale of such products.

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

Approved products should not be advertised.

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

The proposed controls of having to verify age and confirm products will not be "sold-on" are only effective if there is a robust and active enforcement side. What are the proposed enforcement procedures? Are there sufficient resources to cover these procedures?

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

This is a repeat of 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?

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

32 Do you agree with the proposed list of items and process for setting levies? If not, please provide specific suggestions.
You do not have to answer all the questions or provide personal information if you do not want to.

This submission was completed by: (name)

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

Email:

Organisation (if applicable):

Position (if applicable):

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

☐ as an interim licence holder
☐ a person or body corporate intending to apply for a licence
☐ other (please specify): Member of the general public

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.
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 - 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 - most definitely, retail licence applications should be accompanied by evidence of compliance with the local approved 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 - the retail applications should accompany with evidence to demonstrate compliance with a generic LAPP - or with the general legislation, if there isn't 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.

I would request that a clean personal record, i.e. no drug convictions, nor D1C, driving convictions, any quasiraid behaviour within business, and all the above that you have included.

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

Yes the applicant should provide these details stated extending to also provide details in other places such as gambling establishments, where there are any gaming, pools and TAB's

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

1) I would like to see the consumer produce identification that it be copied and kept on file before purchase

2) A client contact form with a waiver portion on it. Information such as "are you on a benefit of any kind? (This would help other agencies that are called upon to help with financial assistance.)"

7 How long should licence holders be required to keep records for?
1. I believe all records should be kept for up to 7 years just like legal documents eg finance.

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

I agree with all of the above.

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?

I would like to see a very substantial fee to be charged to the applicant eg £5 to £10,000 when applying. Also very hefty fines for those penalized. Many of the agencies including Salvation Army are having to pick up the load due to the severe addicitive effects of the selling of synthetic drugs. Agencies that work in the areas of sexual work. Agencies called for food assistance. Benefits when they can no longer be employed due to addictive behaviour that renders them unemployable.

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 with this practice and it should be clearly stated.

11. Do you think any further particulars, information, documents or other material should be prescribed in the regulations? If yes, what should these be?
On going monitoring, ongoing inspections, enforcement of manufacturing methods, in all of the above, with a substantial associated fee regime.

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 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?

Yes I agree. However that it be written in very clear, plain language with no room left for a manipulating of wording i.e. no loop holes for misunderstanding.

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

Yes agree, but would like to ensure that we have it in a way that is "understand". Simple plain English.
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 were managed to achieve re the cigarette industry.
1) Content of the product - displayed in detail
2) Plain English: Easily understood (basic)
3) Very clearly what side effects could occur.
4) "Needs, 'Consume them at your own risk'."
5) Packaging in a way most doesn’t draw attention (added)

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

Same concept as cigarettes - no advertising, plays of fancy, we'd thought advertising gimmicks - instead, PLAIN packaging.
Black or white, no colour.

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

- To state clearly what 1 dose equals.
  i.e. is it 1 dose = 1 tablet etc.
- And to exceed could mean certain reactions - state them.

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

No. This leads to more packets being purchased, consumed, so no split dose.
Again, I would like to see it state what possible reactions can occur with 1 dose, or increased dosage.
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?

Definitely restricted to pill form 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, storage amount limited.

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

Yes - Storage amounts limited. Minimal eg no more than 10 doses of a type and no more than 10 types per premise ie 100 doses. Also that they do not advertising plays to increase consumer buy. Not openly displayed or where they can be easily stolen.

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

They should not be or visible display again like cigarettes - plain packaging. Out of sight so that the consumer is not (or newly introduced consumer is not pulled into any advertising play en route further by packaging and what the drugs promise.)
23 Do you think restrictions or requirements should be set regarding the disposal of approved products? If so, what should they be?

Treated the same way as any potential harmful substance. Harm is mentally, physically, emotionally - which we experience constantly as we deal with the effects of this synthetic legal.

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

I believe no signage at all should be permitted on or in the premises to advertise this product. Minimising the temptation of those with addiction problems. Because we agencies deal with the after-math first hand and we can't choose to have them banned. Them we need to be non negotiable on promoting not sold? If so, please provide specific suggestions.

Within 100 metres of any licensed premise, TAB, school, bus stop, or residential area.
Also extended to NO Malls where it is easier for people to enter unnoticed, or under age tempted to sneak in. Not retail tempted to sell the synthetic. If the premise is out of the open - I believe it also limits a lot.

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

I believe No internet or use at Social media to sell Synmetics in Queensland. No legal advertised in the weekly bulletin, flyers, posters. Passed by cell phones from the retail outlet. (like doctors appointment reminder system).
27 Do you think the regulations should prescribe restrictions or requirements on internet sales of approved products? If so, please provide specific suggestions.

All Internet sales can in no way promote the symmetry.

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

I believe there should be no advertising on site; not to be seen by the customer at all. Which only leaves word of mouth. For those who know about it. No signage inside or outside the premises. Nor windows scroll which boards or front television screen advertising either.

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

I believe costs be very hefty in every way. i.e. enforcement (constant) enforcement, applications to renew, etc., making it difficult. The cost of picking up after the inevitable effects hit our people in the community, does not cost the licensed applicant or the distributor. It costs the likes of Salvation Army and many other affected agencies in our community.

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

I believe there should be a minimum fee for applications, it being substantial to $10,000 and an hourly fee for processing. All of this is put in place because we the community are forced to be the ambulance at the bottom of the cliff.
Fees should reflect the work involved in processing an application and considering the costs of mental, emotional/physical care to clean up or attempt to clean up the effects. Fees also for "ongoing" monitoring of effects and inspections of premises, inspections of the production facilities and enforcement as necessary.

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

Once again, because we the affected community have had no choice except to choose synthetic legal highs to be sold, then the levies should be to the maximum cost possible. Our costs for care is mental health, rehab, bridge programs, counselling, etc. are enormous and most addicts cannot afford this treatment. The community and agencies are left carrying this huge problem and costs. Once again! Ambulance at the bottom of the cliff.

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) Hire Marchand
Salvation Army Corp
Address: (street/box number) 89 Camp Street, Queenstown
(town/city) Queenstown
Email: hire_marchand@nzf.salvationarmy.org
Organisation (if applicable): Salvation Army
Position (if applicable): Community (Social Worker)
Are you submitting this:
(Tick one box only in this section)

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

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

☑ Yes  ☐ No

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

Please return only one copy of your submission no later than 5 pm on Friday 21 March to:
The Manager
Psychoactive Substances Regulatory Authority
Ministry of Health
PO Box 5013
WELLINGTON
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The Manager
Psychoactive Substances Regulatory Authority
Ministry of Health
PO Box 5013
WELLINGTON 6145

18 March 2014
We believe the following should be looked at and by- laws put in place to:-

1 Limit hours of trading to 9-00am to 3-00pm, weekdays only. This would ensure that schoolchildren walking by are not subject to intimidation nor tempted to try the product.
2 Restrict outlets to be sited more than 200m from churches, schools, crèches and other vulnerable sites such as medical and dental surgeries and chemists. We believe that Hamilton Council may have implemented this policy recently.

3 Ensure outlets are not positioned within 200m of a bus stop. Our legal high shop is within 50m of three bus stops frequented by schoolchildren.

4 Make it mandatory for Council authorised toxicity checks to be conducted quarterly with any charge to be paid for by the landlord. Given the nature of the clientele of these outlets we do not doubt that there will be evidence of methamphetamine use and believe there could well be a health and safety risk.

5 Remove all illuminated interior signs and all exterior signage advertising the shop and its products.

6 Make it mandatory for by-laws applying to liquor outlets regarding public notification also pertain to these outlets.

7 Ensure weekly Police checks are conducted to ensure than banned substances are not been sold. Included in this could be a weekly police check of the register of drugs sold.

We have worked hard to rejuvenate Hunters Corner over the past five or six years and we have been highly successful, restoring a sense of pride in the community. We are a proud community and a dynamic, diverse one at that. Unfortunately if this outlet is allowed to continue operating all the hard work and effort we have put in over recent years will have been wasted.

We beg you to treat this matter seriously and do everything in your power to remove this scourge from our streets.

Pat Taylor
Chairman
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?

   - New requirements for the applicant to disclose all employees and associates involved with the disposal and storage of products for police vetting.
   - New requirements for the applicant to disclose and verify the owners of trading address for police vetting.
   - New requirements for the applicant to provide three character references.
   - New requirements for the applicant to divulge any gang associations.
   - New requirements for the applicant to get a police appraisal of the area of trading under consideration.
   - New requirements for the applicant to be onsite when trading is in operation.
   - New requirements for the applicant to have an obligation to provide evidence of compliance on a monthly basis.
   - New requirements for the applicant to have a proven record in selling prohibited substances.

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
   - LAPP is the best way of delivering what the community requires.

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
   - The generic policy should be considered as a basic structure and guidance. The compliance issues will vary from region to region.
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.

| 1. | The applicant's trading address should require the owners of the trading address if residing there and any other persons residing there to be of good repute. |
| 2. | The applicant's trading address should require the owners of that address and persons residing there to have no convictions of dishonesty or relevant offence. |
| 3. | The applicant's trading address should require the owners of that address or persons residing there not to allow exposure of trading to any persons under the age of eighteen. |
| 4. | The Authority has an obligation to take into consideration the negative impact on a residential area when considering licensing residential properties as trading sites. |
| 5. | The Authority has an obligation to take risk assessment on communities when considering licensing residential properties as trading sites. |
| 6. | The Authority has an obligation to take every precaution to mitigate the potential abuse of trading hours, noise control, and supply of products to underage person(s) within a residential zone for any person(s) residing at the trading address. |
| 7. | The Authority has an obligation to inform residents of an impending application and give them the ability to submit objections. |
| 8. | The Authority has an obligation to monitor and provide evidence of compliance on a monthly basis. |
| 9. | The applicant's trading address should not be used for any other purposes other than trading of psychoactive substances. |
| 10. | The applicant's trading address should not be used as a family dwelling. |
| 11. | The applicant's trading address should not be used for multiple businesses under the same trading name. |
| 12. | The applicant's trading name should not advertise or infer the sale of psychoactive substances. |
| 13. | The Authority must consider all citizens complaints related to the trading address. |
| 14. | The Authority must consider all complaints directed to the police department related to the trading address. |
| 15. | The Authority must control the potential abuse of disposal when alerted by members of the public. |
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?

C All records and time of sale.
Video record of all trading during hours of operation

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

10 years

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?

- What effects it has on the community
- What effects it has on children exposed to drug induced persons

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?

Yes
- Evidence of comprehensive trial studies.
- Addictive ratings 1-10 and 8 is uncontrolled addiction.
- Health warning on products.
- Plain packaging.
- Behind locked cabinets.
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
All relevant data must be accompanied by compliance testing carried out by certified Ministry of Health nominated companies.
Ongoing clinical trials correlating data.
All data uploaded to web site for all production and distribution of substances and used to provide data for criminal activity or negative impact in the surrounding areas.

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
This data must be generated by an approved Official New Zealand agency at the applicants cost

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

Plain packaging with large R18 warning and addictive rating 1-10 and 8 being uncontrolled addiction.

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.

- Restricted amounts
- Plain packaging

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

- Yes and halve the dose
- It will cost more to get high and discourage those who cannot afford the costs.

18 Do you agree with the proposal that a dose, in whatever form the product takes, is split wherever possible?
19 Do you think there should be restrictions on the form products can take? If so, what forms do you think should and shouldn’t be allowed?

Anti glamorisation of product marketing

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 lock and key with only registered key holders accessing product.
Storage room must be alarmed and monitored.

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

Yes

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

Disposal must be monitored via camera should the need arise to check disposal compliance

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

Yes
Restricted signage and generic information only

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

Yes
All Residential Zoning, Liquor outlets, schools, dairies, community areas, parks, recreational areas, Liquor ban areas, any area where there are children and old people.

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.

Yes
Adult site warning
Parental warnings
Site unsafe
Flashing R18 restricted site

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

Yes

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

Higher fees

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.

Individual fees for all processes

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

Yes levies for all
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): Resident effected by Legal high Trading

☐ 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.
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?
   Include declaration that applicant is or is not part of a 'chain' of outlets. Such a partnership would permit a retailer to offer reduced prices.

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

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 if it includes a comprehensive list of sensitive sites including Opportunity Shops (community welfare service) and excludes trading from small communities without 7day/24hr in-situ policing.
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.

\[ \text{Refer (i)} \]

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

\[ \text{Yes} \]

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

\[ \text{For the duration of their licence, as described plus camera footage.} \]

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

\[ \text{Duration of licence} \]
8 Do you think there are factors or issues that the Authority should consider when setting discretionary conditions? If so, please provide details.

1) Self-contained premises
2) Opening hours Mon-Fri & 9am-2:30pm equals school hours.
3) No groceries, partic. sports drinks that attract young people.

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?

Prohibit home deliveries which enable anonymity, with no way of monitoring age of purchasers.

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.

Help-line contacts
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).

Require retailers to display handouts on the counter describing downside of legal highs with local Helpline, Addiction services contact information

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

Packets must be unenhanced.

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

Yes
Reduces risk to children, animals
Maybe assist with reducing risk of overdose/suicide.

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?

Restricted to tablet form 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?

Limit on amount stored to reduce risk of burglaries

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

C

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

Non visible to customers purchasing other products
23. Do you think restrictions or requirements should be set regarding the disposal of approved products? If so, what should they be?

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

   No advertising within store - no window displays, no online promotions

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

   V Small communities such as Katikati (pop 4000) with small intimate CBDs where it is impossible to provide a broad area or location of minimum harm.
   
   Katikati's CBD - 900m with 21 sensitive sites

   2) No community that does not have access to 7-day/24-hour in-situ policing !

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

   As (24)
27. 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 to protect youth

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

As (24)

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

Added tax at every level from production to counter to partially cover costs to health services and police.

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

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

As (30)

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

C

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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Psychoactive Substances Regulatory Authority
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PO Box 5013
WELLINGTON
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☑ I do not give permission for my name to be listed in the published summary of submissions.
Response to
Ministry of Health Psychoactive Substances Regulations consultation document

1. Acknowledgement

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

Introduction

1.1. The Waikato District Health Board (Waikato DHB) serves a population of more than 360,270 people within 10 local authorities, stretching from the northern tip of Coromandel Peninsula to south of National Park and from Raglan and Awakino in the west to Waihi in the east. About 60% of the Waikato DHB population lives outside Hamilton.

1.2. The Waikato DHB has five hospitals and two continuing care facilities; community services, older persons and rehabilitation service, population health service and mental health and addiction services (collectively known as its provider arm Health Waikato). It directly employs over 6000 doctors, nurses, allied health professionals and support staff.

1.3. The Waikato DHB also funds and monitors (through contracts) a large number of other health and disability services that are delivered by independent providers such as GPs and practice nurses, rest homes, community laboratories, dentists, iwi health services, Pacific peoples’ health services, and many other non-government organisations and agencies.

1.4. The Waikato DHB is extensively engaged in providing services in the region both directly through the provider wing of the organisation and indirectly through other providers. These include personal health services and public health or population based health services.

1.5. Waikato DHB has a statutory objective to improve, promote and protect the health of communities.

1.6. The following response represents the views of Waikato DHB Population Health. It does not necessarily reflect the views of the Waikato District Health Board. Waikato DHB Population Health provides public health services for the people living within the Waikato DHB region. Population Health is focused on providing early intervention
services that improve, promote and protect the health of population groups within the Waikato DHB region. It works to help ensure all people in the Waikato have opportunities to access services and make choices that enable them to live long and healthy lives.

2. Submission

Questions in the consultation document have been answered in order. A simple yes/no answer has been given where appropriate. Some questions have been answered in more detail, and this is provided.

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

Population Health proposes that immigration status may also be a suitable requirement.

Q.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.

Q.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.

Q.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.

From Population Health’s perspective, these seem appropriate. However, the local public health units should also be consulted with as part of the fit and proper person check to ensure there is no concerns from a public health perspective.

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

Yes, this may show an applicant’s experience with complying with regulatory processes. Population Health also seeks clarification on licensees who operate multiple stores. If one store is found to have breached the Act, will licences at all stores be revoked, or just the offending licence?
Q.6. What records should the regulations require licence holders to keep?

Population Health considers the conditions stated are appropriate.

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

Population Health considers a timeframe should be set but does not have an opinion on what this should be.

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

Population Health advocates for location to alcohol outlets and hours of operation to be considered under discretionary conditions.

Q.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?

Population Health proposes that the authority consider the history of an outlet that held an interim licence, if applicable. If all conditions have been met previously and CPO’s passed, this should have a bearing on the granting of a full licence.

Q.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.

Q.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.

Q.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.

Q.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?

Population Health considers the conditions outlined seem appropriate.
Q.14. Are the proposed requirements and restrictions on labelling sufficient? If not, please make specific suggestions for further requirements and restrictions.

Population Health also proposes that legal age for possession and supply are included on the labelling.

Q.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. Population Health supports and endorses the proposed health warning.

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

Yes. Population Health also supportsplain packaging restrictions in particular.

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

Yes. Population Health supports one dosage packaging. This is likely to minimise harm to the users and will restrict the ability of persons to buy in bulk and then potentially on sell to others, including minors.

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

Yes.

Q.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 opinion.

Q.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.

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

No opinion.

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

Population Health supports restrictions on signage to ensure they are not visible from the street. This would match regulations for tobacco signage.
Q.23-24. Do you think restrictions or requirements should be set regarding the disposal of approved products? If so, what should they be?

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

Population Health supports signage stating the legal age of purchase.

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

Population Health advocates for proximity to alcohol outlets to also be a consideration.

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

No opinion.

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

Population Health supports the measures proposed in the consultation document.

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

Population Health advocates for restricting products along the same lines as tobacco – no advertising at point of sale. Retailer able to provide a price list on request.

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

Yes.

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

Fixed. Population Health seeks clarification on if interim approved products will subject to the same fee.

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

No opinion.

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

Yes.
3. **Further information**

Any comments on this submission or requests for further information can be addressed to:

Dr Richard Wall
Medical Officer of Health
Population Health, Waikato District Health Board
PO Box 595
Hamilton

T: 07 838 2569

E: richard.wall@waikatodhb.health.nz
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

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

   WILL THERE BE ANY REIMBURSEMENT FOR PREMISES SIGNED FOR THE NEXT 3 YEARS IF THE COUNCIL WANTS US TO MOVE PREMISES?

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
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

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

YES

What records should the regulations require licence holders to keep?

name and amount of stock on hand.

How long should licence holders be required to keep records for?
on a weekly basis.*
This is already being done in most circumstances.
*Records to be kept for 12 months

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

prohibiting sale of food
no Internet Sales
Display of Licence on 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?

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?

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?

No
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 IN PRINCIPLE DEPENDING ON THE COST OF SUCH TESTING.**

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?

**AS 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).

YES

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 - THE COST INVOLVED IN THIS WOULD BE FAR TOO MUCH - PEOPLE WOULD JUST PURCHASE MULTIPLE PACKETS & WASTE PAPER ETC.

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

MAY BE A GOOD IDEA TO GIVE MORE INSTRUCTIONS ON THE DOSAGE.
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 - Unsure about this.
Target form.
Smoking form.

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.

Do you think restrictions or requirements should be set for the storage of approved products? If so, what should they be?
No.

Do you think restrictions or requirements should be set regarding the display of approved products? If so, what should they be?
No - they are only sold in R18 shops and can't be seen until you approach the counter to look at the book.
23 Do you think restrictions or requirements should be set regarding the disposal of approved products? If so, what should they be?

No - most retailers would return products to their supplier - who would then dispose of in a sensible manner.

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

Yes - R.18 a copy of warnings etc on back of packet would be good.

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

No - I think they have done this already.

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

Yes - no internet sales or advertising.
27 Do you think the regulations should prescribe restrictions or requirements on internet sales of approved products? If so, please provide specific suggestions.

PROOF OF AGE REQUIRED

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

POINT OF SALE ADVERTISING + SIMILAR ACTION TO A LIQUOR SHOP

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

I THINK A LICENCE SHOULD BE SIMILAR TO A LIQUOR SHOP LICENCE.

MANUFACTURE - $30,000
W/SALE - $20,000
RETAIL - $10,000

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.

NO

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

YES

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: Consultation document  39
Are you submitting this:
*(Tick one box only in this section)*

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

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

☑️ Yes ☐ No

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

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

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

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

Please put ‘Regulations Consultation’ in the subject line.

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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.
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) Adrian Gray

Address: (street/or number) ____________________________

(town/city) ____________________________

Email: Adrian.gray@waitamata.govt.nz

Organisation (if applicable):

Position (if applicable):

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

x other (please specify): Medical Specialist in Addiction.

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

x Yes

x I do give permission for my name to be listed in the published summary of submissions.

Consultation questions

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

The critical concept to be grasped here is that it is not possible to define what substance will be in the product offered for sale.

There are potentially a vast number of synthetic analogues that can be easily manufactured and the marketed under the same name, and the toxicology, in particular the potency, (affinity for cannabinoid receptors), can vary enormously. It would require that EVERY “batch” of any product offered for sale would have to be analysed, to prevent different chemicals being marketed under the same brand name

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?

As stated above, there are already available dozens of different synthetic analogues and the manufacturer can change the composition randomly at any time, without this change being detected. UNLESS every batch is independently analysed.

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

It is doubtful whether any health arning is adequate to pre-inform the likely end-users of this product.

However, because the synthetic cannabinoids are so potent, it is imperative that it be made clear, the potential for psychosis, which may lead to self harm or other life-threatening behaviour.

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

It is probable that these products will be primarily offered in smokeable form. This implies that as a minimum, the same health warnings should apply as to tobacco smoking regarding respiratory complications.

This is compounded and complicated by the fact that the herbal material, onto which the liquid chemical is sprayed, has not been adequately studied for its own toxic effects. In fact there is no information available on what the plant matter is and it could vary widely over time and at different manufacturing sites. It is therefore impossible to predict the potential this plant material may have to cause harm if inhaled.

22 Do you think restrictions or requirements should be set regarding the display of approved products?
If so, what should they be?
Display should be completely restricted as with tobacco products presently. The potential for harm cannot be predicted as yet but the risks to health are at least as great as tobacco.

Consultation questions

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

The advertising of these products should be at least as stringent as those applied to tobacco. There is a large body of evidence regarding the effects of advertising on youth in particular.

As a final concluding comment, I would like to propose that the introduction of these regulations should be accompanied by two other measures

1) The decriminalisation of cultivation and possession of organic cannabis for personal use.

2) The provision of a significant budget for the education and information to the public on the problems associated with cannabis consumption, with emphasis on the effects of the developing adolescent brain
19 March 2014

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

psychoactives@moh.govt.nz

Dear Sir/Madam,

PSYCHOACTIVE SUBSTANCES REGULATIONS CONSULTATION DOCUMENT

1. This is a submission on the Psychoactive Substances Regulations Consultation Document from the Dunedin City Council, PO Box 5045, Moray Place, Dunedin, 9058.

2. The Dunedin City Council is responsible for enabling democratic local decision-making and action by and on behalf of the Dunedin community and for meeting current and future needs of the Dunedin community for performance of regulatory functions in a way that is most cost-effective for household and businesses.

3. The Dunedin City Council thanks the Ministry for the opportunity to comment on the Psychoactive Substances Regulations Consultation Document but is disappointed with the short period for consultation on the regulations. The timeframe made it challenging for the Dunedin City Council to fully consider the proposals and formally endorse a submission. As a result, although the submission has been informally considered by a majority of Dunedin City Councillors and signed by the Chair of the Council’s Planning and Regulatory Committee, it has not been formally endorsed by the Dunedin City Council. The submission is subject to retrospective approval from the Planning and Regulatory Committee which next meets on 1 April.

4. The Dunedin City Council is also disappointed that the local government sector was not consulted during development of the Psychoactive Substances Act 2013 (the Act) given the responsibility that the sector has in developing Local Approved Product Policies (LAPPs) and the significant concerns that many communities have regarding psychoactive substances.

5. The Dunedin City Council supports, in general, the submission made by Local Government New Zealand.

6. The Dunedin City Council is currently developing a LAPP to establish where our community wants the sale of psychoactive substances prohibited. The Dunedin City Council aims to have formally consulted our community and adopted a LAPP by July.

7. The Act does not specify consistency with the relevant LAPP as a matter the Psychoactive Substances Regulatory Authority (the Authority) can consider when assessing applications for retail licenses. This means that the Authority will either not assess whether an application is consistent with the relevant LAPP, or if it does, that any licence application declined on the basis of inconsistency with the relevant LAPP could be challenged in court. This will mean
Dunedin City's LAPP will be unenforceable and that the wishes of our community could be overridden.

8. The Act, however, enables regulations to specify information and documents that must accompany applications for licenses and allows the Authority to refuse applications if those requirements are not met. The consultation document proposes to require applications to be accompanied by evidence of compliance with the relevant LAPP. The Dunedin City Council supports this proposal as it would mean that the wishes of our community, as established in our LAPP, would be reflected in the decisions on retail license applications made by the Authority.

9. The Dunedin City Council requests that the regulations specify that evidence of compliance be a certificate or consent from the relevant territorial authority. This would ensure that the Authority can be confident of the evidence provided and that communities can be confident that applications are being adequately assessed against their LAPP. This would be a similar process to that required when applying for consent under the Gambling Act 2003 to establish new Class 4 gambling venues. Territorial authorities should also be specifically permitted to charge applicants a fee to cover the cost of assessing their application and issuing certificates.

10. The Dunedin City Council supports the proposal for a generic LAPP to apply where communities have not developed and adopted their own. A generic LAPP would provide a degree of regulation for communities that lack the resources to develop and adopt their own policy and would provide a starting point for councils that choose to develop their own LAPPs. The generic policy should be developed with input from the local government sector and the public should be given the opportunity to comment on a draft generic policy.

11. The Dunedin City Council supports a general condition on all retail licenses, to require licenses to be displayed in licensed retailed premises. This will provide the public with assurance that a retail venue has been licensed to operate by the Authority and complies with the Act and the relevant LAPP.

12. Thank you for the opportunity to submit on the proposed regulations under the Psychoactive Substances Act 2013. The Dunedin City Council looks forward to working with Psychoactive Substances Regulatory Authority to ensure the wishes of the Dunedin community (as identified through upcoming consultation on Dunedin's LAPP) are considered when the Authority issues retail licenses.

Yours faithfully,

Councillor David Benson-Pope
Chair, Planning and Regulatory Committee
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. We additionally support the proposal to include consent to undergo a Police check being included on the application form.

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?
   - It is pleasing that the Government is considering a two-phase implementation of the regulations to allow councils time to develop and adopt appropriate policies.
   - Applicants for a retail policy must show that their policy complies with the relevant local approved products policy thus ensuring efficiency for authorities to confirm eligibility of applications for further processing.
   - We believe strongly that the Regulatory Authority must not grant a license to any applicant which fails to so comply.
   - Local authorities should provide a standard template for applicant to provide level of proof. An effective process to model is that of the Gambling Act, in which an applicant seeks from their council written confirmation that their application is consistent with the councils’ LAPP.
   - A generic LAPP should be developed for jurisdictions where councils have chosen not to adopt a specific LAPP and retail licenses should be dealt with when a change of premise is required due to the conditions imposed by an adopted LAPP.
   - Premises operating under an interim license prior to the notification of retail regulations in 2015 should close down until the end of the interim period and apply for a permanent license within the appropriate zone when that option becomes available.

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, applications for retail licenses should contain evidence of compliance with generic policies.

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.
The proposal to include the New Zealand Customs Service (regarding importation compliance) and the Police in the fit and proper person check.

For all licences, we recommend
- The Psychoactive Substances Act lists relevant offences in section 16(2) that are grounds for considering the applicant is likely to fail to comply with the Act. We recommend specifying in the list:
  - Violation of licence conditions and Regulations under the Sale of Liquor Act, Sale & Supply of Alcohol Act or the Medicines Act
- An applicant with any past conviction or licence suspension/cancellation for the unlawful sale of an age-restricted product to a minor should be rejected.
- The regulations should include a requirement for retail licence holders to confirm that their staff or employees who will be selling psychoactive substances are of good character and have undergone police checks to confirm they have not committed offences under any of the Acts or Regulations mentioned above.

Breaches of these Acts and Regulations are particularly relevant as they show past compliance behaviour with licence conditions, and in particular, the supply of controlled and recreational drugs.

When determining whether there might be additional matters, or whether there are other grounds for believing an applicant might not comply with the Act’s requirements, we recommend that the Authority consult with the relevant local authority to ascertain the nature of any relevant experience the council might have with the applicant. It is possible that applicants will have a history of contact with a local authority that either shows them to be either good corporate citizens or, at the other extreme, serial non-compliers.

For research licences, we recommend:
Greater detail on how Research licences can be used and what conditions might be attached to such licences. To minimise risks of product leakage or unsafe research practices around unapproved psychoactive substances, we would recommend the Authority consider:
- Whether the stated purpose and aims of the research are consistent with the Act
- Evidence of professional qualifications and experience relevant to their proposed research, or in the case of a body corporate, the staff member(s) who will conduct the research
- Evidence of affiliation with a suitable body to monitor and assess the quality and ethics of the type of research the applicant proposes to conduct.

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

Yes, please see above.
What records should the regulations require licence holders to keep?

We support the proposals in the consultation document to require licence holders to keep records that will show sufficient detail to trace imported substances and assess any product leakage. This is particularly important to the purposes of the Act for the protection of the public concerning substances that have not yet been tested or approved of as low risk.

To this end, 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

Specific to retail licence holders, we recommend retention of the following records:

- Quantity sold in a single transaction
- Incidence records e.g. like a Liquor Licence Incidence record, for instance, describing attempts by a person under 18 attempting to purchase a psychoactive product; theft or burglary.
- Any feedback from a purchaser relating to adverse effects of a product

In the case of research licence holders, we recommend they keep detailed records of their research for several reasons:

1) To demonstrate their research practices are suited to the stated purpose of obtaining the licence
2) To ensure psychoactive substances or products obtained under their licence can be traced
3) To support any review by the PSEAC of data they have submitted in an application for product approval.
4) To support compliance with other relevant legal and ethical standards for research.
5) To enable monitoring and long-term tracking of human participants in the research for health purposes.

As such, we recommend research licence holders retain records of:

- Quantities of psychoactive substances used, consumed, and otherwise destroyed and disposed of during the research process
- Their research methods, processes, data or other information required by the Authority/PSEAC for approval of a psychoactive product.
- The research data generated or collected
- Identification details of human participants involved in the research

This data should be collated and made available to health services and other relevant stakeholders.
7 How long should licence holders be required to keep records for?

7 years to enable audit

Research:
It is widely acknowledged that in clinical trials, some medicines will be approved that are subsequently found to have unforseen side effects.

Record keeping for research and clinical trials should meet relevant standards for similar human medical/drug trials whilst also establishing the long term effects – not just identifying acute risks from NPS products.

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

We support the discretionary conditions proposed for retail licences. In addition advocate for Central and Local Government should work closer together on designing the appropriate mix of matters that might be taken into account when developing an LAPP, particularly those matters which may be left to councils’ discretion and those that might be determined nationally by the Authority itself.

In addition, we recommend for retail licences:

- Restrictions on opening hours from 9am to 3pm to reduce the opportunity for school age children to purchase psychoactive substances. These hours would also restrict the likelihood of people intoxicated on alcohol purchasing substances and using them incorrectly.
- The authority should take into account communities with poor wellbeing profiles when deciding to approve local retailer trading locations.
- Sale to intoxicated persons should also be defined and prohibited, covering intoxication by any drug including alcohol.
- A requirement to seek age identification from any person who appears to be under the age of 25 years old prior to sale.
- Shops licensed to sell approved products should specialise in the sale of these substances. A requirement for staff training on
  - identifying under 25 year olds and appropriately seeking identification
  - signs of intoxication, health or addiction issues
  - how to open a conversation about health or addiction issues when appropriate, and effective ways to offer or guide people to resources for help
  - refer people to appropriate intervention and treatment services who are resourced by NPS generated levies
- A limit on the range of non-related products, such as clothing, which is be able to be sold in retail premises licensed to sell approved products.

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?

For retail licences, we recommend:
In the absence of an LAPP or generic LAPP, physical proximity to premises regularly used by young people and vulnerable groups should be considered by the authority.
Likely impact on the character of an area.
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?

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, this information and data should be provided for the substance.

In addition, a specific requirement for the same data as above should be provided for the final product for which approval is sought, as the product may contain combinations of substances, psychoactive or otherwise.

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?
Overall yes, this information and data should be provided for the substance.

NPS are often used in combination with other legal and illegal psychoactive substances. Risks of recreational drug use also increase when users are from vulnerable groups such as risk taking adolescents, those who are at risk of mental illness and those already dependent on alcohol and drugs. It is also acknowledged that in clinical trials, some medicines will be approved that are subsequently found to have unforeseen side effects. Whilst toxicology and clinical trials may well be effective at identifying acute risks from NPS products, establishing long term effects is considerably more challenging.

Determining the measure of 'low risk' will be difficult to define and potentially be scientifically inaccurate due to trying to translate the skewed distribution of harm among users into an overall concept of 'low risk'. Thus the baseline measure for determining 'low risk' should be assessed against the scheduled substance that evidences 'lowest risk of harm' to the individual consumer.

Regulations should stipulate that clinical trial methods examine the NPS in question in relation to other substances and risk factor mentioned above.

In addition we recommend:

- Data on the same factors listed at '12' and '13' should be provided not only for the substance for which approval is sought, but for the final product for which approval is sought, as the product for which approval is sought may contain combinations of substances, psychoactive or otherwise.
- Information on effects and risks at different levels of dosage of the final product should be provided.
- The intended quantities and dose quantities per package of the final product, alongside directions regarding suitable dosage and use, should be included in the product approval application, in order to evaluate effects and risk levels at the recommended dosage.

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

We support the labelling requirements proposed, particularly the poisons centre (or other centres established for monitoring adverse reactions) and relevant drug addiction support lines.

Upholding the spirit and integrity of the purpose of the act, plain packing of products is a must to ensure lack of appeal to minors. Further, imagery and slogans on packaging for branding can be considered as advertising, so plain packaging will ensure that Section 56(3) of the Act is met i.e. that advertising of an approved product “must be limited to material that communicates objective information about the product”. This will also reduce the burden on the regulatory authority to decide on this question. This also supports the intention of the act that advertising only include objective and factual information.

In addition we recommend labels include details of:

- All contents of the product and their quantities (not only the active ingredients), grouped as psychoactive and non-psychoactive
- Any known side-effects of the product

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).
No. We recommend that a bold, short and simple title “HEALTH WARNING” be prominent (covering at least 10% of the exterior product packaging, and the exterior of any sub-units of packaging, followed by the four compulsory warnings proposed.

Because products will have been approved as ‘low risk’, users will likely consider the product completely safe, or might discount their consideration of risk. A prominent warning will remind people to consider the known risks of the substance and the recommended dosage and directions.

In addition, suggest adding two further warnings:
- All psychoactive substances carry risk of adverse reaction
- Effects of long-term, regular use of this product have not been assessed

Ref:

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

We strongly support that the content of labels and inserts, their appearance and accessibility be approved by the authority.

See question 14 regarding support for plain packaging.

The other requirements proposed appear sufficient.

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

Yes. This can reduce the risk of overdose and risk to children. It also supports the intention of the Act to protect the health of users (Chan, 2000).


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

Yes, please see 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?

Yes. We believe products in the following forms should not be approved:
- Additional regulations should be applied for smokeable products, covering any public indoor or other confined space. Non-consumers should not be subject to second hand smoke from such products.
- Appeal to minors – support that product forms with appeal to minors should not be allowed.
- Liquid or other easily injectable forms, and should not come in/with Injection equipment.
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 – level of security should be high.
Products or substances stolen and put on the black market may be cheaper and more available to young people away from the oversight of regulations. They may also be converted into stronger or more dangerous drugs in forms that are unapproved and untested.

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

Yes. Two out of three psychoactive product retail stores in Hamilton were recently burgled. Products stolen and put on the black market may be cheaper and more available to young people away from the oversight of regulations.

We recommend taking steps to reduce the likelihood and impact of burglary by limiting amounts kept in retail stores, which are obvious and highly visible targets, to a sufficient quantity for 2 days of normal trade.

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

Product display should be behind a counter area or locked cabinet that makes shoplifting difficult. Young people or vulnerable people with little money may be more likely to shoplift products and this will limit their access.

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

A process for disposal that can be trusted and tracked to product retailers should be a requirement of the regulations. We recommend a requirement for disposal via a public health regulatory agency such as a District Health Board or the Police. A simple form should be completed by the regulatory agency recording the product type and amount, identity and relevant licence number of the person or company it has been received from, and a confirmation that the regulatory agent has seen the product as described (type, amount) and disposed of it according to requirements.

This is evidenced from careless dumping of psychoactive products from stores (dairies) that were prohibited from selling such products after the introduction of the Act in 2013. The dumped products reappeared on the black market and in the hands of minors at very low prices. Should other products be recalled, such dumping could occur again.

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

18+ signs
No consumption on premises
Prominent signage detailing signs of addiction
Prominent signage of harm reduction interventions
Prominent signage detailing where help can be accessed for addiction, dependence or health issues
Prominent signage detailing an appropriate reporting number to call to report adverse effects.
25 Do you think the regulations should specify further places where approved products may not be sold? If so, please provide specific suggestions.

To avoid leakage of product to young people through shoplifting, the premises where products are sold should have entry restrictions to persons 18 years and older.

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

Yes. We support:

- Restriction of advertising from any other media as per section 56(1)(d) of the Act.
- We require in the regulations that any advertising must be consistent with the Advertising Standards Authority’s Advertising Code of Ethics

We recommend:

- There should be a restriction on product endorsement with fines consistent with section 56(5) of the Act. Anyone with a large online following of young people who publicly endorses products is likely to influence use among young people under the age of 18 and contravenes the intention of the Act to restrict advertising.

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

- We support restrictions on advertising on sites designed to appeal to minors.
- We recommend a reliable proof of age requirement is established to enter a site and purchase products. For instance, the RealMe service could be used to verify age prior to online purchasing. This would also be a sensible precaution for online alcohol sales.

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

We support that the regulations contain detail that ensure on-site advertising is restricted to objective information only.

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?

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

Yes – levies should be collected to enable:
- The establishment of data collection and monitoring systems including:
  - 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).
  - Newly approved products to be reviewed for evidence of harms every three years
  - Development and operation of systems for reporting adverse effects of psychoactive products (e.g. CARM, and systems for relevant medical facilities such as emergency departments, GPs and mental health clinics)

Fees or should be collected from retailers to enable:
- Development, delivery and evaluation of standard training on safe retailing practices e.g.
  - Identifying under 25 year olds and appropriately seeking identification
  - Signs of intoxication, drug-related health or addiction issues
  - How to open a conversation about health or addiction issues when appropriate, and effective ways to offer or guide people to resources for help

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) ____________________________________________
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): as a citizen of New Zealand

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.
Consultation questions

1. Is the list of proposed information requirements for licence applications comprehensive enough?
   
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   Yes. We additionally support the proposal to include consent to undergo a Police check being included on the application form.

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- The proposal to include the New Zealand Customs Service (regarding importation compliance) and the Police in the fit and proper person check.

For all licences, we recommend
- The Psychoactive Substances Act lists relevant offences in section 16(2) that are grounds for considering the applicant is likely to fail to comply with the Act. We recommend specifying in the list:
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- Their research methods, processes, data or other information required by the Authority/PSEAC for approval of a psychoactive product.
- The research data generated or collected
- Identification details of human participants involved in the research

This data should be collated and made available to health services and other relevant stakeholders.
7 How long should licence holders be required to keep records for?

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<td>In the absence of an LAPP or generic LAPP, physical proximity to premises regularly used by young people and vulnerable groups should be considered by the authority.</td>
</tr>
<tr>
<td>Likely impact on the character of an area.</td>
</tr>
</tbody>
</table>

6 Psychoactive Substances Regulations: Consultation document
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?

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, this information and data should be provided for the substance.

In addition, a specific requirement for the same data as above should be provided for the final product for which approval is sought, as the product may contain combinations of substances, psychoactive or otherwise.

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?
Overall yes, this information and data should be provided for the substance.

NPS are often used in combination with other legal and illegal psychoactive substances. Risks of recreational drug use also increase when users are from vulnerable groups such as risk taking adolescents, those who are at risk of mental illness and those already dependent on alcohol and drugs. It is also acknowledged that in clinical trials, some medicines will be approved that are subsequently found to have unforeseen side effects. Whilst toxicology and clinical trials may well be affective at identifying acute risks from NPS products, establishing long term effects is considerable more challenging.

Determining the measure of ‘low risk’ will be difficult to define and potentially be scientifically inaccurate due to trying to translate the skewed distribution of harm among users into an overall concept of ‘low risk’. Thus the baseline measure for determining ‘low risk’ should be assessed against the scheduled substance that evidences ‘lowest risk of harm’ to the individual consumer.

Regulations should stipulate that clinical trial methods examine the NPS in question in relation to other substances and risk factor mentioned above.

In addition we recommend:
- Data on the same factors listed at ‘12’ and ‘13’ should be provided not only for the substance for which approval is sought, but for the final product for which approval is sought, as the product for which approval is sought may contain combinations of substances, psychoactive or otherwise.
- Information on effects and risks at different levels of dosage of the final product should be provided.
- The intended quantities and dose-quantities per package of the final product, alongside directions regarding suitable dosage and use, should be included in the product approval application, in order to evaluate effects and risk levels at the recommended dosage.

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

We support the labelling requirements proposed, particularly the poisons centre (or other centres established for monitoring adverse reactions) and relevant drug addiction support lines.

Upholding the spirit and integrity of the purpose of the act, plain packing of products is a must to ensure lack of appeal to minors. Further, imagery and slogans on packaging for branding can be considered as advertising, so plain packaging will ensure that Section 56(3) of the Act is met i.e. that advertising of an approved product “must be limited to material that communicates objective information about the product”. This will also reduce the burden on the regulatory authority to decide on this question. This also supports the intention of the act that advertising only include objective and factual information.

In addition we recommend labels include details of:
- All contents of the product and their quantities (not only the active ingredients), grouped as psychoactive and non-psychoactive
- Any known side-effects of the product

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).
No. We recommend that a bold, short and simple title "HEALTH WARNING" be prominent (covering at least 10%) of the exterior product packaging, and the exterior of any sub-units of packaging, followed by the four compulsory warnings proposed.

Because products will have been approved as 'low risk', users will likely consider the product completely safe, or might discount their consideration of risk. A prominent warning will remind people to consider the known risks of the substance and the recommended dosage and directions.

In addition, suggest adding two further warnings:
- All psychoactive substances carry risk of adverse reaction
- Effects of long-term, regular use of this product have not been assessed


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

We strongly support that the content of labels and inserts, their appearance and accessibility be approved by the authority.

See question 14 regarding support for plain packaging.

The other requirements proposed appear sufficient.

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

Yes. This can reduce the risk of overdose and risk to children. It also supports the intention of the Act to protect the health of users (Chan, 2000).


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

Yes, please see 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?

Yes. We believe products in the following forms should not be approved:
- Additional regulations should be applied for smokeable products, covering any public indoor or other confined space. Non-consumers should not be subject to second hand smoke from such products.
- Appeal to minors – support that product forms with appeal to minors should not be allowed.
- Liquid or other easily injectable forms, and should not come in/with Injection equipment.
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 – level of security should be high. Products or substances stolen and put on the black market may be cheaper and more available to young people away from the oversight of regulations. They may also be converted into stronger or more dangerous drugs in forms that are unapproved and untested.

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

Yes. Two out of three psychoactive product retail stores in Hamilton were recently burgled. Products stolen and put on the black market may be cheaper and more available to young people away from the oversight of regulations.

We recommend taking steps to reduce the likelihood and impact of burglary by limiting amounts kept in retail stores, which are obvious and highly visible targets, to a sufficient quantity for 2 days of normal trade.

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

Product display should be behind a counter area or locked cabinet that makes shoplifting difficult. Young people or vulnerable people with little money may be more likely to shoplift products and this will limit their access.

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

A process for disposal that can be trusted and tracked to product retailers should be a requirement of the regulations. We recommend a requirement for disposal via a public health regulatory agency such as a District Health Board or the Police. A simple form should be completed by the regulatory agency recording the product type and amount, identity and relevant licence number of the person or company it has been received from, and a confirmation that the regulatory agent has seen the product as described (type, amount) and disposed of it according to requirements.

This is evidenced from careless dumping of psychoactive products from stores (dairies) that were prohibited from selling such products after the introduction of the Act in 2013. The dumped products reappeared on the black market and in the hands of minors at very low prices. Should other products be recalled, such dumping could occur again.

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

18+ signs
No consumption on premises
Prominent signage detailing signs of addiction
Prominent signage of harm reduction interventions
Prominent signage detailing where help can be accessed for addiction, dependence or health issues
Prominent signage detailing an appropriate reporting number to call to report adverse effects.
25 Do you think the regulations should specify further places where approved products may not be sold? If so, please provide specific suggestions.

To avoid leakage of product to young people through shoplifting, the premises where products are sold should have entry restrictions to persons 18 years and older.

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

Yes. We support:

- Restriction of advertising from any other media as per section 56(1)(d) of the Act.
- We recommend the regulations that any advertisement must be consistent with the Advertising Standards Authority's Advertising Code of Ethics.

We recommend:

- There should be a restriction on product endorsement with fines consistent with section 56(5) of the Act. Anyone with a large online following of young people who publicly endorses products is likely to influence use among young people under the age of 18 and contravenes the intention of the Act to restrict advertising.

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

- We support restrictions on advertising on sites designed to appeal to minors.
- We recommend a reliable proof of age requirement is established to enter a site and purchase products. For instance, the RealMe service could be used to verify age prior to online purchasing. This would also be a sensible precaution for online alcohol sales.

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

We support that the regulations contain detail that ensure on-site advertising is restricted to objective information only.

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?

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

Yes – levies should be collected to enable:

- The establishment of data collection and monitoring systems including:
  - 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).
  - Newly approved products to be reviewed for evidence of harms every three years
  - Development and operation of systems for reporting adverse effects of psychoactive products (e.g. CARM, and systems for relevant medical facilities such as emergency departments, GPs and mental health clinics)

Fees or should be collected from retailers to enable:

- Development, delivery and evaluation of standard training on safe retailing practices e.g.
  - identifying under 25 year olds and appropriately seeking identification
  - signs of intoxication, drug-related health or addiction issues
  - how to open a conversation about health or addiction issues when appropriate, and effective ways to offer or guide people to resources for help

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) Daniel John Harrison
(Address) 39 Graham Street
(town/city) Auckland Central

Email: Daniel.harrisonACE@aucklandcouncil.govt.nz
Organisation (if applicable): Auckland Council
Position (if applicable): Code Compliance Certificate Technical Assessor

Are you submitting this:
(Tick one box only in this section)
☐ as an interim licence holder
☐ a person or body corporate intending to apply for a licence
☐ other (please specify): ...............................................................

Do you wish to receive updates about the development of the psychoactive substances regulations?
☐ Yes          ☐ No
(If yes, please make sure you provide an email address.)

Please return only one copy of your submission no later than 5 pm on Friday 21 March to:
The Manager
Psychoactive Substances Regulatory Authority
Ministry of Health
PO Box 5013
WELLINGTON
Email: psychoactives@moh.govt.nz

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

Please put ‘Regulations Consultation’ in the subject line.

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

☐ I do not give permission for my personal details to be released under the Official Information Act 1982.
☐ I do not give permission for my name to be listed in the published summary of submissions.
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 proposed information requirements appear to be comprehensive enough. One addition could be that for a person who previously held an interim licence, were there any issues i.e. Was their licence suspended at all during the interim period, were they part of a test for R18 shoppers and failed by selling to an underage person etc.

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?

   I suspect it would be hard to provide evidence of this. Location relative to “sensitive” areas can easily be identified due to the shops location but providing evidence (for example) that you are operating within the LAPP’s acceptable hours of trade (if included in the LAPP) would be hard to provide. Perhaps it would be good for the applicant to include a copy of the local LAPP with a declaration that states they have read it, understood it, and are not in breach of it.

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?

   Again, I feel that a declaration that states you are aware of the policy in place for the area and that you comply with it, accompanied by a signed copy of the policy would be suitable. To then operate outside of that policy could see your licence revoked.
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 these are enough

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

Yes this is a good idea as a person may have had an issue within another licensing process which does not show on a Police or Customs check.

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

Records kept should include all movements of stock received and sold and should include licence numbers as the Authority has stated. Records should also be kept of any product that is disposed of (i.e. Written off) with details as to how the product was disposed of.

7. How long should licence holders be required to keep records for?
If licences are to be issued with a 3 year life span then a 5 year history of records would be suitable.

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

I do not think that a premises with an adjoining doorway to a dairy should be considered a suitable outlet to retail these products. Generally both outlets would have the same owner and they are only trying to make money as easily as possible. Any outlet that sells these substances should suitably be secured from the business next door as if they were owed by different people.

Restrictions on opening hours should only be applied when there is no LAPP in place and the location of the outlet is within a specified distance of what may be regarded as a "sensitive site". I do not feel that any restriction is required if an LAPP is in place as the premises that sell these products will not be advertising outside of their outlets and any LAPP will no doubt include that these outlets are not within a certain distance of sensitive sites.

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

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 that this should be included as it ensures that the manufacturer is aware of the process.

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 I agree that this sounds like a good idea that some form of testing is done and supplied with the application as a base for the PSEAC to work with.

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.

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

I believe the proposed requirements and restrictions are sufficient.
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 the proposed requirements relating to health warnings are sufficient.

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

I believe the proposed packaging requirements and restrictions are sufficient.

C

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

I do not agree with restricting a packet to one dose as users of these products use them, in some cases, on a regular basis (i.e., to relieve the pressure of a busy working day). The user should have the ability to buy a pack size that will last for a couple of days or over a weekend. The larger pack size would generally offer a slightly better price than buying individual packs so it gives the consumer better value. "Better value" may not be something that those opposed to these products would like to see but just like any other consumer product (including alcohol) it is an option that should be available to the consumer otherwise the consumer is really being penalised simply because he/she makes the choice to use these products. A larger pack size may also help to reduce the amount of people who hang around stores waiting for them to open.

C

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

Yes I agree.
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 there should be restrictions on the form of these products and I believe a tablet is one of the best forms as a tablet can easily be halved if required. I do not agree with capsules as these can be opened and from the BZP days I remember hearing of people who would open the capsules to remove the powder so they could snort it through their nose. Tablets would need to be imprinted so they are easily identifiable from similar products (ie. medicines, Panadol etc).

I would like to see the removal of herb products designed to be smoked and see it replaced with a vaporising method similar to that used by electronic cigarettes.

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?

I think there should be a requirement to store a product at or below a certain temperature if a high (or low) temperature will adversely affect a product.

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

I do not think restrictions are required for the storage of products.

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 think the display of products should be restricted as they are already packaged in a way that does not appeal to minors. However, like fireworks, they should be kept on shelving or in cabinets that are not directly accessible by customers.
23. Do you think restrictions or requirements should be set regarding the disposal of approved products? If so, what should they be?

I think a record of what was disposed of and how should be kept so if anything pops up on the black market there is a way of helping to identify where it may have come from.

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

I think there should be the ability for the Authority to require signage if they see fit, however, I do not think signage requirements are needed at this time.

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

I do not think products should be sold in an outlet that sells any product that is intended for a minor. Currently, products can be sold in specialty stores yet some of these stores may have products (i.e. games, novelty products) that appeal to a younger audience and attract young people to the shop.

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

I think that advertising should be restricted to include only the fact that the advertiser has these products available. It should be limited to the point where they cannot advertise the effects of the products (as this would appeal to some youth), they cannot advertise images of the consumable part of the product (i.e. pictures of tablets) and it should have to include that the products are R18. For example "R18 Social Tonics available in-store". Pictures of the outer packaging should be allowed as they will be packaged in a way that is plain and not appealing 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.

I think the best way to minimise underage internet purchases is for the internet site (seller) to request a copy of the purchases ID before product is supplied. This provides a much better way of minimising underage buying. Access to any website will be easy for any age, restricting who can actually get their hands on product by supplying ID will surely help to minimise harm.

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

No I don't think the regulations should prescribe restrictions or requirements on the advertising of approved products.

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

The fees seem extremely high but I do not know the actual costs of processing the applications so if the proposed fee did indeed reflect the true costs incurred by the Authority then I can understand it. I would only hope that this is monitored to ensure the fees are not excessive to the actual costs.

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

I support a fixed fee for processing applications for product approvals. It is an easier to manage system and can be adjusted easily without having to work out all the hourly costs.
31 Should fees be set for other specific functions? If yes, please state what they should be set for.

No

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

Yes I 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): ...........................................................................................................................................

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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WELLINGTON
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☐ I do not give permission for my name to be listed in the published summary of submissions.
The Manager  
Psychoactive Substances Regulatory Authority 
Ministry of Health  
PO Box 5013  
Wellington 6145  
To The Manager

From: Joseph Liava’a

Re: Submission on the New Psychoactive Substances (NPS) Regulation

Thank you for the opportunity to be involved in the consultation on this document and acknowledge the public health progress this Act enables. The NPS regime promotes and protects health and wellbeing of communities, whilst breaking the cycle of continual introductions of new NPS as well as providing low-risk alternatives to existing drug use.

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.

Additional Considerations:

Local Approved Products Policies (LAPP)
These policies have few strong measures compared to the provision possible in Local Alcohol Policies. We believe that with the introduction of potentially many new, unknown and likely intoxicating substances, strong controls like those possible for alcohol and within Local Alcohol Policies should be available to local authorities managing psychoactive substances. Namely:

- The ability to limit hours of sale  
- The ability to limit total numbers of outlets and outlet density  
- Location in relation to liquor stores  
- The ability to introduce liquor bans

Generic Local Approved Products Policy
We support the proposal to create a Generic Local Approved Products Policy that applies to all in council areas or territorial authorities where no Local Approved Products Policy exists.

We recommend that this generic policy establish broad restrictions on locations in general terms. To reduce the exposure of young people and vulnerable people to the harmful effects of psychoactive products, we suggest:

- restricting premises selling approved products to a minimum of 150m away from sensitive sites — including kindergartens, early childhood centres, schools, places of worship, youth centres, mental health and addiction services or other community facilities.  
- Stores should not be on the main route between sensitive sites and the main residential area for a local population

Regulations to support the assessment of ‘low risk’
Determining the measure of ‘low risk’ will be difficult to define and potentially be scientifically inaccurate due to trying to translate the skewed distribution of harm among users into an overall concept of ‘low risk’. Thus the baseline measure for determining ‘low risk’ should be assessed against the scheduled substance that evidences ‘lowest risk of harm’ to the individual consumer.

We are also 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:
  - 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 support 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 supporting 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\(^2\).

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 road-side tests for the presence of such drugs will be required.

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.

\(^1\) 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

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. We additionally support the proposal to include consent to undergo a Police check being included on the application form.

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?
   - It is pleasing that the Government is considering a two-phase implementation of the regulations to allow councils time to develop and adopt appropriate policies.
   - Applicants for a retail policy must show that their policy complies with the relevant local approved products policy thus ensuring efficiency for authorities to confirm eligibility of applications for further processing.
   - We believe strongly that the Regulatory Authority must not grant a license to any applicant which fails to so comply.
   - Local authorities should provide a standard template for applicant to provide level of proof. An effective process to model is that of the Gambling Act, in which an applicant seeks from their council written confirmation that their application is consistent with the councils’ LAPP.
   - A generic LAPP should be developed for jurisdictions where councils have chosen not to adopt a specific LAPP and retail licenses should be dealt with when a change of premise is required due to the conditions imposed by an adopted LAPP.
   - Premises operating under an interim license prior to the notification of retail regulations in 2015 should close down until the end of the interim period and apply for a permanent license within the appropriate zone when that option becomes available.

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, applications for retail licenses should contain evidence of compliance with generic policies.

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 support:

The proposal to include the New Zealand Customs Service (regarding importation compliance) and the Police in the fit and proper person check.

For all licences, we recommend

- The Psychoactive Substances Act lists relevant offences in section 16(2) that are grounds for considering the applicant is likely to fail to comply with the Act. We recommend specifying in the list:
  - Violation of licence conditions and Regulations under the Sale of Liquor Act, Sale & Supply of Alcohol Act or the Medicines Act

- An applicant with any past conviction or licence suspension/cancellation for the unlawful sale of an age-restricted product to a minor should be rejected.

- The regulations should include a requirement for retail licence holders should to confirm that their staff or employees who will be selling psychoactive substances are of good character and have undergone police checks to confirm they have not committed offences under any of the Acts or Regulations mentioned above.

Breaches of these Acts and Regulations are particularly relevant as they show past compliance behaviour with licence conditions, and in particular, the supply of controlled and recreational drugs.

When determining whether there might be additional matters, or whether there are other grounds for believing an applicant might not comply with the Act’s requirements, we recommend that the Authority consult with the relevant local authority to ascertain the nature of any relevant experience the council might have with the applicant. It is possible that applicants will have a history of contact with a local authority that either shows them to be either good corporate citizens or, at the other extreme, serial non-compliers.

For research licences, we recommend:

Greater detail on how Research licences can be used and what conditions might be attached to such licences. To minimise risks of product leakage or unsafe research practices around unapproved psychoactive substances, we would recommend the Authority consider:

- Whether the stated purpose and aims of the research are consistent with the Act
- Evidence of professional qualifications and experience relevant to their proposed research, or in the case of a body corporate, the staff member(s) who will conduct the research
- Evidence of affiliation with a suitable body to monitor and assess the quality and ethics of the type of research the applicant proposes to conduct.

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

Yes, please see above.
6 What records should the regulations require licence holders to keep?

We support the proposals in the consultation document to require licence holders to keep records that will show sufficient detail to trace imported substances and assess any product leakage. This is particularly important to the purposes of the Act for the protection of the public concerning substances that have not yet been tested or approved of as low risk.

To this end, 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

Specific to retail licence holders, we recommend retention of the following records:
- Quantity sold in a single transaction
- Incidence records e.g. like a Liquor Licence Incidence record, for instance, describing attempts by a person under 18 attempting to purchase a psychoactive product; theft or burglary.
- Any feedback from a purchaser relating to adverse effects of a product

In the case of research licence holders, we recommend they keep detailed records of their research for several reasons:
1) To demonstrate their research practices are suited to the stated purpose of obtaining the licence
2) To ensure psychoactive substances or products obtained under their licence can be traced
3) To support any review by the PSEAC of data they have submitted in an application for product approval.
4) To support compliance with other relevant legal and ethical standards for research.
5) To enable monitoring and long-term tracking of human participants in the research for health purposes.

As such, we recommend research licence holders retrain records of:
- Quantities of psychoactive substances used, consumed, and otherwise destroyed and disposed of during the research process
- Their research methods, processes, data or other information required by the Authority/PSEAC for approval of a psychoactive product.
- The research data generated or collected
- Identification details of human participants involved in the research

This data should be collated and made available to health services and other relevant stakeholders.
7 How long should licence holders be required to keep records for?

7 years to enable audit

Research:
It is widely acknowledged that in clinical trials, some medicines will be approved that are subsequently found to have unforeseen side effects.

Record keeping for research and clinical trials should meet relevant standards for similar human medical/drug trials whilst also establishing the long term effects – not just identifying acute risks from NPS products.

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

We support the discretionary conditions proposed for retail licences. In addition advocate for Central and Local Government should work closer together on designing the appropriate mix of matters that might be taken into account when developing an LAPP, particularly those matters which may be left to councils’ discretion and those that might be determined nationally by the Authority itself.

In addition, we recommend for retail licences:
- Restrictions on opening hours from 9am to 3pm to reduce the opportunity for school age children to purchase psychoactive substances. These hours would also restrict the likelihood of people intoxicated on alcohol purchasing substances and using them incorrectly.
- The authority should take into account communities with poor wellbeing profiles when deciding to approve local retailer trading locations.
- Sale to intoxicated persons should also be defined and prohibited, covering intoxication by any drug including alcohol.
- A requirement to seek age identification from any person who appears to be under the age of 25 years old prior to sale.
- Shops licensed to sell approved products should specialise in the sale of these substances. A requirement for staff training on
  - identifying under 25 year olds and appropriately seeking identification
  - signs of intoxication, health or addiction issues
  - how to open a conversation about health or addiction issues when appropriate, and effective ways to offer or guide people to resources for help
  - refer people to appropriate intervention and treatment services who are resourced by NPS generated levies
- A limit on the range of non-related products, such as clothing, which is be able to be sold in retail premises licensed to sell approved products.

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?

For retail licences, we recommend:
In the absence of an LAPP or generic LAPP, physical proximity to premises regularly used by young people and vulnerable groups should be considered by the authority.
Likely impact on the character of an area.

6 Psychoactive Substances Regulations: Consultation document
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?

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, this information and data should be provided for the substance.

In addition, a specific requirement for the same data as above should be provided for the final product for which approval is sought, as the product may contain combinations of substances, psychoactive or otherwise.

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?
Overall yes, this information and data should be provided for the substance.

NPS are often used in combination with other legal and illegal psychoactive substances. Risks of recreational drug use also increase when users are from vulnerable groups such as risk taking adolescents, those who are at risk of mental illness and those already dependent on alcohol and drugs. It is also acknowledged that in clinical trials, some medicines will be approved that are subsequently found to have unforeseen side effects. Whilst toxicology and clinical trials may well be affective at identifying acute risks from NPS products, establishing long term effects is considerably more challenging.

Determining the measure of ‘low risk’ will be difficult to define and potentially be scientifically inaccurate due to trying to translate the skewed distribution of harm among users into an overall concept of ‘low risk’. Thus the baseline measure for determining ‘low risk’ should be assessed against the scheduled substance that evidences ‘lowest risk of harm’ to the individual consumer.

Regulations should stipulate that clinical trial methods examine the NPS in question in relation to other substances and risk factor mentioned above.

In addition we recommend:
- Data on the same factors listed at ‘12’ and ‘13’ should be provided not only for the substance for which approval is sought, but for the final product for which approval is sought, as the product for which approval is sought may contain combinations of substances, psychoactive or otherwise.
- Information on effects and risks at different levels of dosage of the final product should be provided.
- The intended quantities and dose-quantities per package of the final product, alongside directions regarding suitable dosage and use, should be included in the product approval application, in order to evaluate effects and risk levels at the recommended dosage.

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

We support the labelling requirements proposed, particularly the poisons centre (or other centres established for monitoring adverse reactions) and relevant drug addiction support lines.

Upholding the spirit and integrity of the purpose of the act, plain packing of products is a must to ensure lack of appeal to minors. Further, imagery and slogans on packaging for branding can be considered as advertising, so plain packaging will ensure that Section 56(3) of the Act is met i.e. that advertising of an approved product “must be limited to material that communicates objective information about the product”. This will also reduce the burden on the regulatory authority to decide on this question. This also supports the intention of the act that advertising only include objective and factual information.

In addition we recommend labels include details of:
- All contents of the product and their quantities (not only the active ingredients), grouped as psychoactive and non-psychoactive
- Any known side-effects of the product

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).
No. We recommend that a bold, short and simple title “HEALTH WARNING” be prominent (covering at least 10%) of the exterior product packaging, and the exterior of any sub-units of packaging, followed by the four compulsory warnings proposed.

Because products will have been approved as ‘low risk’, users will likely consider the product completely safe, or might discount their consideration of risk. A prominent warning will remind people to consider the known risks of the substance and the recommended dosage and directions.

In addition, suggest adding two further warnings:
- All psychoactive substances carry risk of adverse reaction
- Effects of long-term, regular use of this product have not been assessed

Ref:

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

We strongly support that the content of labels and inserts, their appearance and accessibility be approved by the authority.

See question 14 regarding support for plain packaging.

The other requirements proposed appear sufficient.

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

Yes. This can reduce the risk of overdose and risk to children. It also supports the intention of the Act to protect the health of users (Chan, 2000).


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

Yes, please see 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?

Yes. We believe products in the following forms should not be approved:
- Additional regulations should be applied for smokeable products, covering any public indoor or other confined space. Non-consumers should not be subject to second hand smoke from such products.
- Appeal to minors – support that product forms with appeal to minors should not be allowed.
- Liquid or other easily injectable forms, and should not come in/with Injection equipment.
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 – level of security should be high. Products or substances stolen and put on the black market may be cheaper and more available to young people away from the oversight of regulations. They may also be converted into stronger or more dangerous drugs in forms that are unapproved and untested. |

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

| Yes. Two out of three psychoactive product retail stores in Hamilton were recently burgled. Products stolen and put on the black market may be cheaper and more available to young people away from the oversight of regulations. We recommend taking steps to reduce the likelihood and impact of burglary by limiting amounts kept in retail stores, which are obvious and highly visible targets, to a sufficient quantity for 2 days of normal trade. |

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

| Product display should be behind a counter area or locked cabinet that makes shoplifting difficult. Young people or vulnerable people with little money may be more likely to shoplift products and this will limit their access. |

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

| A process for disposal that can be trusted and tracked to product retailers should be a requirement of the regulations. We recommend a requirement for disposal via a public health regulatory agency such as a District Health Board or the Police. A simple form should be completed by the regulatory agency recording the product type and amount, identity and relevant licence number of the person or company it has been received from, and a confirmation that the regulatory agent has seen the product as described (type, amount) and disposed of it according to requirements. This is evidenced from careless dumping of psychoactive products from stores (dairies) that were prohibited from selling such products after the introduction of the Act in 2013. The dumped products reappeared on the black market and in the hands of minors at very low prices. Should other products be recalled, such dumping could occur again. |

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

| 18+ signs No consumption on premises Prominent signage detailing signs of addiction Prominent signage of harm reduction interventions Prominent signage detailing where help can be accessed for addiction, dependence or health issues Prominent signage detailing an appropriate reporting number to call to report adverse effects. |

10 Psychoactive Substances Regulations: Consultation document
25 Do you think the regulations should specify further places where approved products may not be sold? If so, please provide specific suggestions.

To avoid leakage of product to young people through shoplifting, the premises where products are sold should have entry restrictions to persons 18 years and older.

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

Yes. We support:
- Restriction of advertising from any other media as per section 56(1)(d) of the Act.
- We a requirement in the regulations that any advertising must be consistent with the Advertising Standards Authority’s Advertising Code of Ethics.

We recommend:
- There should be a restriction on product endorsement with fines consistent with section 56(5) of the Act. Anyone with a large online following of young people who publicly endorses products is likely to influence use among young people under the age of 18 and contravenes the intention of the Act to restrict advertising.

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

- We support restrictions on advertising on sites designed to appeal to minors.
- We recommend a reliable proof of age requirement is established to enter a site and purchase products. For instance, the RealMe service could be used to verify age prior to online purchasing. This would also be a sensible precaution for online alcohol sales.

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

We support that the regulations contain detail that ensure on-site advertising is restricted to objective information only.

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?

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

Yes – levies should be collected to enable:
- The establishment of data collection and monitoring systems including:
  - 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).
  - Newly approved products to be reviewed for evidence of harms every three years
  - Development and operation of systems for reporting adverse effects of psychoactive products (e.g. CARM, and systems for relevant medical facilities such as emergency departments, GPs and mental health clinics)

Fees or should be collected from retailers to enable:
- Development, delivery and evaluation of standard training on safe retailing practices e.g.
  - Identifying under 25 year olds and appropriately seeking identification
  - Signs of intoxication, drug-related health or addiction issues
  - How to open a conversation about health or addiction issues when appropriate, and effective ways to offer or guide people to resources for help

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) 
Address: (street/box number) (town/city) 
Email: 
Organisation (if applicable): 
Position (if applicable): 

Are you submitting this: 
(Tick one box only in this section) 
☐ as an interim licence holder 
☐ a person or body corporate intending to apply for a licence 
☐ other (please specify): 

Do you wish to receive updates about the development of the psychoactive substances regulations? 
☐ Yes ☐ No 
(If yes, please make sure you provide an email address.)

Please return only one copy of your submission no later than 5 pm on Friday 21 March to: 
The Manager 
Psychoactive Substances Regulatory Authority 
Ministry of Health 
PO Box 5013 
WELLINGTON 
Email: psychoactives@moh.govt.nz 

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

Please put ‘Regulations Consultation’ in the subject line.

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

☐ I do not give permission for my personal details to be released under the Official Information Act 1982.

☐ I do not give permission for my name to be listed in the published summary of submissions.
19 March, 2014

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

Submission on
Psychoactive Substances Regulation Bill

From Clendon Manurewa CAYAD Reference Group
(CAYAD - Community Action Youth and Drugs)
Introduction:

Community Action Youth and Drugs (CAYAD) is a national programme to reduce drug related harm among young people. CAYAD operates in 25 sites in cities, towns and rural areas across New Zealand using a community action approach. Each CAYAD site engages their local community to develop projects to achieve four outcomes:

1. Increased informed community discussion and debate about issues related to illicit drugs;
2. Effective policies and practices to reduce harm adopted;
3. Increased local capacity to support young people in education, employment and recreation;
4. Reduced supply of drugs to young people.

CAYAD's are based in local communities, a major focus of their role is to identify and support effective solutions to alcohol and drug issues within their communities so that there are more positive opportunities and outcomes for children and young people. This is achieved by working across sectors with community groups, Marae, government agencies, schools, youth and treatment services, parents/whanau, Auckland Council and Police.

The CAYAD Reference Group membership is made up of residents and stakeholders from the Clendon/Manurewa community who invest in proven and culturally appropriate early intervention programmes to address underlying social issues facing our young people. We would like to contribute the following feedback towards the Psychoactive Substances Regulation Bill.
Is the list of proposed information requirements for licence applications comprehensive enough?
CAYAD Reference Group agrees information from individual applicants must include:
- residential address
- date of birth
- gender
- any other names the applicant is known by

CAYAD Reference Group also strongly recommends that rather than "consent" to undergo a Police check, is changed to a Police vetting and that references also be in place.

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?
CAYAD Reference Group are of the same opinion that retail licence regulations be implemented in phase two to allow councils to have their local policies in place allowing applications to be accompanied by information showing compliance with council policy.

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?
Agreement that:
- All licence holders must advise the Authority of any conviction offences
- Whether there has been a serious or repeated failure by the applicant to comply with any requirement of the Act
- Require applicants to provide details of their involvement in other regulatory regimes, such as alcohol licensing processes

What records should the regulations require licence holders to keep?
Agree that all licence holders must advise the Authority of the importation before it takes place, and provide details of the name, quantity and date of importation of the substance and hold these records up to 5 years.

Do you think there are factors or issues that the Authority should consider when setting discretionary conditions?
Strongly recommend the Authority set discretionary conditions on a licence with regard to:
- restrictions on opening hours
- Prohibiting the sale of food (confectionery, soft drinks and other household goods at the licence location) to ensure the purpose of the Act is met
- physical separation of licensed premises with an adjoining doorway e.g. to diary or on licence premise

Do you think there are factors or issues that the Authority should consider when setting discretionary conditions?
Agree that a product approval application should include information on proposed manufacturing methods and how they will comply with the Psychoactive Substances Code of Manufacturing Practice.
Should the regulations prescribe other matters the Authority must take into account when deciding on an application?
CAYAD Reference Group advocates that the Authority liaise with community to be satisfied that the application requirements have been met. That the application does not contain any material false or misleading information and that there is no more than a low risk of harm to individuals using the product.

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?
CAYAD Reference Group does 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. Information and data should include:
- 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

Are the proposed requirements and restrictions on labelling sufficient?
CAYAD Reference Group agrees that labels must not appeal to minors and recommend plain packaging. Also agree with the Acts set of rules on labelling - active ingredients and their quantity, an appropriate health warning, contact details for the importer, manufacturer, wholesaler or retailer of the product.

The CAYAD Reference Group would also support that labelling requirements clearly show:
- a bar code
- a batch number
- an expiry date
- the recommended dose
- contact details for the importer, manufacturer, wholesaler or retailer of the product that include a physical New Zealand street address (not a PO Box number)
- clearly visible, legible and in English
- placed in a prominent position on the product, where it won't be damaged or removed when the container is opened
- designed to maximise safe use of the product

These requirements offer a measure of consumer protection, and the bar code in particular, will assist with record keeping and with tracing of products.
Are the proposed requirements relating to health warnings sufficient?
We support the four compulsory warnings proposed in the regulations to satisfy the
Act's requirement for appropriate health warnings.
1 Do not drive a vehicle or operate machinery after consuming.
2 Do not consume with other drugs, alcohol or medicines.
3 Do not consume if you are breastfeeding, pregnant or think you could be pregnant.
4 Do not exceed the stated dose.

Are the proposed packaging requirements and restrictions sufficient?
We support the proposals being considered for inclusion in regulations:
- requiring packaging to be tamper proof and child proof
- enabling the Authority to refuse packaging that associates approved products
  with youth culture
- prohibiting the use of swear words and other words with inappropriate
  connotations, especially as product names
- prescribing detail for the content of inserted material, such as repeating the
  health warnings that are required on labels and setting out any contraindications.

Do you agree with the proposal to restrict a packet to one dose?
CAYAD Reference Group agrees to restrict to one dose size to help protect consumers
Of approved products in whatever form the product takes e.g. split wherever possible
which is in line with the purpose of the Act.
Also agree that products be prohibited in certain forms e.g. products intended to be
injected should not be permitted also raises the issue about whether smoking
psychoactive products will be consistent with New Zealand's policies on smoking
tobacco.

Do you think restrictions or requirements should be set for the storage of
approved products?
If a particular product requires storage within a certain temperature range, a condition to
that effect can be put on the product approval.

Do you think restrictions or requirements should be set regarding the display of
approved products?
CAYAD Reference Group agrees that the products not be visible from the street.

Do you think there should be signage requirements in the regulations?
Yes CAYAD Reference Group support regulations regarding signage as marketing and
advertising of psychoactive substances is a major health concern for all New
Zealanders.
CAYAD Reference Group recommend a total ban on all visual pollution from large
sandwich boards on grass verges and foot paths outside legal high stores, billboards
and other environmental settings.
Do you think the regulations should prescribe restrictions or requirements for advertisements of approved products?
CAYAD Reference Group agree to regulate marketing of psychoactive substances including advertising, promotion and sponsoring cultural and sport events, in particular those aimed at young people.

Do you think the regulations should prescribe restrictions or requirements on internet sales of approved products?
CAYAD Reference Group support the Act include restrictions on advertising on sites designed to appeal to minors and restricting access to the site by minors and require health warnings to be placed on the site.

Do you think the regulations should prescribe restrictions or requirements on the advertising of approved products?
Regulations should be prescribed to ensure promotions such as buy one get one free do not happen.

Do you agree with the proposed list of items and process for setting levies?
Recommend levies rather then fees as you can prescribe different levies for different classes of people for example the levy on importers could be set at a different amount to the levy imposed on retailers.

This submission was completed by;
Name: Clendon Manurewa CAYAD Reference Group
Address: Te Matariki Community Centre
17 Palmers Rd
Clendon 2103

Contact person;
Email: winnie.hauraki@aucklandcouncil.govt.nz
Position: Senior CAYAD Advisor
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. We additionally support the proposal to include consent to undergo a Police check being included on the application form.

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 definitely should.
   - Including the compliance on the applications helps efficiency when processing. It means cost saving and not wasting time on applications that are non-complying.
   - We believe strongly that the Regulatory Authority must not grant a license to any applicant which fails to comply.
   - Local authorities should provide a standard template for applicant to provide level of proof. An effective process to model is that of the Gambling Act, in which an applicant seeks from their council written confirmation that their application is consistent with the councils’ LAPP.
   - A generic LAPP should be developed for jurisdictions where councils have chosen not to adopt a specific LAPP and retail licenses should be dealt with when a change of premise is required due to the conditions imposed by an adopted LAPP.
   - Premises operating under an interim license prior to the notification of retail regulations in 2015 should close down until the end of the interim period and apply for a permanent license within the appropriate zone when that option becomes available.

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, applications for retail licenses should contain evidence of compliance with generic policies.

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 support:

- The proposal to include the New Zealand Customs Service (regarding importation compliance) and the Police in the fit and proper person check.

For all licences, we recommend:

- The Psychoactive Substances Act lists relevant offences in section 16(2) that are grounds for considering the applicant is likely to fail to comply with the Act. We recommend specifying in the list:
  - Violation of licence conditions and Regulations under the Sale of Liquor Act, Sale & Supply of Alcohol Act or the Medicines Act
- An applicant with any past conviction or licence suspension/cancellation for the unlawful sale of an age-restricted product to a minor should be rejected.
- The regulations should include a requirement for retail licence holders to confirm that their staff or employees who will be selling psychoactive substances are of good character and have undergone police checks to confirm they have not committed offences under any of the Acts or Regulations mentioned above.

Breaches of these Acts and Regulations are particularly relevant as they show past compliance behaviour with licence conditions, and in particular, the supply of controlled and recreational drugs.

When determining whether there might be additional matters, or whether there are other grounds for believing an applicant might not comply with the Act’s requirements, we recommend that the Authority consult with the relevant local authority to ascertain the nature of any relevant experience the council might have with the applicant. It is possible that applicants will have a history of contact with a local authority that either shows them to be either good corporate citizens or, at the other extreme, serial non-compliers.

For research licences, we recommend: Greater detail on how Research licences can be used and what conditions might be attached to such licences. To minimise risks of product leakage or unsafe research practices around unapproved psychoactive substances, we would recommend the Authority consider:

- Whether the stated purpose and aims of the research are consistent with the Act
- Evidence of professional qualifications and experience relevant to their proposed research, or in the case of a body corporate, the staff member(s) who will conduct the research
- Evidence of affiliation with a suitable body to monitor and assess the quality and ethics of the type of research the applicant proposes to conduct.

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

Yes, please see above.
6 What records should the regulations require licence holders to keep?

We support the proposals in the consultation document to require licence holders to keep records that will show sufficient detail to trace imported substances and assess any product leakage. This is particularly important to the purposes of the Act for the protection of the public concerning substances that have not yet been tested or approved of as low risk.

To this end, 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

Specific to retail licence holders, we recommend retention of the following records:

- Quantity sold in a single transaction
- Incidence records e.g. like a Liquor Licence Incidence record, for instance, describing attempts by a person under 18 attempting to purchase a psychoactive product; theft or burglary.
- Any feedback from a purchaser relating to adverse effects of a product

In the case of research licence holders, we recommend they keep detailed records of their research for several reasons:

1) To demonstrate their research practices are suited to the stated purpose of obtaining the licence
2) To ensure psychoactive substances or products obtained under their licence can be traced
3) To support any review by the PSEAC of data they have submitted in an application for product approval.
4) To support compliance with other relevant legal and ethical standards for research.
5) To enable monitoring and long-term tracking of human participants in the research for health purposes.

As such, we recommend research licence holders retrain records of

- Quantities of psychoactive substances used, consumed, and otherwise destroyed and disposed of during the research process
- Their research methods, processes, data or other information required by the Authority/PSEAC for approval of a psychoactive product.
- The research data generated or collected
- Identification details of human participants involved in the research

This data should be collated and made available to health services and other relevant stakeholders.
7 How long should licence holders be required to keep records for?

7 years to enable audit

Research:
It is widely acknowledged that in clinical trials, some medicines will be approved that are subsequently found to have unforeseen side effects.

Record keeping for research and clinical trials should meet relevant standards for similar human medical/drug trials whilst also establishing the long term effects – not just identifying acute risks from NPS products.

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

We support the discretionary conditions proposed for retail licences. In addition advocate for Central and Local Government should work closer together on designing the appropriate mix of matters that might be taken into account when developing an LAPP, particularly those matters which may be left to councils’ discretion and those that might be determined nationally by the Authority itself.

In addition, we recommend for retail licences:

- Restrictions on opening hours from 9am to 3pm to reduce the opportunity for school age children to purchase psychoactive substances. These hours would also restrict the likelihood of people intoxicated on alcohol purchasing substances and using them incorrectly.
- The authority should take into account communities with poor wellbeing profiles when deciding to approve local retailer trading locations.
- Sale to intoxicated persons should also be defined and prohibited, covering intoxication by any drug including alcohol.
- A requirement to seek age identification from any person who appears to be under the age of 25 years old prior to sale.
- Shops licensed to sell approved products should specialise in the sale of these substances. A requirement for staff training on:
  - identifying under 25 year olds and appropriately seeking identification
  - signs of intoxication, health or addiction issues
  - how to open a conversation about health or addiction issues when appropriate, and effective ways to offer or guide people to resources for help
  - refer people to appropriate intervention and treatment services who are resourced by NPS generated levies
- A limit on the range of non-related products, such as clothing, which is be able to be sold in retail premises licensed to sell approved products.

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?

For retail licences, we recommend:

In the absence of an LAPP or generic LAPP, physical proximity to premises regularly used by young people and vulnerable groups should be considered by the authority.

Likely impact on the character of an area.
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?

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, this information and data should be provided for the substance.

In addition, a specific requirement for the same data as above should be provided for the final product for which approval is sought, as the product may contain combinations of substances, psychoactive or otherwise.

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?
Overall yes, this information and data should be provided for the substance.

NPS are often used in combination with other legal and illegal psychoactive substances. Risks of recreational drug use also increase when users are from vulnerable groups such as risk taking adolescents, those who are at risk of mental illness and those already dependent on alcohol and drugs. It is also acknowledged that in clinical trials, some medicines will be approved that are subsequently found to have unforeseen side effects. Whilst toxicology and clinical trials may well be affective at identifying acute risks from NPS products, establishing long term effects is considerable more challenging.

Determining the measure of ‘low risk’ will be difficult to define and potentially be scientifically inaccurate due to trying to translate the skewed distribution of harm among users into an overall concept of ‘low risk’. Thus the baseline measure for determining ‘low risk’ should be assessed against the scheduled substance that evidences ‘lowest risk of harm’ to the individual consumer.

Regulations should stipulate that clinical trial methods examine the NPS in question in relation to other substances and risk factor mentioned above.

In addition we recommend:
- Data on the same factors listed at ‘12’ and ‘13’ should be provided not only for the substance for which approval is sought, but for the final product for which approval is sought, as the product for which approval is sought may contain combinations of substances, psychoactive or otherwise.
- Information on effects and risks at different levels of dosage of the final product should be provided
- The intended quantities and dose-quantities per package of the final product, alongside directions regarding suitable dosage and use, should be included in the product approval application, in order to evaluate effects and risk levels at the recommended dosage.

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

We support the labelling requirements proposed, particularly the poisons centre (or other centres established for monitoring adverse reactions) and relevant drug addiction support lines.

Upholding the spirit and integrity of the purpose of the act, plain packing of products is a must to ensure lack of appeal to minors. Further, imagery and slogans on packaging for branding can be considered as advertising, so plain packaging will ensure that Section 56(3) of the Act is met i.e. that advertising of an approved product “must be limited to material that communicates objective information about the product”. This will also reduce the burden on the regulatory authority to decide on this question. This also supports the intention of the act that advertising only include objective and factual information.

In addition we recommend labels include details of:
- All contents of the product and their quantities (not only the active ingredients), grouped as psychoactive and non-psychoactive
- Any known side-effects of the product

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).
No. We recommend that a bold, short and simple title “HEALTH WARNING” be prominent (covering at least 10%) of the exterior product packaging, and the exterior of any sub-units of packaging, followed by the four compulsory warnings proposed.

Because products will have been approved as ‘low risk’, users will likely consider the product completely safe, or might discount their consideration of risk. A prominent warning will remind people to consider the known risks of the substance and the recommended dosage and directions.

In addition, suggest adding two further warnings:
  o All psychoactive substances carry risk of adverse reaction
  o Effects of long-term, regular use of this product have not been assessed

Ref:

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

We strongly support that the content of labels and inserts, their appearance and accessibility be approved by the authority.

See question 14 regarding support for plain packaging.

The other requirements proposed appear sufficient.

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

Yes. This can reduce the risk of overdose and risk to children. It also supports the intention of the Act to protect the health of users (Chan, 2000).


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

Yes, please see 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?
Yes. We believe products in the following forms should not be approved:

- Additional regulations should be applied for smokeable products, covering any public indoor or other confined space. Non-consumers should not be subject to second hand smoke from such products.
- Further, smokeable products pose a health risk to the consumer from the very nature of smoking. Restricting smokeable products would reduce health costs associated with smoking related illnesses and the effect on the taxpayer.
- Additionally, smokeable synthetic cannabis smells noxious. At my workplace this an issue as there are a lot of homeless who live around the building and use these products, which smell and potentially effect travels into the building.
- Additionally I feel smokeable products make them more appealing to young people as they are not a large change from cigarettes. Since synthetic cannabis has been legalised myself and my workmates have noticed an increasing number of young people (15-20) sleeping rough. Their behaviour started out as normal teenagers hanging out with rough sleepers and using the product, to becoming rough sleepers themselves and begging for money in Aucklands CBD. Several social workers have mentioned to me that they know these kids, who come from decent families, and feel that these products have made mental health issues worse and this is partly due to the easily accessible nature of these products.
- Appeal to minors – support that product forms with appeal to minors should not be allowed.
- Liquid or other easily injectable forms, and should not come in/with Injection equipment.

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 – level of security should be high.
Products or substances stolen and put on the black market may be cheaper and more available to young people away from the oversight of regulations. They may also be converted into stronger or more dangerous drugs in forms that are unapproved and untested.

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

Yes. Two out of three psychoactive product retail stores in Hamilton were recently burgled. Products stolen and put on the black market may be cheaper and more available to young people away from the oversight of regulations.

We recommend taking steps to reduce the likelihood and impact of burglary by limiting amounts kept in retail stores, which are obvious and highly visible targets, to a sufficient quantity for 2 days of normal trade.

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

Product display should be behind a counter area or locked cabinet that makes shoplifting difficult. Young people or vulnerable people with little money may be more likely to shoplift products and this will limit their access.

23 Do you think restrictions or requirements should be set regarding the disposal of approved products? If so, what should they be?
A process for disposal that can be trusted and tracked to product retailers should be a requirement of the regulations. We recommend a requirement for disposal via a public health regulatory agency such as a District Health Board or the Police. A simple form should be completed by the regulatory agency recording the product type and amount, identity and relevant licence number of the person or company it has been received from, and a confirmation that the regulatory agent has seen the product as described (type, amount) and disposed of it according to requirements.

This is evidenced from careless dumping of psychoactive products from stores (dairies) that were prohibited from selling such products after the introduction of the Act in 2013. The dumped products reappeared on the black market and in the hands of minors at very low prices. Should other products be recalled, such dumping could occur again.

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

- 18+ signs
- No consumption on premises
- Prominent signage detailing signs of addiction
- Prominent signage of harm reduction interventions
- Prominent signage detailing where help can be accessed for addiction, dependence or health issues
- Prominent signage detailing an appropriate reporting number to call to report adverse effects.

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

To avoid leakage of product to young people through shoplifting, the premises where products are sold should have entry restrictions to persons 18 years and older.

I think the number of outlets within a certain distance from each other should be regulated. There are over 4 outlets on Queen St, Auckland CBD alone.

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

Yes. We support:
- Restriction of advertising from any other media as per section 56(1)(d) of the Act.
- We a requirement in the regulations that any advertising must be consistent with the Advertising Standards Authority's Advertising Code of Ethics.

We recommend:
- There should be a restriction on product endorsement with fines consistent with section 56(5) of the Act. Anyone with a large online following of young people who publicly endorses products is likely to influence use among young people under the age of 18 and contravenes the intention of the Act to restrict advertising.

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

We support that the regulations contain detail that ensure on-site advertising is restricted to objective information only.

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?

No comment

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

Yes – levies should be collected to enable:

- The establishment of data collection and monitoring systems including:
  - 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).
  - Newly approved products to be reviewed for evidence of harms every three years
  - Development and operation of systems for reporting adverse effects of psychoactive products (e.g. CARM, and systems for relevant medical facilities such as emergency departments, GPs and mental health clinics)

Fees or should be collected from retailers to enable:

- Development, delivery and evaluation of standard training on safe retailing practices e.g.
  - Identifying under 25 year olds and appropriately seeking identification
  - Signs of intoxication, drug-related health or addiction issues
  - How to open a conversation about health or addiction issues when appropriate, and effective ways to offer or guide people to resources for help

32 Do you agree with the proposed list of items and process for setting levies? If not, please provide specific suggestions.
You do not have to answer all the questions or provide personal information if you do not want to.

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

Are you submitting this:  
(Tick one box only in this section)  
☐ as an interim licence holder  
☐ a person or body corporate intending to apply for a licence  
☐ other (please specify): Private person .................................................................

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.
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?

   [Blank Box]

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]

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?

   [Blank Box]
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 I believe that this is adequate information required.

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

Yes they should.

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

Only if required by Authorities.

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.

No.

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?

As long as all conditions and issues concerning the applicant are covered.

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?

Not Sure. Alcohol does not have all these restrictions. Only what is required.

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).

Alcohol has limited restrictions so let's keep it uniform.

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. it's like selling one cigarette. That's illegal.

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

No.
19. Do you think there should be restrictions on the form products can take? If so, what forms do you think should and shouldn't be allowed?

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

Depending on turnover, products have to be stored in a secure and locked situation on the premises. (No formal restriction or requirements needed.)

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

As above...

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

Should be displayed as each individual retailer requires.
23 Do you think restrictions or requirements should be set regarding the disposal of approved products? If so, what should they be?

Would not be disposing any product, simply send back to wholesaler.

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

Yes. Do not think advertising the products on windows is necessary. Maybe a small M.O.H. sticker as an approved retailer on the counter, and a larger framed one on the wall behind the counter.

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

Shops that have children shopping in them, either on their own or accompanied by a parent or older person. They should be restricted to R18 Adult shops. Same as an R18 Bottle Store. Where underage is not permitted.

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

Yes, but where are these advertisements going to appear.
27 Do you think the regulations should prescribe restrictions or requirements on internet sales of approved products? If so, please provide specific suggestions.

Yes, as this type of selling requires the buyer to read what they are purchasing.

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

Already answered in Question 26.

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

No. Certainly not for retail. The licence fees should be less than that proposed, and should be able to be paid off monthly or quarterly. A 3-year lump sum is a lot of money for the average retailer to find. Also depends on how many retailers are supplying in each town. These fees could also be paid in conjunction with your retail list payments to the COT.

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.

No more fees please.

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

Whatever it takes to process the levies but certainly not all the proposed cost as stated.

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): ..............................................................................................................

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☑ Yes  ☐ No
(If yes, please make sure you provide an email address.)

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☐ I do not give permission for my name to be listed in the published summary of submissions.
Question: Should retailers be able to relocate premises (licensed)?

Answer: Retailers should be able to relocate their premises to another location within the District Council regulated areas. Retailers have various reasons to relocate *(licenced retailers)*

C)

1. Lease
2. Landlord
3. Undesirable location to sell products, i.e. vulnerable to burglary or intimidation.
4. Building damage, i.e. earthquake, fire, flood, etc.

*These substances/products have been a longtime part of yearly turnover for certain retailers, mainly k18 adult shops and to cease selling a product that is part of your business can have long lasting and devastating consequences.*