Tauranga City Council – Submission on Psychoactive Substances Regulations

As way of introduction, Tauranga City Council (TCC) submits that we believe our community do not want these products available in our city, and they want us as leaders to do everything we can to eradicate them. We have some concerns as to whether regulating the industry will result in minimising the harmful effects on our community, in particular on our youth. The legal status of these products comes with a connotation of being safe, when in fact they can be dangerous and addictive. In short, we have serious concerns about the short and long term effects; the legalisation of these products will have on our communities and their health and wellbeing.

In saying that, we understand we have a mechanism available to work within the current legislation through making a submission on the regulations that will require strict controls on the import, manufacture and supply of psychoactive substances. Our submission to the regulations follows and we would appreciate it if you would recognise all of the points, as we believe they are essential in regulating this potentially harmful industry.

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

In addition to the information currently being considered for retail licence applications, TCC submits that applicants should be required to provide similar information to that for a liquor licence. For example:

- Indication of the hours of operation sought (there may be a desire for the community to separate trading hours from times when students are transitioning to and from school)
- Indication of the level of training of staff who intend to sell substances (arguably some of the substances are of higher risk than alcohol, so there should be a certified manager on site as required under ss216-228 of the Sale and Supply of Alcohol Act).
- Sales staff and licensees should face a “three strikes and you are out” regime similar to the “holdings” specified in ss289 and ss290 of the Sale and Supply of Alcohol Act.
- Indication of process to deal with intoxicated patrons or attempts to purchase psychoactive substances underage. See also question 8.
- Indication of how far they will be based from a school or community facility (as provided for in the Council’s Local Approved Products Policy or the national generic policy).

Additionally TCC submits:

- The physical/approved address of the retail outlet should be made clear on all licences.
- It should be illegal to operate without an approved licence. No person or entity should be able to operate while the licence is being considered.
• it is expected that licences will only be granted to people who are set up as businesses, with normal business practices. (NB: we are concerned about the people who are selling these products from their residences and are allowing youth to purchase “tick” or barter for these products, therefore increasing use and encouraging addiction. See also question 25.)

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. TCC supports the proposal that retail licence applications should be accompanied by evidence of compliance with the Local Approved Products Policy (if one exists). If documentation is required from a local authority to confirm or negate this should be fully cost recoverable. Ratepayers should not be subsidising this activity. See also question 31.

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 would avoid a retailer setting up near the boundary between a Council with a policy and one without so they can easily reach both markets.

However, there is a concern as to how this policy will be consulted on, as the Psychoactive Substances Act 2013 requires a local authority to consult with the community using the special consultative procedure under the Local Government Act 2002. TCC support the requirement to consult on this matter as it is an issue which has negative impacts across all ages, but particularly youth, and so it is an issue which many people in the community have strong views on. Therefore provision needs to be made for this generic policy to be consulted on in a similar way.

TCC would also like to know more about what the expectations are around who will develop the generic policy.

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

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

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

In addition to the above, TCC supports LGNZ’s suggestion that the Authority should consult with the relevant local authority to ascertain the nature of any relevant experience the Council may have with the applicant. The costs of this search should
be recoverable from the applicant, and not fall on the ratepayer to fund. See also question 31.

Additionally, in circumstances where a licensee is found to have committed offences (or similar) after they have been granted fit and proper person status, there needs to be a mechanism to act promptly to suspend or cancel a licence operated by that person.

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

Yes, the Authority should consider a history of failures or non-compliance with a similar regulatory regime, e.g. under the Sale and Supply of Alcohol Act.

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

TCC agree that records should also be held by all aspects of the industry, from the importer to the manufacturer and retailer.

TCC submits that with retailers, all sales of approved products should be subject to a regime similar to that used for the sale of pseudoephedrine when it was classified as a Class C Controlled Drug. That is:

- Photo ID provided and name, address and contact details taken before a sale is made.
- Records should show which products were purchased, the quantity, and the payment method (see also question 8).
- Records should be forwarded to the Police or Ministry of Health for collation and retention.
- Licences should be required to be displayed inside the principal entrance to an outlet.

Retailers should have to record when the product is delivered, tracking right through to the point of sale.

Additionally, TCC submits that there should be a national database to store this information, to ensure that information is being shared with the rest of the industry. Sales record requirements should be in line with s54A of the Medicines Regulations 1984.

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

TCC submits that these records should be held for no less than 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.

TCC submits that the following should also be considered when considering setting discretionary conditions:
• Hours of operation (may restrict hours of trading at certain times of the day, taking into account high school hours for example).
• Provision of other goods and services (should be restricted so as to not ‘normalise’ the product).
• Access point into the retail outlet/shop frontage. It should not be obvious from the street that this is a retailer of these products.
• Provision of CCTV and retention of recordings (to prevent criminal activity).
• There should be a maximum amount imposed of only selling a single dose in a single sale. There should also be a restriction on how many single sales transactions per day/week/month an individual can partake in.
• A sales tax on approved products to reflect the cost of consumption on the NZ health system, the police and the local community.
• A standardised pricing regime should be established to ensure all retailers are selling the same dosage for the same price.
• There should be a limit around the maximum quantity of these products allowed in a store at any given time. See also question 21.
• Normal business practices must apply in terms of payment — “tick” or other types of credit should not be allowed. This will be monitored through the use of records of how payment is received (see also question 6).
• Allowing the police, the authority or its representatives to access financial records of any retail outlet, distributor or manufacturer (to prevent criminal activity).
• Whether the amenity and good order of the locality would likely be reduced to more than a minor extent by issuing the licence (as with s105(h) and s106 of the Sale and Supply of Alcohol Act 2012).

Additionally, an assessment tool should be developed to allow for assessment of impairment or intoxication. This could be similar to the tool used for assessment of intoxication by alcohol used by the police but targeted towards psychoactive substances. Retail staff should also be familiar with intoxication assessment to prevent sales to those already impaired. See also question 1.

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 is not transferable, but this only relates to the person, not the premises).

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

TCC submits that should be a clear and unambiguous means for members of the community to lodge objections against applications with the Authority as provided for in s154-158 of the Sale and Supply of Alcohol Act 2012.

Additionally, account should be taken of other licensing issues/non-compliance in other areas if the applicant is operating in other 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?

In regards to the approval of a product TCC submits that the requirements of this should be in line for that of approving a pharmaceutical product, and that each product should have its own approved certificate of approval, as in the pharmaceuticals industry.

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

See question 10.

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?

See question 10.

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?

See question 10.

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

TCC submits that labelling and packaging must be restricted as appropriate, including the following:
   - All products should be labelled "psychoactive substances".
   - Labelling should be comprehensive and accurate, including the concentration of the active ingredients.
   - It is suggested the use of words such as "Legal", "Natural", "High" or "Cannabis" be banned due to the association of those words. (Legal or natural implies it is safe, high or cannabis implies that it is desirable).
   - Products should be labelled R18 (this would be useful for parents who discover any products in the minor's possession).
   - Consideration should also be given to part 4 of the Medicines Regulations 1984 in regards to the labelling of these products and the level of detail that should be required.

Additionally, the regulations should include strict penalties including priority withdrawal of inadequately labelled product, public apology advertising, infringement fines and potential for loss of licence.
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).

TCC recommends that health warnings include the following:
- A warning that prolonged use can trigger psychosis.
- Information on what to do in the case of an overdose.
- A warning that it is an R18 product.
- Instructions for proper use of the product.
- A phone number for help with addiction.

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

TCC supports all the regulations proposed in regards to packaging.

Additionally, regulations should require plain packaging minus images or colours that would promote use of the product, particularly amongst youth.

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

Yes, as this would control dosage and go some way in preventing overdose.

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

Yes. Dosage affects people differently, so one dose may still be enough for someone to overdose.

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?

TCC submits that products should only be available in a tablet or similar form. Products that can be injected or inhaled should be banned, due to the consequential health problems associated with these products and the fact that they are associated with the misuse of drugs and other volatile substances that cause harm to others.

If smoking products are allowed, regulations should be consistent with the sale of tobacco.

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?

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

There should be a limit around the maximum quantity of these products allowed in a store at any given time. See also question 8.

Care should be taken within the industry to ensure these products are not contaminated; storage should be in line with s32 of the Medicines Regulations 1984.

Additionally, TCC submit that retailers should store these products in a locked cabinet, in a storage unit that is not visible to the customer and that there should be some security mechanisms (such as a security camera) in place to reduce the risk of theft.

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

TCC submits there should be restrictions. For example, products should not be visually displayed; they should be behind opaque doors to discourage purchase by visual stimulation. The regulations should be in line with 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?

This is already covered by the Hazardous Substances and New Organisms Act, which TCC supports.

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

Yes. TCC submits that there should be R18 signage and a sign with health warnings to be displayed at the point of sale.

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

TCC submits that the following should also be excluded:

- Gaming venues (e.g. TAB, Racecourse, Casino);
- Cafes/Restaurants;
- Takeaway shops;
- Licenced gun retailer;
- Accommodation providers;
- Hair salons; and
- Residential dwellings and all premises in residentially zoned areas.
26. Do you think the regulations should prescribe restrictions or requirements for advertisements of approved products? If so, please provide specific suggestions.

TCC would like to restrict ALL advertising on these products, whether externally or inside the premises. This should be in line with s22 of the Smoke-free Environments Act 1990.

There should also be restrictions around event and other sponsorship linked to these products.

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

TCC submit that internet sales of these products should be banned as sales over the internet cannot be controlled, and any restrictions are likely to be unenforceable. Allowing internet sales increases the chance of minors purchasing these products and increases the risk of overdoses.

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

See question 26.

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

No comment.

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

A fixed fee will make the cost more transparent to the applicant.

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

Yes. TCC submits that Councils should also be able to recover costs for verifying that an applicant meets the conditions of a local policy, and for researching and providing information on Council’s previous history with the applicant. These fees should be set by the local authority however, not the Psychoactive Substances Regulatory Authority. See also questions 2 and 4.

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

Additionally, it is noted in the consultation document that the costs of developing these regulations and running the authority should be recovered from the industry so it doesn’t
fall on the taxpayer. TCC submits that developing a Local Approved Products Policy should also be recoverable from the industry so that it doesn’t fall on the ratepayer.

It is also suggested that any costs involved in the Ministry of Health undertaking research and assistance with addiction in this area should be recovered from the industry.

33. Additional Points?

It is noted that s23 of the Psychoactive Substances Act does not state inconsistency with a local authority’s Local Approved Products Policy (LAPP) as a reason for suspension or cancellation of a licence. TCC submits that this should be the case. If a licence is granted and then is later found to be inconsistent with the local LAPP, the licence should be able to be revoked or suspended.

TCC are very concerned about the terminology that surrounds these “approved products”. Our understanding is that these products are being called “low risk social tonics” within the industry; however anecdotal evidence suggests that some of the low risk products on the markets are still dangerous and addictive. We do not support this terminology being used. TCC proposes that these products should be referred to as “psychoactive substances” as per the legislation.

TCC does not support the use of animals in its clinical trials to ensure the products meet the standards to become an approved product.

TCC believes that the minimum requirements for tobacco, alcohol and pharmaceuticals should apply in all areas of this industry and should be applied to the regulations.

TCC believes investment needs to be made into psychoactive substance research and addiction support services.
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 local authority

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?
   No submission

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. This is an unnecessary additional cost which would produce no tangible benefit.

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. Further there does not appear to be any provision in the Act for a “generic plan”, and one would be arguably ultra vires.
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.

No submission

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

No. Other licences held are not relevant to character, or any other test which applies to the assessment of whether or not a licence ought to be granted. Taking into account irrelevant factors is unlawful and is a ground of judicial review.

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

In my submission, record keeping for retailers can be limited to receipts for the purchase of approved products.

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

Psychoactive Substances Regulations: Submission form
In my submission, a time consistent with record keeping obligations in other spheres, for example Taxation, would be appropriate. I submit that 7 years is an appropriate length of time.

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

I submit that the following matters ought to be taken into account:
1. the conditions of the interim licence and compliance history;
2. the opening hours of any off-licence liquor retail shops in the area;
3. the effect on profitability of the applicant of any restrictive condition imposed. In my submission a reasonable rate of return on investment ought to be provided for.

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 submit that the Authority ought to consider the history of compliance with any interim licence granted.

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?

No submission

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 submission

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

I submit that the current requirements are sufficient.
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 submit that they are.

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

No submission

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

Yes, I submit that there ought to be a "dose limit" applied to individual packets. I further suggest a limit on the number of packets that may be sold in any single transaction.

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

No submission
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 submission

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

Yes, I agree that there ought to be restrictions on the storage of psychoactive substances, relating to the manner in which they are stored. I submit that the principal concern is that products may be unsecured, leading to a risk of theft and consequently unregulated distribution.

In my submission secure storage, for example in a "safe", or other secure location is appropriate.

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

Yes, I agree that there ought to be restrictions on the storage of psychoactive substances, relating to the manner in which they are stored. I submit that the principal concern is that products may be unsecured, leading to a risk of theft and consequently unregulated distribution.

In my submission secure storage, for example in a "safe", or other secure location is appropriate.

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

I submit that no further restrictions are appropriate.
23 Do you think restrictions or requirements should be set regarding the disposal of approved products? If so, what should they be?

No submission

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

No submission

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

No submission

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

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

No submission

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

No submission

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

No submission

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

I support a fixed fee model to provide greater certainty to applicants.
31. Should fees be set for other specific functions? If yes, please state what they should be set for.

No, or at least not without abandonment or significant reduction in the proposed levy.

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

This question is unclear. Many of the foreshadowed services are unnecessary (for example the “hotline”), or merely “fluff” for example “stakeholder engagement”. These ought to be reduced to only those that are actually necessary or which provide a significant benefit to applicants/licencees or users of the products. The process for setting levies has been dealt with by you in a very broad brush manner. A meaningful assessment could only be carried out if the data used was provided as part of the consultation process. Accordingly I am not in a position to make an informed submission.

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 - yes
☐ 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

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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

Email: psychoactive@moh.govt.nz

21 March 2014

SUBMISSION ON THE PSYCHOACTIVE SUBSTANCES REGULATIONS

- We ARE an interim license holder (RET001)
- We DO wish to receive updates about the development of the Psychoactive Substances Regulations.
- We ARE AVAILABLE to speak to this submission, or provide more information if requested.

A. INTRODUCTION

We support the intention of the Psychoactive Substances Bill to regulate rather than prohibit – or leave uncontrolled – low risk substances.

The Hempstore Aotearoa Tapui ("The Hempstore") is an Auckland-based importer, manufacturer and retailer of hemp and related products. We are New Zealand’s only specialist hemp store. We also provide a range of natural herbal products as well as related items such as books, magazines and smoking and vaporizing supplies.

In 2013 The Hempstore became the world’s first licensed retailer of psychoactive products.¹

Our philosophy is that people should be free to live happy lives and enjoy themselves, as long as they don’t harm or endanger anyone else. People should be able to make informed choices, and they need safe access to legally-regulated substances, so they are not forced into taking more harmful illegal alternatives.

The Hempstore has imported and retailed herbs and psychoactive substances since we opened in 1997. We have always strived to supply these types of products in a responsible manner. For example, we have always imposed a R18 age limit for all our smoker’s supplies, herbal remedies and party pills, whether or not they were controlled by law. We believe they are for adults only, and we strive to operate as if best-practise regulations were already in place.

We therefore welcomed the introduction of the Psychoactive Substances Act to regulate the availability of low risk substances. We commend the initiative shown in developing the risk assessment framework, the Manufacturing Code of Practise and this consultation document.

As the Associate Minister of Health Peter Dunne says in the introduction to the consultation document, a prohibitionist response would have been "largely ineffectual".²

However, as this submission will make clear, we do not agree with all the proposals and we hold serious concerns about many issues not raised in this consultation document. These are addressed in Section C, below. We also believe the risk assessment framework is fundamentally flawed and must be revised.

SCOPE OF THE CONSULTATION

It is very difficult for us to give feedback on regulations that are not yet written and have not been presented in this consultation document. It is therefore regrettable that the invitation to take part in this consultation, emailed to us on 19 February 2014, says "there will not be a second consultation". Given the rushed passage of the legislation, and the incomplete nature of this consultation document, we hold serious concerns that there will be additional issues raised that will need to be addressed. It is very important we get this right. There should be a further round of consultation after the regulations have been drafted and prior to their adoption.

B. THE CONSULTATION QUESTIONS

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

Yes, we agree with the proposed information requirements.

Recommendation: No change.

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, if this will speed up processing retail license applications and remove uncertainty.

However, LAPPs must only be valid if they are in accordance of the Act's intention to regulate the controlled availability of approved Products (and not prohibit them).

There must be exemptions for Interim Retail License holders who were granted a license prior to their LAPP being enacted to continue to trade (whilst technically in breach of the LAPP), or to allow the interim license holder to relocate premises in order to comply with the LAPP.

It is unconscionable, unjust and manifestly unfair to allow local body politicians to implement LAPPs that they know local interim license holders cannot comply with, while also not allowing license holders to relocate to comply. It was not the intention of the Act to allow local body LAPPs to create a de facto prohibition.

Recommendation: We agree full license holders must comply with any LAPP, however there must be an exemption during the interim period, or license holders must be allowed to move premise in order to comply with any LAPP enacted after the issuing of interim licenses.

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?

At this stage, given the generic LAPP has not been presented for comment, we cannot say whether we agree with it or not. We do not know what it says. However, if it is properly based on the intentions of the Act and does not attempt to create a de facto prohibition, then in principle this is a good idea and it will assist smaller local councils who may not have the resources or advice needed to do a good job writing their own LAPP.

**Recommendation:** Any generic LAPP should be made available for public consultation before being adopted.

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

Given New Zealand’s high rate of cannabis use and that the chance of being arrested and convicted for cannabis is mostly a lottery and not related to dishonesty (etc), cannabis offences should not be counted as a “relevant offence”. The presence of a cannabis conviction on an applicant’s record is not an indicator that they are dishonest or not of good character.

Character references and other evidence of an applicant’s standing in the community should be allowed to be considered if requested by the applicant.

**Recommendation:** Cannabis offences should not be relevant, unless particularly serious or relevant in terms of fraud etc. Character references should be considered.

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

Yes, if these are relevant.

**Recommendation:** No change to that proposed.

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

We agree with the proposals for holders of Import, Manufacture and Wholesale licenses.

It may be wise to ensure holders of Research licenses maintain records of every person who has tried their substances or products.

We agree with the record keeping proposals for holders of Retail licences. Invoices can easily show the license number of each party, and the batch number of each product.
Records for exports should be limited to commercial sales (i.e., business to business). It is neither practical nor necessary to maintain a register for every item sold that is exported, most of which would be small personal amounts. We note there is already a condition that license holders can only export to countries where that psychoactive substance is not illegal. There are also privacy issues that would need to be considered.

**Recommendation:** Agree with proposals, with the addition of Research license holders maintaining records of sales and/or use. Records of exports should be limited to commercial sales.

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

The standard length for retaining records is 7 years. In terms of retail and wholesale sales, we are unaware of any reasons why it should be different for records of sales of psychoactive products. The situation for manufacturers is different. We believe it would be prudent for them to retain their records – especially relating to product development, testing and batches – for however long the Substance or Product is being manufactured or sold.

**Recommendation:** 7 years for sales record. Manufacturer’s records to be retained for however long the Substance or Product is being manufactured or sold.

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

We agree that holders of Retail licenses should display their licenses. This could either be in the entry way or near where the products are displayed or sold from.

We agree applicants for Retail licenses should declare whether they will sell from websites.

There should be physical separation of premises that hold Retail licenses from non-licensed premises. Having no internal access seems the most pragmatic way to resolve this.

**Trading hours:** We choose to open from 10am to 5:30pm, which helps us avoid people who have already consumed alcohol. However we believe any restrictions on trading hours belong in LAPPs enacted by local authorities, subject to the following:

- Given the prohibitionist intentions stated by some local politicians, regulations should clearly state that holders of Retail licenses are allowed to trade during standard business hours and that LAPPs cannot further restrict this.

- Trading hours for Psychoactive Products treated separately from opening hours for the store. Retail stores must be allowed to remain open to sell other items, even if their License or LAPP restricts hours for the sale of Psychoactive Products.

- The maximum Psychoactive Product trading hours should be aligned with local alcohol off-license hours (which in most places are 6am to 11pm).

- Restricting trading hours to 9-3, as some have proposed, may counterproductively increase local nuisance by concentrating more sales in a shorter time and encouraging adult consumers to take time off work.

**Recommendations:** Licenses should be displayed.
Website sales should be declared.

There should be physical separation of non-licensed premises.

There should be no regulations on opening hours, other than those prescribed in LAPPs.

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?

We support taking into account those matters proposed, and suggest consideration should also be given to:

- Whether or not the applicant is a member of PITA and follows their Code of Conduct;
- Whether or not the applicant has a staff induction and ongoing training program;
- Whether or not the or the manager or staff have suitable training in Host Responsibility and/or Harm Reduction;
- The effect of not approving a particular substance, product, manufacturer or retail outlet;
- Ensuring the market operates efficiently, including avoiding monopolistic or cartel behaviour;
- Other enterprises the applicant is involved with (in the case of a body corporate, its directors and major shareholders). Membership of political organisations, trade unions, and NGOs should not be considered.
- The testing requirements should be restricted to novel (synthetic) substances; otherwise it will unintentionally prohibit, or impede, the availability of traditional natural herbal products.

We trust the Authority shares our concern it would not be a desired outcome if relatively strong synthetic substances are legal and approved, while the mild natural herbs are prohibited due to there not being a big enough market for them to be worthwhile paying for the testing and licensing.

There has been no campaign or public demand for natural herbal products to be included; most members of the public have no idea and would be concerned to discover much of the contents of their local health food store could be deemed “Unapproved Psychoactive Products” if the Authority ever decides to check!

Recommendation: The Authority should take into account the efficient operation of the marketplace, and the effect of not approving any given application.

Regulations should clarify that natural herbs and herbal products are not covered by the Psychoactive Substances Act, unless marketed or sold for psychoactive effects.

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, with the proviso that commercially sensitive technical information should be held in confidence and not released publicly.

**Recommendation: No change.**

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

We are unaware of any other relevant matters that should be prescribed in the regulations.

**Recommendation: No change.**

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?**

We agree novel compounds should be subject to testing for safety and toxicology.

- Human trials of volunteers will be needed. There should be no inducement to participate.

- However animal testing, especially determining an LD50, is unnecessary and barbaric. We strongly oppose it.

- Importantly, the Authority should require clinical information showing whether the toxicity and pharmacology of a substance or product changes if used in combination with commonly-used drugs such as alcohol, cannabis and amphetamines.

- Natural herbs and herbal products should not be subject to the same testing requirements as novel compounds.

- Applicants should be allowed to cite published research not performed by them. Basic tests of specific substances should not have to be repeated by every applicant. This would help reduce compliance costs and also afford the existing body of scientific work due respect. For example, there is a wealth of published research on the JW-series of cannabinoids. This work should be accepted rather than repeated.

- We do not agree that new applicants be prohibited from citing the research of already approved Products. If the intention is to stop newer applicants getting a “free ride”, then a better approach would be to (a) use Intellectual Property law to protect the rights of existing Licence holders; and (b) allow License holders to charge fees or royalties for the use of their research. All evidence previously accepted by the Authority as worthy should be accepted in the application process, and no testing should have to be needlessly repeated.

We remain concerned the research and testing requirements proposed in the Act and Regulations, and discussed in the Regulatory Impact Statements, have grossly underestimated the costs and timescales involved.

- The testing regime proposed, while short on detail, appears based on that for medicines. However, psychoactive substances and products are not making medicinal or therapeutic claims about specific pathologies, and ought not to require such a high threshold of testing.
- After consulting with experienced laboratories and research centres we understand that the cost of the proposed testing regime could be tens of millions of dollars or even more.

- This will make it unviable for any products to be submitted for approval, especially given New Zealand's small population base.

Our concern is that the testing requirements are so onerous and expensive that the Bill will become a de facto prohibition on low-risk psychoactive substances. The consequences of this could include:

- Increase in illegal cannabis use and/or alcohol use;
- Less control over underage access to cannabis-type products;
- Increased harms from illicit market such as contaminants, violence, organised crime;
- Likelihood the substances continue to be available, as happened in the UK & EU where banned substances are sold as “bath salts” or “plant food” etc.

The Authority should also consider the benefits of using a particular substance or product (if this information is supplied by the Applicant).

**Recommendation:** novel compounds should be subject to comprehensive testing for safety and toxicology. The Authority has grossly underestimated the likely costs of this research and testing required and there is a very real risk there will be a de facto prohibition. The Authority should also take into account any benefits from using a particular Substance or Product.

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.

**Recommendation:** No change.

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

[generally supports the packaging and labelling requirements proposed in the consultation document. Our specific suggestions around this are:]

Any inner packs should have on them the brand name, active ingredient and strength (mg/g). Consideration should be given to requiring pills to have a unique embossed logo and/or the strength, similar to pharmaceuticals.

Plain packaging would be counterproductive. Branding is an important way for consumers to know which products they can trust. In the event of any recall or ban, it is crucial that consumers can easily and readily distinguish between banned products and licensed products.
Such a distinction would be compromised if all products were in plain packaging, with increased health risks to consumers.

Bar codes should be unique to each formulation and pack size. They should not be able to be – re-used’ if a new product is released. Consideration should be given to having a new bar code for every batch that is manufactured.

Finally, we caution that the National Poisons Centre has unfortunately become politicised. Although their role has been formalised by the Act, which compels their contact information to be included in any warning, we note they have a clearly stated position of opposing all legal highs and are acting more like a lobby group than an information clearinghouse.

Recommendation: Inner packs should contain the brand, active ingredient and strength. There should not be plain packaging. The role of the National Poisons Centre should be reassessed.

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 imported and distributed synthetic cannabis and other social tonics from 2001 to 2011. In 2008 we developed our own synthetic cannabis product line called Space™. This was manufactured to GMP standards, and was sold until July 2011. The outer packaging listed the batch number and manufacturing date, with a clear warning that stated:

**WARNING: R18 - FOR ADULTS ONLY.**
*Keep out of reach of children.*
*Use responsibly in a well-ventilated place.*
*Do not overuse or mix with other substances.*
*Do not drive or operate heavy machinery.*

Similar warnings have appeared on most products sold in New Zealand. We note that the products we now sell – including Diablo, Giggle and Tai High – have far more comprehensive warnings than that proposed in the consultation document.

For the interim license period only, we support the proposed health warning as it is concise, easily understood, and likely to actually be read by the consumer.

However in the absence of any data showing that, for example, every approved product has a detrimental effect on driving, the current warning seems more based on presumption than hard science. That is acceptable during the interim period, but when considering the full application any health warnings should be evidence-based and specific to that product. If every pack has the same generic warning it may be incorrect, or not read by consumers.

Specific products could require more detailed health warnings, or may not have those health risks. Contraindications specific to each substance or product should also be included in any health warning. These include any substances, foods, medicines or activities that should not be undertaken while under the influence of the product.

We further support requiring licensed Retail outlets display specific warnings next to any psychoactive products that are on display, or if they are not displayed, a generic health warning that applies to all approved psychoactive product could be displayed.
16 Are the proposed packaging requirements and restrictions sufficient? If not, please make specific suggestions for further requirements.

Yes. However the timetable could be accelerated for some areas, for example tamper-evident and child-resistant packaging is readily available and could be implemented very quickly.

**Recommendation: No change.**

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

No. This proposal is inconsistent with how society treats alcohol, tobacco, foods and medicines. In fact, tobacco is prohibited from being sold in single doses in order to raise the price point and make it less attractive to youth. If tobacco was sold in single doses it would be very cheap. The same can be said of alcohol. Forcing Psychoactive Products to be sold in single doses would dramatically lower prices and make them more accessible to youth, the poor and other vulnerable groups.

Limiting pack sizes to one dose may also encourage consumers to not bother reading the pack to find out how many to take, but just “take the whole lot”. This is a potentially dangerous attitude to foster. Regulations should encourage consumers to read the pack and follow instructions around dosage and any specific health warnings.

**Recommendation: Do not limit pack sizes to one dose.**

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

By definition, this is not necessary for any substance or product deemed “low risk”. It seems odd to assume that consumers could overdose from something that the Authority has already decided is low risk.

We note that alcohol, tobacco, pharmaceuticals and foods are all sold in forms that are multi-dose. While some pharmaceuticals are split dose, there is always more than one dose per pack.

A split dose is also impractical for smokeable products.

**Recommendation: Do not require a split dose.**

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

There should be no restrictions on the form, other than the proposed ban on injectable substances. Rather than a blanket restriction on form, the Authority should consider the form
when assessing each product. All approved products should have a clear logo or watermark on the front and pack of the package (and any inserts or inner packs) that says, for example:

**WARNING: CONTAINS A PSYCHOACTIVE SUBSTANCE**

Psychoactive Products should be able to resemble foods or drinks, as long as the above warning is on the pack. Eating or drinking psychoactives is a traditional and often less risky method of consumption. Dosage can be more easily managed with edibles and tinctures. Furthermore, a tablet or pill is very similar in form to a lozenge or lolly, so banning "foods" could also ban party pills, which was not the intention of the Act.

Smoking products should be allowed. These are the most popular form of psychoactive substance. If they were not allowed in a smokeable form, most consumers would switch back to illicit (real) cannabis, which again was not the intention of the Act.

Loose herbal mixes can also be vaporised, or steeped in hot water to make a tea (and this is fairly common among our customers). We also note that the harms from smoking tobacco should not be assumed to apply to smoked or vaporised *Damiana* (the standard base for most synthetic cannabis products), and that nicotine is specifically indicated as a vector of tobacco-related cancers. More research is needed to prove any harmful effects from smoking particular substances or products, before considering prohibiting this product form.

**Recommendation:** There should be no restrictions on the form, other than the proposed ban on injectable substances. The Authority should consider the proposed form when assessing each application. Permissible forms should include foods, drinks and smokeable products.

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?

We agree with the proposals in the consultation document.

**Recommendation:** No change.

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

We agree with the proposals in the consultation document.

**Recommendation:** No change.

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

Displays a menu inside the store that gives customers information such as active ingredient, strength and price in tabular form to enable them to make an informed choice. The menu groups products by active ingredient, and also lists identical products that we don’t sell so that consumers can avoid active ingredients they don’t like.

We are concerned that any restriction on displaying licensed Psychoactive Products within our premises would compromise our ability to let customers make the best choice for them. A ban
on displaying packets would also mean customers are unable to read health warnings prior to purchase. This again would appear to be contrary to the intention of the Act. We note that the prohibition on retail display of tobacco products means our customers are only exposed to health warnings after they have purchased the product.

**Recommendation:** There should not be any restrictions on point of sale displays, subject to the following:

- Point of sale displays are not easily visible from the street;
- Point of sale displays are not intended to be attractive to minors;
- Point of sale displays and wall posters include any health warnings applicable to that product, as well as the active ingredient and strength.

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

We agree with the proposals in the consultation document, particularly about following HAZNG regulations and guidelines for disposal of hazardous substances.

**Recommendation:** No change.

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

The Act already contains signage requirements and restrictions for internal and external signage. The Regulations could require further signage and we believe consideration should be given to requiring the following:

Outside retail premise or in entry, a plain A4-size black and white sign:

- "LICENSED PREMISE: PSYCHOACTIVE SUBSTANCES ACT 2013"

Inside retail premise: signage modelled on that used in the liquor industry, for example:

- "It is an offence to sell or supply Psychoactive Substances to anyone aged under 18."
- "It is an offence for anyone aged under 18 to purchase Psychoactive Substances"  
- "We cannot serve intoxicated people" etc

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

No. This was already considered by Parliament and the Health Select Committee. The number of retail outlets has reduced from an estimated 3,4000 to 140 or so. There appear no reasons to further prohibit any other category of retail outlet.

The reduction in retail outlets may actually be counter-productive by concentrating any problems so they become more visible. For example, queues of consumers waiting to purchase products are only seen in areas with very few outlets. Having more outlets would reduce this.

**Recommendation:** No changes.
26 Do you think the regulations should prescribe restrictions or requirements for advertisements of approved products? If so, please provide specific suggestions.

Instore advertising, marketing and displays must remain permitted. However even a cursory read of the advertising restrictions appears to leave open many other forms of advertising and promotion, including:

- Billboards and other outdoor advertising
- Vehicle signage
- Airplane banners
- Overhead banners
- Sponsorship of teams, clubs etc
- Promo girls at events, etc

**Recommendation:** Consideration should be given to banning all forms of advertising and promotion, other than within the licensed premise.

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

We oppose the requirement that sales of Psychoactive Products must be the "primary purpose" of any website. This would mean we would be required to build an entirely new website with a completely different domain name. This would lower consumer confidence and trust, as they wouldn't readily know the new site is ours. It is important that good, responsible retailers such as us are supported in enhancing their reputations. This can only be done if consumers can tell who is selling what.

We agree with the other proposals around this in the consultation document; however we hold serious concerns about the proposal to enforce "regular audits to track sales". This sounds Orwellian, or at the very least, a privacy breach for customers, who it should be remembered are purchasing a legal product from a lawful retailer. It would be outrageous to consider recording the name and details of every purchaser of alcohol, tobacco, organic foods or natural remedies.

**Recommendations:** Sales of Psychoactive Products should not be required to be the primary purpose of the website.

Any audits to track sales should be made by independent third parties and should not track the names or personal details of customers, unless there has been a breach of law. Any tracking of personal details should be limited to that particular breach.

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

We assume this question relates to instore advertising, as other forms are covered in Q26 above.

The Act already specifies instore advertising should not be easily visible from the street, or designed to appeal to minors. Other existing consumer laws provide protections around
truthfulness etc. Instore advertising and displays are an important part of enhancing consumer information so they can make an informed choice that is right for them.

**Recommendation: It would be helpful for the Regulations to specify that branding is allowed in store, as this is an important aspect of consumer health and safety.**

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

No.

The proposed fees for Wholesale, Import and Research licenses seem too low. The relative amount of each proposed fee raises questions about why so little of the Authority's attention is given to these categories of licenses.

The proposed Retail license application fee is too high, and is clearly much more than the "full cost of processing" the application. Likewise, the annual levy is also too high, and cannot possibly be a reflection of the actual costs involved with renewing a license or performing an inspection.

Compared to existing fees for Liquor Licenses and Misuse of Drugs Act licenses - which are in the hundreds of dollars despite requiring lots of paperwork and inspecting premises - it seems grossly unfair and out of proportion to the work involved and the benefit obtained.

Most benefit from sales of Psychoactive Products falls on the manufacturer or wholesaler, who could reasonably be estimated to sell at least 100 times what any individual store sells. Yet the Manufacture License is only a little more than 3 times the cost of the Retail license.

Applying a fixed fee per outlet does not take into account the harm or costs imposed by each outlet or the products they sell. The proposed $15,000 application fee is peanuts to the big sellers - who may be causing more harm in their communities - but a seller who causes fewer problems must pay the same fee. We expect some high-volume sellers may even argue the license fee should be higher, and that any such anti-competitive behaviour will be resisted by the Authority.

A fixed fee per outlet encourages longer trading hours and other tactics to boost trade. The has chosen to trade only during standard shop hours (10am to 5:30pm). One reason for this is that we want to sell products to people who are planning ahead, rather than spontaneous purchases during the evening when people may already be under the influence. A high fixed fee will encourage stores to stay open later in order to spread these extraordinary compliance costs over longer trading hours. A high fixed fee will not reward or encourage responsible retailers.

In contrast to the high turnover trade achieved in regional centres, retail stores such as ourselves who are in metropolitan areas do not sell large volumes of Psychoactive Products.

**The proposed fees and levies would cause us to carefully consider whether we could feasibly remain a license holder.**

Rather than using grossly-inflated fees and levies to pay for the work of the Authority, we support the introduction of an excise tax on approved Psychoactive Substances. Such a tax

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should be commensurate with their risk, and careful consideration should to be given to finding a price point that does not encourage a black market to develop.

The best way to do this is to levy an excise tax on the weight of active ingredients (e.g., mg of active per gram of product), and commensurate with their risk of harm.

- This would ensure a system that is consistent to how we already collect tax on alcohol and tobacco sales. In both cases, the tax is paid by the manufacturer, who then passes it on to their customers by building it into their prices.
- This is the most efficient system, with the lowest compliance cost and only a small number of manufacturers to monitor.
- This also ensures that the revenues from each product are commensurate with sales – and, it is presumed, harms caused by those sales.
- A fixed levy, by comparison, means a "bad" product or retailer that contributes the most harm pays the same amount as a "good" product or retailer that causes no harm. Such a system would do little to encourage responsible retail behaviour.

**Recommendation: Reduce License fees and levies for Retail Licenses to their actual cost, which should be no more than $1000/year.**

If needed, increase the fees and levies for other licenses to their actual cost.
Place an excise tax on the active ingredient, or to levy the manufacturers based on their product sales.

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

In principle we support paying actual costs of each application, i.e. an hourly fee, as this would encourage applicants to get it right the first time by having their affairs in order before applying. It also means that a license renewal would be charged at the amount it actually cost – if no revisits were required the fee would be less, whereas if a license holder required multiple visits they would pay more. The proposed fixed fee means good applicants are subsidising the extra work needed for bad applicants. It should not be difficult for the Authority to calculate their fixed and hourly costs and charge at an appropriate rate, just as private businesses do.

**Recommendation: Charge at actual cost.**

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

Yes. Rather than taking the total cost of everything the Authority does and dividing that by the expected "demand" for licenses, while not charging for much of its other work, the Authority should charge for all functions it supplies. That would bring down the cost of licenses as applicants would not be subsidising the other currently-unbilled functions performed by the Authority.

**Recommendation: Charge the actual cost for each service provided, rather than forcing some license holders to subsidise the work provided to others.**
32. Do you agree with the proposed list of items and process for setting levies? If not, please provide specific suggestions.

No. It would be far better to tax or levy the active ingredient contained in approved substances or products. This would be consistent with levies on petrol, alcohol, tobacco etc. It would also mean, as explained above, that revenues from each product would be commensurate with how many are sold, and presumably the level of harm caused to users and the community.

The proposed flat-rate fees will mean lower risk products will subsidise the costs imposed by the more risky products. A high selling product contributes less per product sold, even though it may be causing more harm than a lower selling product that must pay the same fee. This is unfair, inequitable, and spreads the benefit from one product to another product potentially owned by a competitor.

Recommendation: Place an excise tax on active ingredients, and base the fees and levies for license holders on their actual cost.

C. OTHER ISSUES NOT RAISED IN THE CONSULTATION DOCUMENT

It is unclear whether the definition of Psychoactive Substances and Products includes natural herbs and teas

Currently, if herbs are treated as natural remedies they should be legal under the definition of a herbal remedy in the Medicines Act. But if the forthcoming Natural Health Bill restricts herbal remedies and supplements to an approved list only (as intended), then all natural herbs not on that list will be captured by the Psychoactive Substances Bill and deemed to be unapproved.

Any given substance or product may or may not be covered by the PSA, depending on how it is marketed and intended to be taken. The threshold appears to be whether the product in question is made or sold for psychoactive effects, and whether it is covered by other legislation.

Chamomile tea clearly has psychoactive effects, is an approved food, and may have medicinal or therapeutic effects. It may even have industrial uses. Yet invariably, the packaging of chamomile and other teas will contain statements that promote mood- and mood-altering effects. It is not clear which law governs the sale of chamomile tea, or whether it is even legal. A strict interpretation, given the statements found on the packaging, is that Chamomile tea is an unapproved psychoactive product.

The New Zealand Customs Service has sometimes chosen to take such an interpretation when processing imports of natural herbs made by and others. Customs has detained herbal teas and forced us to pay ESR to test them. We are also aware they have seized imports of other herbs made by other people and have cited the PSA when doing so.

Having unclear laws is not good for anyone. It should not be up to the whims of individual Customs officers to decide to ignore imports of herbal teas destined for supermarkets, while seizing imports of the same or similar teas made by us and others.

Recommendation: For the sake of clarity, the Regulations should make clear that natural herbs in their natural state are not covered by the PSA, unless they are marketed for their psychoactive effects.
Crucial terms in the Act are undefined, including what is meant by ‘low risk’

The Act says ‘low risk’ products must be approved but does not define what that means. Risk is a function of harm and the probability of that happening. The principal components of harmfulness are the substances toxicity and its addictiveness. The probability of harm happening is related to availability – which is greatly reduced and more controlled now than ever before – as well as packaging including ease of counterfeiting, and whether or not there is an antidote. All of these can be measured in terms of scientific standards.

The Act also does not clearly define what a Psychoactive Substance is, or other terms crucial to interpreting and correctly following the law, including what is meant by “primary purpose”, and “induce”.

Recommendation: The Authority should produce objective measures of the components of “low risk” and clearly define all terms in the Act.

Exemptions for Interim Retail License holders who do not comply with new LAPPs

In our oral and written submissions to the Psychoactive Substances Bill, The Hempstore proposed including a new provision that would allow local bodies to enact local policies similar to the local alcohol plans allowed by the Sale and Supply of Alcohol Act 2012.

We believed allowing some flexibility in local control was the right thing to do, and we told the Health Select Committee⁴ that if those local policies were so restrictive we didn’t get a license, then “so be it”. However, we strongly cautioned against allowing grandstanding local politicians too much leeway, and we advocated that any LAPP must follow the principles of the PSA and not amount to prohibition in another name.

This year, after Interim Retail Licenses were issued, several local bodies have adopted very restrictive LAPPs that have amounted to de facto prohibitions. It appears they have noted where license holders are located and deliberately crafted the wording of their LAPPs to put those license holders in breach of the LAPP.

The Authority has played into the hands of narrow minded local politicians by not allowing any Interim Retail License holders to move premise in order to comply with their LAPP, and has instead suspended their licenses. This was not the intention of the Act, nor what those of us who proposed LAPPs had in mind.

This untenable situation is compounded by the Authority’s proposal to consider full Retail Licenses in Phase 2, in order to let local politicians “determine where psychoactive products can be sold within a council district”.⁵

The proposed time frame means full retail licenses will not be considered for several years. Rather than allowing “a managed approach and an integrated licensing system”, the adoption of

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⁴ The Hempstore, Submission to the Psychoactive Substances Bill 2013. Available at www.parliament.nz/resource/0001580391

any more restrictive LAPPs in that time will mean more retail stores closing, further undermining the good intentions of the Act. It will also result in:

- Effective prohibitions on retail outlets, decided at the whim of local politicians;
- Entrenching monopolies and existing operators, who may not actually be the most suitable;
- Shutting out competition, thereby reducing consumer choice and service;

Interim Retail License holders who find themselves in breach of a new LAPP should be given an exemption for the Interim period, or allowed to relocate in order to bring themselves into line with any new LAPP.

**Recommendation:** There must be an exemption for Interim Retail License holders who do not comply with LAPPs adopted after their license was issued.

The Authority should work with local bodies to ensure they adopt LAPPs that are fit for the purpose and do not amount to de facto prohibitions.

Retail Licenses should be considered in Phase 1, not Phase 2.

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**Food and drinks should be available for purchase alongside Psychoactive Products**

The availability of food and drink is an important aspect of harm reduction and host responsibility.

While the Act prohibits the sale of Psychoactive Substances from dairies, convenience stores and petrol stations, the Authority currently imposes a blanket ban on the sale of food and drink and has instead been considering and granting exemptions to this ban on a case-by-case basis.

The Hempstore’s Interim Retail License contains an exemption that allows us to sell specialist (i.e., hemp) food, drinks and household goods.

While we support the intention of the Authority in using this to weed out diaries and the like, there must be a better way of defining and excluding such businesses.

There is nothing in the Act or the consultation document that regulates on-site consumption. It is important that venues are safe places for consumers. As with alcohol, the availability of food and drinks may reduce any adverse effects and the likelihood of unintentionally consuming too much.

**Recommendation:** The sale of food and drinks should be allowed as an important aspect of harm reduction and host responsibility. This is especially important for locations that allow on-site consumption.

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**Staff and management training**

When assessing applications the Authority should consider whether or not applicants have:

- Any suitable experience and qualifications, including work in the community;
- Staff training, including Host Responsibility, Harm Reduction, and the provisions of the PSA;
- Membership of PITA and compliance with their Code of Conduct, which we note goes further than the requirements of the Act itself.

We understand training programs tailored to workers in the Psychoactive Substances industry are being developed. When they are available, consideration should be given to making suitable training mandatory, at least for Managers.

**The risk assessment framework is fundamentally flawed and must be revised.**

The framework accepts reports from Centre for Adverse Reaction Monitoring (CARM) and the National Poisons Centre (NPC) as evidence of adverse effects. Two medium adverse effects, or one serious adverse effect, are sufficient to have the licensed for a product revoked. An example of a serious adverse effect is a seizure.

There are several problems with this approach:

- The categorisation of adverse effects into mild, medium and serious categories appears to be somewhat arbitrary. Many of the medium effects appear to actually be rather mild, especially when compared to the effects of drinking alcohol and other legally available substances.

- It is inconsistent with how we treat adverse effects from medicines.

- The National Poisons Centre has become politicised and its impartiality has come into question. It is now a crusading organisation that campaigns to prohibit these legally-regulated substances.

- Reports to the NPC may be made anonymously. Any anonymous reports should be further investigated and verified before being accepted.

- Reports to the NPC may be made multiple times for the same event. Multiple reports of the same event are unaccounted for.

- It is possible false reports to the NPC have been made by competitors or opponents of the products in order to have them banned. Whether this has happened is unknown.

- Product licences can therefore be revoked far too easily, which will discourage the significant investment required to research any substances.

**Recommendation:** Remove NPC reports from the risk assessment framework. Only reports from CARM should be used: these are vetted by doctors, are not multiple reports of the same event, and are unlikely to be false reports.

**Regulations and Authority decisions should be regularly reviewed**

The Act will be reviewed in five years, but a lot can happen in that time and it’s highly likely there are more issues not yet considered or discussed in the consultation document. Since the review is so far away, there should be annual reviews of all decisions made by the Authority and all regulations that have been issued.
Real cannabis law reform is needed

Serious consideration should be given to reforming our cannabis laws. There is only demand for synthetic fake cannabis because real natural cannabis is illegal, even though it is demonstrably less harmful.

- According to the Ministry of Health, 46% of all Kiwis aged 16-64 phoned at home will admit to a government survey they have used cannabis (1,224,600 people). Around one in six – almost 540,000 adults – say they’re regular users.4 According to the WHO, this gives New Zealand the highest rate of using cannabis in the world.7

- A recent Australian epidemiological review published in the Lancet shows cannabis use is not a significant contributor to the global burden of disease. The burden to society of cannabis users is very low and overshadowed by the much smaller number of opioid and methamphetamine users, and tobacco and alcohol users.8

- The NZ Police’s Drug Harm Index shows that most harms relating to cannabis are caused by the law itself.9

- Unlike alcohol, cannabis use is not associated with violence.10

- US states that legalised medicinal use of cannabis have experienced lower rates of road deaths.11

There is a huge demand in New Zealand society for cannabis, and as long as it remains illegal there will be widespread demand for products containing synthetic cannabinoids, which are likely to be more harmful.

Recommendation: The Misuse of Drugs Act (MoDA) should be repealed and replaced with a new law that, like the Psychoactive Substances Act, is fit for the purpose and focused on the health and welfare of New Zealanders.

The recommendations of the Law Commission’s review of MoDA should be implemented. However, the Law Commission’s report is a rather timid starting point. Cannabis legalisation experiments underway in Washington State, Colorado and Uruguay have prompted or accelerated discussion about changing pot laws in many nations, and momentum is building in advance of a special United Nations convention on drugs scheduled for 2016.

The US drug czar recently admitted to Associated Press that after 40 years and us$1 trillion, the Drug War has failed to meet any of its goals:

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"In the grand scheme, it has not been successful. Forty years later, the concern about drugs and drug problems is, if anything, magnified, intensified." \[12\]

**Recommendation: New Zealand should look to these innovative jurisdictions for inspiration on how to legally regulate and control the availability of cannabis so as to minimise harm and reduce the use of more harmful substitute drugs.**

Finally, it has been refreshing to find ourselves agreeing with Associate Minister of Health Peter Dunne’s call for evidence-based approach to regulating drugs:

"[T]he Psychoactive Substances Act... could well become the model by which narcotic drugs, currently controlled under the Misuse of Drugs Act, are regulated for the future... The yardstick of level of risk – based on sound pharmacological and toxicological evidence – would become the determinant of availability, not public sentiment or prejudice... the regulatory regime introduced for psychoactive substances could well have wider application and that we should not be averse to that possibility. After all, most experts now concede the so-called “war” on drugs has failed, and new initiatives are required." \[13\]

Although we have not often agreed with Mr Dunne, we are in complete agreement here.

Thank you for the opportunity to make this submission.

Yours faithfully,

Chris Fowlie

Managing Director,

THE HEMPSTORE AOTEAROA

\[12\] Associated Press. 13 May 2010: After 40 years, $1 trillion, US War on Drugs has failed to meet any of its goals, available at http://www.foxnews.com/world/2010/05/13/ap-impact-years-trillion-war-drugs-failed-meet-goals

Making a submission

Submissions close on Friday 21 March 2014 at 5 pm.

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

Please detach and return this part of the document.

Consultation questions

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

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

   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
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.

If the applicant has failed any liquor licensing or sale of tobacco regulations should be taken into consideration

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

Yes and that should be taken into consideration as per question 4

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

They should display that they are licensed and any breaches of that license should be displayed on the window of the premises.

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.

There should be absolutely no discretionary conditions to allow licensing 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?

Yes as below:

Regardless of the LAP the public must be able to contest interim or full retail licenses.

Regardless of the LAP the public must be able to request modifications to opening and closing times of interim or full retail licenses.

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?
There should be prescribed Psychoactive Substances licensing officers provided by the Ministry to City Councils and paid for by the industry to enforce compliance of stores/importers/manufacturers.

It is concerning that the MoH has still not defined what is a low risk Psychoactive Substance, public must have input into the definition of "low risk".

Public must have input into determining whether the product is addictive, if the product is proven to be addictive then it should be banned.

The following short term negative health effects should be independently tested prior to the approval of the product using the same processes as required for the pharmaceutical industry. If any of these short term negative health effects manifest then the product should be banned.
- reduction/loss of cognitive functions
- reduction/loss of organ functions
- reduction/loss of motor functions
- reduction/loss of some/all five sense
- reduction/loss of control over emotions
- psychosis/depression/aggression/paranoia/risk taking/suicidal behaviour
- hallucinations
- hyperactivity/secantary
- sleeplessness/crowsness
- increased/decreased appetite

The following long term negative health effects as below which may take decades to manifest. They should be independently tested using long term epidemiology studies with the products being banned should long term health effects occur in the population as a result of these products.
- permanent psychosis/depression/aggression/paranoia/risk taking/suicidal behaviour
- premature organ failure
- immunological related illnesses
- cancer
- birth/genetic defects

Driving and heavy machinery operation should be illegal when under the influence of a Psychoactive Substance with penalties similar to drunk driving.

The Psychoactive Substance industry must independently fund the development of detection devices of Psychoactive Substances and provide them free of charge so that law enforcement officers, Council officers and Private firms can test individuals.

The Psychoactive Substance industry must independently fund the monitoring of alcohol/illegal drug/Psychoactive Substance usage and rehabilitation.

The Psychoactive Substance industry must independently fund all rehabilitation of Psychoactive Substance users.

The Psychoactive Substance industry must independently fund education to not take Psychoactive Substances.

The Psychoactive Substance industry must independently fund further epidemiological research into the effects of Psychoactive Substance usage on health, crime, social impacts, alcohol and illegal drug usage.

The Psychoactive Substance industry must fund (via targeted taxes) all costs associated with the new regulation regime?

Loss leader pricing should be banned and minimal pricing of Psychoactive Substances applied including all taxes.

The Ministry of Health must be held accountable for any resulting health and social issues from approved Psychoactive Substances and be prepared to immediately ban and fund the solutions.

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

Yes as per question 11.

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

Labelling should follow the same as cigarette labelling.

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).

Labelling should follow the same as cigarette labelling.
16 Are the proposed packaging requirements and restrictions sufficient? If not, please make specific suggestions for further requirements.

Labelling should follow the same as cigarette labelling.

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

Yes to minimise overdoses and to ensure appropriate pricing controls.

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?

Should not be allowed to inject (break skin) or inhale via cigarettes (as we are trying to ban smoking).
20. Do you think there should be restrictions or requirements on the storage of psychoactive substances? If so, what should the restrictions or requirements be?

Yes as per Cigarette restrictions.

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

Yes as per Cigarette restrictions.

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

Yes as per Cigarette restrictions.

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

Yes as per illegal drug disposal.
24. Do you think there should be signage requirements in the regulations? If so, please give specific suggestions.

Yes as per Cigarette restrictions.

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

They should only be sold in specialty stores and far away from residential, schools, community places.

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

Yes as per Cigarette restrictions.

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

Internet sales should not be allowed as this will be impossible to regulate and monitor.
28. Do you think the regulations should prescribe restrictions or requirements on the advertising of approved products? If so, please provide specific suggestions.

Yes as per Cigarette restrictions.

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

Fees must be paid for by the industry, no public money use.

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

Fees must be paid for by the industry, no public money use.

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

Fees must be paid for by the industry, no public money use.
Do you agree with the proposed list of items and process for setting levies? If not, please provide specific suggestions.

Fees must be paid for by the industry, no public money use.

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 concerned New Zealander who opposes legalisation of psychoactive substances

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.

X I am fine with all details of my submission being made public
SUBMISSION TO THE MINISTRY OF HEALTH

Public Consultation on Psychoactive Substances Regulations

From Hastings District Council

21 March 2014

Introduction

The Hastings District Council thanks the Ministry of Health for the opportunity to make a submission on the development of regulations being drafted to give effect to the Psychoactive Substances Act 2013.

The Hastings District Council has a Local Approved Products Policy (LAPP) adopted under the provisions of the Act, and this has been in effect since 6 December 2013. This policy seeks to keep retail outlets selling approved products contained in commercial areas and away from a number of other activities.

This submission is based on input from Councillors and Council officers with delegated authority to make a submission. Due to time constraints, this submission has not been ratified by the full Council.

We would note that we are concerned about the short period of time provided to make a submission, as this prevents the full Council having input to the submission document.

Councils Submission

The consultation document has been used as a guide for this submission. The matters not submitted on are outside of Councils normal scope.

We have also reviewed the submission being made on by Local Government New Zealand and we support the submission they are making.

Generally, the Council does not support any sale of Psychoactive Substances for consumption, as we perceive these products to be dangerous, addictive and completely harmful. Council is also concerned about the short and long term health effects of these products, with Police and local health professionals communicating their strong concerns to us.

Council has recently submitted to Parliaments Health select committee expressing these concerns, in particular the ready availability of these products to children, the impact on mental health and the social costs of these products.

Council's preference would be a complete ban on the sale of these products.

The Consultation Document

1. Licence Applications. The proposal is for retail licence applications to be accompanied by some information showing compliance with a Councils LAPP. We envision that this will take the form of a letter or certificate of some type from the Territorial Authority (TA) confirming compliance with the LAPP. Council supports this concept and makes the following points;
a. Where there is an LAPP in force, Licence applications should be incomplete without this document and unable to be lodged with the Psychoactive Substances Regulatory Authority or progress until it is provided.

b. Councils must be provided with the mechanism to recover any costs of investigation and reporting required in providing this document. It will not be appropriate for this activity to be funded or subsidised by ratepayers.

c. It is unclear what is meant by a "generic LAPP". The LAPP is a document created by a TA through the Special Consultative Procedure. There appears to be no mechanism suggested for a generic policy.

2. Licence Conditions. Currently, there is no record keeping being undertaken by retail sellers. Council submits that all sales of approved products should be subject to a regime similar to that used for the sale of pseudoephedrine-based products. That is, photo ID provided and name, address and contact details taken before a sale is made. Records should be forwarded to either the Police and/or Ministry of Health Enforcement officers on a regular basis. This information will be important to ensure that people are not buying for on-selling, and also so that contact with consumers can be made if a product is later found to be hazardous.

   a. Licence holders should be required to record the name, address and contact details of each purchaser.
   b. Photo Id should be required for all sales.
   c. Records should show the products purchased and the quantity.
   d. Records should be forwarded to the Police and Ministry of Health for collation and retention.
   e. Licenses should be required to be displayed inside the principle entrance to an outlet.

3. Discretionary Conditions. It is appropriate for the Authority issuing the licence to have some discretion to add conditions to a licence that they believe are appropriate. We suggest that the following be considered:

   a. hours of operation
   b. provision of other goods and services
   c. access point into the retail outlet
   d. Provision of CCTV and retention of the recordings

4. Labelling and packaging. Council agrees that controls on labelling and packaging are appropriate. Currently, the packaging and labelling of these products appears to be geared towards attracting a young, counter-culture market. We have attached an example of the type of packaging being used currently to illustrate this. We would make the following points;

   a. Labelling should be consistent and clear, including the concentration of the active ingredients.
   b. Regulations should also require plain packaging that does not promote the use of the product.
   c. It is suggested that the use of words such as “Legal”, “Natural” be banned due to the association of these words (that is, Legal or Natural implies that it is safe).
d. Health warnings should include that use can lead to psychosis.

5. **Place of Sale and Advertising.** The consultation document suggests that regulation place further restriction on the types of places where approved products can be sold. Council supports any mechanism that restricts the availability and “normalisation” of approved products, or where the provision of other goods and services may be used to mask the sale of products to otherwise prohibited persons. We agree with the LGNZ submission that these products should only be available from specialised shops that do not sell other, unrelated, items.

6. **Local government Policies for approved products.** We note that the consultation document asks no questions under this section, in contrast to the remainder of the document. We also note that under the Act as it is written, there is no clear connection between an LAPP and the Authority as decision maker. Regulations therefore will provide the only mechanism by which an LAPP can be considered. Reading the Act, it appears that the only way to achieve this will be for the information requirements for making an application to include documentation from a Council confirming that the proposal complies with the LAPP. Without this an application would be incomplete and unable to be lodged. Council submits that the regulations must therefore proscribe the following:
   a. The mechanism by which compliance with an LAPP is communicated to the Authority. This may be a certificate or similar document signed by a duly authorised officer of the TA.
   b. Cost recovery for the TA in providing this to an applicant.
   c. The requirements for information to be included with an application to retail approved products.
   d. A feedback mechanism where an LAPP comes into effect after a premises has established.

7. **Advertising –** This is not an area that Council normally regulates. However, we note that current packaging appears to be aimed at a young market, with counter culture imagery and phrasing aiming to promote the use of the product. We would suggest the following limits on advertising:
   a. No advertisement of approved products in any form which can be seen outside of the premises.

8. **Internet sales restrictions –** This is not an area that Council normally regulates; however we are aware of concerns that have been raised around the availability of alcohol that can be purchased online by under-aged persons. We agree therefore that regulations should include restrictions on internet or on-line sales.
   a. Internet sales should only occur following a registration process and independent confirmation of a purchasers age.

9. **Fees and Levies.** The setting of fees for the functions of the Authority is outside the realm of the TA. However, we would note that we agree that fees should be set at a cost recovery level. We would also note the following;
a. Fees for TA costs in providing documentation should be available, but set by the TA.
b. Any levies taken from the industry for the Ministry to fund its functions should be set at a level that covers the costs of doing so. This industry should not be subsidised by the tax payer.
c. Levies taken should include the cost of conducting research into the long term health effects of the use of approved products.

10. Training. Although not mentioned in the consultation document, it is recommended that regulations be used to set the minimum level of training required by a seller of approved products. This would be similar to the General Manager requirements of the Sale and Supply of Alcohol Act 2012. Such a trained Manager of a retail outlet would be responsible for ensuring that sales conditions are met and culpable if they are not.

Summary

Our Council remains deeply concerned about the sale and consumption of psychoactive substances. Short and long term health effects remain unknown, and the nature of these products is such that they are harmful to all users.

At the time of writing this submission, the two outlets in Hastings have had their licences suspended by the Ministry of Health due to non-compliance with our LAPP. While we welcome this move, it has resulted in threats being made against our Mayor and Councillors, which we have to take seriously. This may be symptomatic of the addictive nature of these products and the levels of psychosis that they seem to cause.

The licencing process so far has created a significant level of harm in our community, which is expressed to us anecdotally by Police, Moh, youth workers and other Government departments. This harm includes mental health admissions and increased agitation and violence on the streets.

The experience in this District then, is that the stores selling approved products are attractors of undesirable elements of our community. Of the two existing licenced retailers in Hastings, both have been subjected to armed robbery in the last few months, both during the day. The Police have advised that these appear to be opportunistic crimes, encouraged by the large volume of cash that is changing hands. While this may not be a direct "health" issue, it is a real symptom from the availability of these drugs and the way in which the law operates in practice.

The submission to the Health Selection committee by our Council highlighted the ease with which young people, in some cases as young as 12, are obtaining these products. This appears to be occurring through third parties purchasing significant quantities of product and then on-selling it. Locally, our Police are working to defeat this practise, but as there are no controls or records on purchases this task is made harder. As a minimum, retailers should be required to collect the information in point 2, above.

Council retains the belief that the psychoactive substances approved by the Ministry should be banned.
If the current regime is retained, then the regulations will need to tie in the LAPPs adopted by Councils and the issuing of Licences by the Ministry.

We would like to talk to this submission, if the opportunity arises.

Signed:

Ross McLeod, Chief Executive, Hastings District Council

Contact for Service;

Phil Evans
Community Safety Manager
Hastings District Council
Private Bag 9002
Hastings 4156
06871-5000
philipe@hdc.govt.nz

Attachment; Packaging examples
Submission by
Hamilton City Council

Ministry of Health’s Psychoactive Substances Regulations: A Consultation Document

21 March 2014

Hamilton City Council (HCC) adopted a Local Approved Products Policy (LAPP) on 27 February 2014.

The key points of the submission are:

1. The information requirements for licence applications can be made more comprehensive.

2. All licences should be issued personal to an individual, not a body corporate.

3. A recognised qualification for managers of retail premises of psychoactive substances should be developed.

4. The Authority should consult with the relevant Police, District Health Board and Local Authority representatives when determining ‘fit and proper’ person assessment.

5. A regulatory framework for selling psychoactive substance similar to alcohol licensing should be considered.

6. Current holders of interim licences should be given priority when processing for full licences begins.

7. Prioritisation for full licences should be given to those retail premises that sell approved products as part of a wider product range.

8. A ‘risk framework’ similar to that applying under the Sale and Supply of Liquor Act should be developed and applied to the issuing of licences.

9. Fees should be set at a cost recovery level. This should include costs incurred local authorities for responding to requests relating to applications.

10. There needs to be great clarity around the decision making roles of the Authority and local authorities.

Responses to questions in the consultation document

The consultation document has a broad scope and deals with a number of matters that extend beyond the normal focus of councils, such as manufacturing, labelling and importation. This submission responds to those questions relevant to territorial authorities.
Licence Applications

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

   i. The proposed information requirements are not comprehensive enough. To minimise risk around a premise’s operation and to ensure councils have sufficient information to understand whether the retail premise is compliant or not with the LAPP, the applicant should also be required to provide:

   - The trading name and retail name of the business.
   - A current phone number (with the latter adding to the verification of the individual).
   - A precise address of the retail premise.
   - A floor-plan of the retail premise which clearly shows any adjoining doorways to another property (if adjoining doorways are present in the retail premise, the operator’s name, address and telephone numbers of those business must be supplied).

   ii. Applicants must make a statutory declaration under the interim licence application process; the regulations should require a statutory declaration in the full licence application process.

   iii. All licences should be issued personally to an individual not a body corporate. This is to ensure the fit and proper person test is applied to individuals, and to all licences applications. Personnel of a body corporate can change at any time, and there is no mechanism currently to apply the fit and proper test retrospectively. In comparison, liquor licences are issued to an individual, not a body corporate. The same should apply to these licences.

   iv. The Authority should establish a recognised qualification for managers of psychoactive substance retail premises in the same way that these are required under the Sale and Supply of Alcohol Act 2012 (section 217).

   v. Section 216 of the Sale and Supply of Alcohol Act 2012 sets out requirements for on-licences to have a qualified duty manager on the premise at all times during trading hours. The same requirement should apply to these licences. The qualification process should:

   - Subject the qualification holder to the ‘fit-and-proper’ person criteria.
   - Require the qualification holder to be trained in substance abuse and addiction awareness.
   - Require the qualification holder to be trained and conversant in the Act and regulations.
   - Require annual renewal.
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. HCC supports retail licence applications being accompanied by information showing compliance with a council's LAPP. The regulations could require Councils to provide to the Authority a copy of their LAPP and any up-to-date map that accompanies the Policy. HCC's preference is for the Authority to prioritise applications, notify HCC of these and seek input on that basis. Councils must be provided with the mechanism to recover any costs of providing the information. A national costing schedule should be developed for this purpose and be included in the regulations similar to the new national fee system in the Sale and Supply of Alcohol Act 2012.

3. Should retail licence applications be accompanied by evidence of compliance with a generic approved products policy if no policy is in effect in the applicant's area?
   i. HCC supports a generic policy to avoid a retailer setting up on the boundary between a council with a LAPP and one without. The content of a generic policy should include:
      - Creating a default definition of sensitive sites.
      - Setting a minimum buffer zone around sensitive sites.
      - Setting a minimum buffer zone between psychoactive substance retailers.
      - Creating a standard as to how those buffer distances are measured (we recommend 'boundary of property' measurements, rather than 'centre of property').

Fit and Proper Test

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?
   i. The information requirements for licence applications are not comprehensive enough and the licence model should more closely reflect the licence framework set out for the Sale and Supply of Alcohol Act 2012. For example, 'serious or repeated failure' should be aligned to the thresholds in the Sale and Supply of Alcohol Act 2012. These are outlined in sections 247 (Unauthorised sale or supply) and 258 (Licensee's offences in respect of manager) of that Act.

   ii. Other opportunities for alignment between the two statutory regimes include the management of licensed premises (subpart 7), which covers the appointment of managers, their role and required training and criteria for the issue of licences (section 105).

   iii. HCC recommends that the Authority consult with the relevant Police, District Health Board and local authority to ascertain the nature of any relevant local experience with the applicant. It is possible that applicants will have a history of contact with a local authority that shows them to be either good corporate citizens or, at the other extreme, serial non-compliers.
Licence Conditions and Discretionary Conditions

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

and

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

The licence holder needs to maintain live records showing the products purchased and the quantity.

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

Through HCC's consultation process on its LAPP, a number of submitters raised the need for a range of safety mechanisms and initiatives to be put in place.

It was determined that these would be most appropriately addressed by discretionary conditions around harm reduction and could include:

a) The installation of CCTV.
b) Security guards.
c) A reduction in trading hours.

i. The following table provides a selection of 'verbatim' comments made by submitters to HCC's draft LAPP around discretionary conditions.

<table>
<thead>
<tr>
<th>Verbatim Comments to HCC's Draft Psychoactive Substances Policy on Discretionary Conditions</th>
</tr>
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<tbody>
<tr>
<td>&quot;Retailers should be subject to similar restrictive hours such as off-licences for liquor. This will ensure that people are not encouraged to purchase substance while drinking within the CBD e.g. 9am-10pm.&quot;</td>
</tr>
<tr>
<td>&quot;Require approved retail premises to install CCTV cameras connected to the CitySafe CCTV network at their own expense (including on-going maintenance and repair of vandalism) as an on-going requirement to maintain a licence. The retailer should be required to immediately cease trading if a CCTV feed is lost.&quot;</td>
</tr>
<tr>
<td>&quot;I walk to work every day and I often feel frightened walking past the bus stop on Victoria Street. I am finding my self more and more crossing the street to avoid passing this store and the people who stay there all day.&quot;</td>
</tr>
<tr>
<td>&quot;Until there is legislation to ban legal highs, this policy is about the best that Council can do. The policy should be based on the principle that harm to the public and other retail and industrial premises, should be minimised. Obligations by the legal high premises could be increased, such as increasing security around the exterior of the premises e.g. cameras or attendance at community meetings or attendance at a training seminar run by Drug Free Aotearoa before getting a licence.&quot;</td>
</tr>
<tr>
<td>&quot;I submit that there should be conditions to the license for selling psychoactive substances, a minimum of the retailer must provide their own security at their own cost for the opening hours of their premise. The cost to the city ratepayers needs to stop for the service of security that they are at present providing (Citysafe) and the hours of sale of psychoactive substances be restricted to 9am - 3pm, this would allow school children and workers to get to their destination free of harassment.&quot;</td>
</tr>
<tr>
<td>&quot;Any licence approved should only be granted to a person that has surrounding neighbours approval first. This is because as proved to date, the customers using these stores cause undue disruption to all neighbours.&quot;</td>
</tr>
</tbody>
</table>
ii. **A risk framework should be developed**, in much the same way as has been done for alcohol licensing, to identify retail premises as high, medium or low risk. A high risk premise would then be subject to a range of conditions while low risk premises could be subject to fewer conditions or none. The use of a framework would allow the Authority to apply harm mitigation specific to a particular licensee and their location but is based on objective rationale. The Police and District Health Enforcement Officers are in the best position to guide the Authority in this area of discretion.

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. HCC does not agree with the concept of processing applications in the order they are received.
   
   ii. HCC submits that priority should be assigned to applicants who already hold an interim licence, because they have already been through an application process and they will need certainty on the continuation of their interim licence under clause 9 (2) of Schedule 1 of the Act.
   
   iii. Prioritisation should also be given to those retail premises that sell approved products as part of a wider product range, for example specialist tobacco shops. In our view this minimises harm to the user and this view was supported by submission HCC received on its draft policy.

10. **Do you agree with the proposed fees for the different licences? If not, please provide specific suggestions.**
   i. Local authorities should also be able to recover their costs in providing information for licence applications. We suggest a fee schedule to cover local authority costs in providing information to the Authority under the Act be established and included in the regulations.

**Further Information**

For any questions on the submission points, please contact Tegan McIntyre (Programme Manager - Policy and Bylaws) on 07 838 6637, or email tegan.mcintyre@hcc.govt.nz

Yours faithfully

[Signature]

Barry Harris  
CHIEF EXECUTIVE

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Although this submission has been circulated to HCC's Elected Members for consideration and feedback, it has not been adopted through the formal committee process. HCC’s submission is to be considered and adopted retrospectively at the 30 April 2014 Strategy and Policy Committee meeting. We will advise you after this meeting if HCC makes any changes to its submission.
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?
   
   In my opinion — yes — it is very comprehensive and water tight.

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 it is the only way to ensure compliance in all areas

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?

   Has too to ensure that all players are playing by the same rules — may be a little advantage if no policy
4 Are the factors the Authority should take into account when determining whether a licence applicant is a fit and proper person or whether a body corporate is of good repute in section 16(2) enough? The section 16(2) factors are:

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

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

Well covered and comprehensive in my opinion

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

Definitely – this is the only way to ensure transparency

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

Everything – product suppliers – volume sold – any adverse effects reported etc.

7 How long should licence holders be required to keep records for?
Standard requirements of 7 years as these are such new products. By keeping records, if any problems down the track at least MOH have an idea of how much of the product has been in distribution.

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?

Yes – criminal background, we need to be sure people selling are of good repute to ensure as much compliance with the law as possible.

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 to help ensure public safety

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?

Maybe – these are relatively new products and no real long term data is possible so this may be a little unrealistic

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?

Only to a certain extent due to the nature of the product being very new

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

Yes – R18 is the main one along with chemical in question on packaging.
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 see new ones have poisons centre info and 111 advice – I feel this is enough. They are only little packages, there is only so much able to be printed on them.

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 – this will drive the product underground and raise prices even further. It is unrealistic to restrict in my opinion, I hear in my area that the local gangs are selling it, if selling restricts to 1 dose, then this will help them but take away the safety net of buying from a reputable seller with some sort of control such as we have at the moment.

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

No – same reasons as 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?

I agree with the product being able to be smoked, but am not so sure about pills, once you have taken a pill the effects are not known until it has dissipated in the body, and you can’t go back, at least with a smoke it can be a slower more controlled process.

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 – since the product has to be out of public view, mainly in R18 shops or similar I feel this is adequate.

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

Storage – not for sale straight away – should be in locked areas, preferably safes or similar. Perhaps after hours the product should be locked up also in case of break in.

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

No as you have to be 18 to access the majority of shops, and those that are not R18 have to keep product out of public sight in case minors see it. These are adequate restrictions in my opinion.
23 Do you think restrictions or requirements should be set regarding the disposal of approved products? If so, what should they be?

No – once it is off the shelves it is the license holder's responsibility to dispose of.

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

No

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

No – keep the status quo. It appears to be working the way it is. No dairies, petrol stations etc.

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

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

No – if it is legal to buy it then anybody should be able to buy it where they want. The thing is to impose higher fines if anybody is abusing the privilege and on-selling it.

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

No advertising.

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

Yes – everybody is equal then and aware of what they are expected to provide and at what cost.

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

Fixed fee. One cost for all.
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: jenny@rangitaane.iwi.nz
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): interested party .................................................................

Do you wish to receive updates about the development of the psychoactive substances regulations?
☐ Yes  ☐ No  yes please
(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?

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

   Yes. The Drug Foundation also supports the inclusion of a proposal to include consent to undergo a Police check on the application.

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

   Yes. Licenses should not be granted if applicants do not comply with their local LAPP. However, in order to support this process, local authorities should provide applicants with a standard template to help them to provide proof of compliance. This is likely to speed up the process for applicants, reduce work for the Authority and local councils and remove uncertainty.

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 – in principle. However any generic local approved products policy needs to be developed through robust consultation. There are widely varying views as to what a generic LAPP would look like.

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 Drug Foundation supports the proposal to include the New Zealand Customs Service and the Police in the fit and proper person check.

Applicants should also be able to provide character references and other evidence of their standing in the community (e.g. Board membership, community service) if they choose to do so.

Another matter the Authority may want to consider is whether or not the applicant is a member of the Psychoactive Industry Training Association and has therefore signed up to their Code of Conduct.

Although section 16(2) of the Act includes all Misuse of Drugs Act 1975 offences as factors that the Authority must take into account when determining if someone is a fit and proper person, we assert that possession and use offences under MoDA should not be taken into account. Given that almost 50 percent of adult New Zealanders have used an illegal drug, possession and use convictions are likely to say less about someone’s character and more about someone’s ethnicity, luck or previous history of dependence.

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

Yes. As well as the factors set out in 16(2) of the Act, the Authority should also consider:

- Relevant offences under the Sale of Liquor Act, Sale and Supply of Alcohol Act, and the Smoke Free Environments Act.
- Violation of licence conditions and Regulations under the Sale of Liquor Act, Sale and Supply of Alcohol Act or the Medicines Act.

The Drug Foundation also recommends that the Authority should reject any applicant who has been convicted of, or had a license suspended or cancelled for, the unlawful sale of an age-restricted product to a minor.
6 What records should the regulations require licence holders to keep?

The Drug Foundation supports the record keeping requirements proposed in the consultation document and the logic behind these proposals.

Given the limited knowledge we have around these substances and the fact that this is a new approach, it is important to collect data that will help New Zealand to evaluate the success or otherwise of the Psychoactive Substances Act and relevant regulations, and amend these as required. This includes data that can only be collected by those involved in the supply, manufacture and development of these products.

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 price of sale, 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:

- Incidence records along the same lines of Liquor Licence Incidence record, e.g. 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:

- To demonstrate their research practices are suited to the stated purpose of obtaining the licence.
- To ensure psychoactive substances or products obtained under their licence can be traced.
- To support any review by the PSEAC of data they have submitted in an application for product approval.
- To support compliance with other relevant legal and ethical standards for research.
- 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?

With the exceptions addressed below, records should be kept for the standard 7 years to enable audit.

For manufacturing licences, records should be kept for as long as that product or substance is being manufactured or sold. This is particularly important in regards to records around batches and product development.

Any record keeping relating to research or clinical trials should meet relevant standards for similar human medical/drug trials. As there can be a significant time differential between consumption and effect, this is critical for establishing the long term effects of a product or substance and for protecting the health of trial participants and the wider public should adverse effects arise in the future.

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

The Drug Foundation agrees:
- That licence holders should display their licences.
- That intent to sell via the internet should be declared.

We also agree that there should be physical separation of licensed premises from non-licensed premises.

When the Authority does grant a retail licence the following conditions should be universally applied:

- Sale to intoxicated persons is prohibited.
- Staff must seek age identification from any person who appears to be under the age of 25 years prior to any sale of these products.

While we agree with other submitters that there should be restrictions on opening hours for retail stores, we disagree as to what those hours should be. Although we understand the logic behind wanting to restrict hours from 9am-3pm this is disproportionately restrictive given that these products are going to have to pass 'low risk' tests that alcohol would fail. Any national restrictions on maximum retailing hours for these products should be more closely aligned to those applied to alcohol off-licences (7am-11pm). Restrictions also need to take into account that these products are substitutes for illegal drugs (which are available 24/7).
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.

For retail licences, the Drug Foundation recommends:
- The Authority should also take into account the profile of the community the store would be operating in, paying particular attention to pre-existing deprivation and poor wellbeing and whether or not other outlets are already in the area. New Zealand needs to learn from its experience with alcohol and ensure that stores aren’t concentrated in poorer communities with greater pre-existing health and social problems.
- The Authority should also consider whether the manager or staff have undergone suitable training and whether or not the applicant has a staff induction or ongoing training programme in place.
- The Authority should also take into account the effect of not granting the licence, including the development of monopolies and the potential for refusal to undermine the purpose of the Act.

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.
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.

In addition the Drug Foundation recommends:

- Data on the factors listed in questions '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. This should include information on likely levels of impairment at different doses and the likely impact on tasks such as driving.
- Product approval applications should also include the intended quantities and dose-quantities per package alongside directions regarding suitable dosage and use.
- The information provided on proposed directions for use should include proposals for product specific health warnings and harm reduction advice.
Are the proposed requirements and restrictions on labelling sufficient? If not, please make specific suggestions for further requirements and restrictions.

The Drug Foundation supports the labelling requirements proposed.

As per earlier comments, we do not support the ongoing use of the National Poisons Centre as the primary agent of monitoring adverse reactions. However, we note that they are still able to play a role (that CARM cannot) in offering 24/7 advice to those suffering from adverse reactions. It therefore makes sense that their number should be included in any labelling of these products.

The Drug Foundation also supports:

- The inclusion of the Alcohol and Drug Helpline number on all labelling.
- The requirement that labels appear on both inner and outer packages.

Labels should also include:

- 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.
- Basic harm reduction advice for the product or information on how to access this advice e.g. Drug Foundation website.

In regards to plain packaging, we agree that plain packaging would help to prevent these products from appealing to minors. We also agree that branding is a form of advertising and that Section 56(3) of the Act is clear that all advertising "must be limited to material that communicates objective information about the product." By that logic, it makes sense to support the use of plain packaging in regards to these products.

However, unlike tobacco, these products are going to be significantly varied in terms of their strength, composition and effects — even among a single class of products (e.g. synthetic cannabis). As products within the same class (e.g. pills or smokeables) tend to look similar, it’s the packaging that helps people to distinguish one product from another. While we support restricting what can appear on packaging, we do not support the use of a completely standardised format and colour scheme for every product.

This is because it is important that people (and consumers in particular) can easily identify and distinguish between different products. If something goes wrong with a product and it needs to be recalled, the unique packaging of that product is going to be helpful in quickly removing it from the market and communicating to people which product is harmful and should be avoided. It is also going to help people to describe the particular product (that they may have only used once, or may have got from a friend) that has caused them to have an adverse reaction.
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 Drug Foundation supports the use of the health warnings listed but agrees that there should be two additional warnings:

- All psychoactive substances carry risk of adverse reaction.
- Effects of long-term, regular use of this product have not been assessed.

Health warnings need to be tailored to each product's specific risk profile. While some warnings should be applied to all products, some products are going to require additional warnings. Other products may be specifically developed to not need certain warnings (such as mixing with alcohol). The Authority needs to use both the clinical data provided by testing and its ability to set discretionary conditions on licenses to ensure that product warnings are tailored to the product in question.

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

The Drug Foundation strongly supports that the content of labels and inserts, their appearance and accessibility be approved by the Authority.

We also support requirements for packaging to be tamper and child proof and the ability of the Authority to refuse packaging that associates approved products with youth culture.
17  Do you agree with the proposal to restrict a packet to one dose? Please give reasons for your answer.

The Drug Foundation can see both potential benefits and risks in restricting a packet to one dose.

On the plus side, it gives consumers certainty around how much to take – particularly in regards to products such as synthetic cannabis where measuring a dose is more difficult than it is with a pill. Dose restrictions could also limit people’s intake and reduce the risk of overdose – although in fairness the ‘low risk’ nature of any approved substances should mean the risk of overdose is small anyway.

On the negative side, restricting a packet to one dose is likely to bring down the purchase price of these products and make them more financially accessible to young people and vulnerable populations. We note that in regards to alcohol and tobacco, New Zealand has regulated in the other direction (e.g. banned packs of 10 cigarettes and single sales) for exactly this reason. It seems both counterintuitive and disproportionate to do the opposite for new psychoactive products (which again are likely to be less harmful than both alcohol and tobacco).

Ultimately we do not agree that there should be a blanket provision that all packets should be restricted to one dose. This is another case where the Authority needs to use data on the risk profile of a product and its discretion to tailor restrictions to the nature of the product.

Rather than regulating one dose only packets, the regulations would be better to focus on ensuring that consumers are supported to make informed choices and take action to prevent harm. We have made a number of recommendations to that effect throughout this submission, and would expect any harm reduction information/activities to include information around dosage and the importance of not taking too much of a product you are unfamiliar with.

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

Again, the Drug Foundation believes that this should be a discretionary rather than blanket provision and any decisions about split doses should be made by the Authority based on the evidence of the risk profile of each individual product. See also our comments above around harm reduction.
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. The Drug Foundation agrees that the regulations should stipulate that products intended to be injected should not be permitted.

We will be interested to see if any smokeable products pass the ‘low risk’ test, given the evidence around the negative health effects of smoking anything. Although we don’t expect that people would (generally) smoke these products as frequently as people smoke cigarettes, we would still expect smokeable products to be excluded by the nature of their mode of administration. However there are ways that smokeable products can be consumed without smoking them (such as vaporisation) but this could also be achieved if the product took other forms (e.g. ‘resin’).

One potential risk in explicitly restricting smokeable products is that as most synthetic drug users seem to be synthetic cannabis users, and smoking is the most common form of consumption, people may move back to illicit drugs if smokeable products are unavailable. Therefore, rather than putting a blanket restriction on smokeable products it may pay for products to be allowed to go through the testing process and decisions made on an individual basis. We note that any smokeable products that do pass the ‘low risk’ test would already be covered by the Smokefree Environments Act.

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. The Drug Foundation believes that psychoactive substances need to be stored securely (where they cannot contaminate other products or the wider environment and cannot be accessed by children, the public or other unauthorised persons) and that storage facilities need to have sufficient levels of security to prevent these substances from leaking into the black market.

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

Yes. Again, the Drug Foundation believes that psychoactive products need to be stored securely (where they cannot contaminate other products or the wider environment and cannot be accessed by children, the public or other unauthorised persons) and that there needs to be a sufficient levels of security to prevent these substances from leaking into the black market.

Given that retail stores are already being targeted by thieves, it may be worth stipulating a maximum amount of product that can be kept in store at any one time. Without knowing how much stores are selling per day — and assuming that there is likely to be significant variation between stores — it is difficult to propose what this maximum amount would be. Also stores with higher levels of security should be allowed to keep more product on site than stores with lower levels of security.
22 Do you think restrictions or requirements should be set regarding the display of approved products? If so, what should they be?

Yes. Product display should be locked and behind the counter to make shoplifting more difficult and to better restrict access to those aged 18 and over. Product displays should not be visible from the street.

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

Yes.

There are two factors that need to be taken into account. The first is that disposal processes for approved products needs to be certain — there must be no chance that once disposed of, products will find their way back onto the market. We note that when the Act was introduced in 2013 there was widespread dumping of product which then ended up on the black market and frequently made its way into the hands of minors. The regulations need to prevent this from happening again. As such, disposal processes need to be clear, enforceable and easily monitored.

We recommend that disposal processes need to be overseen by the Authority or the Authority needs to delegate sufficient powers to agencies (such as the Police or District Health Boards) to allow them to oversee this process. A form could be completed by the regulatory agency — recording the product type and amount, identity and relevant licence number of the person or company the products have been received from — and confirming that the regulatory agent has seen the product as described (type, amount) and disposed of it according to requirements. This information will need to be checked against the information provided by licence holders to ensure that all relevant products have been accounted for.

The second factor that needs to be considered is the method of disposing of approved products and their packaging in a manner that ensures public health and safety and environmental protection. Different products/packaging may require different methods of disposal. While this is not something we have any particular expertise in we assume that New Zealand already has regimes in place for safely disposing of potentially hazardous chemicals/materials that would work equally well for these products. We also note that the United Nations Office on Drugs and Crime Guidelines for the Safe handling and disposal of chemicals used in the illicit manufacture of drugs may be helpful in developing appropriate regulations.

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

Yes. All retail stores should have to prominently display the signage described below:
- It is an offence to sell or supply Psychoactive Substances to anyone aged under 18.
- It is an offence for anyone under 18 to purchase Psychoactive Substances.
- Prominent signage detailing signs of dependence and where to access help.
- Prominent signage detailing harm reduction techniques.
- Prominent signage detailing an appropriate reporting number to call to report adverse effects.

The name of the Duty Manager should also be clearly displayed.
25 Do you think the regulations should specify further places where approved products may not be sold? If so, please provide specific suggestions.

| Discount stores (e.g. $2 shops). |
| Any store or venue with particular appeal to young people (e.g. arcade, movie theatre). |

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

The only loophole the Drug Foundation can see in the Act's restrictions around advertising is around products sold by internet sale (which are exempted from s56(3)).

We recommend that advertising for approved products sold by internet sale:

1) Must be limited to material that communicates objective information about the product, including (without limitation) —
   i) the active ingredients of the product and the appropriate quantity of each active ingredient;
   ii) the price of the product

2) May only appear on an internet site for the primary purpose of the internet sale of approved products or in premises where approved products are sold

3) If the advertising appears in premises where approved products are sold then it should be subject to the restrictions outlined in s56(3) of the Act.

The offences and penalties for breaching these regulations should be the same as someone who contravenes subsection (1), (2) or (4) of s56 of the Act.

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 Drug Foundation supports all of the proposed requirements. There also needs to be a more robust method of verifying age before purchasing than is currently the case with alcohol.

We also note that there needs to be some clarity around where responsibility sits for monitoring compliance of internet sites, including controlled purchase operations.

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

The Drug Foundation supports the proposal that that 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.

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

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

32 Do you agree with the proposed list of items and process for setting levies? If not, please provide specific suggestions.
While the Drug Foundation agrees with the proposed set of items listed, as time goes on there will undoubtedly be more added to the list of activities the Authority needs to engage in to ensure the smooth administration of this regime. In the interests of ensuring ongoing funding, and ensuring that people are contributing financially to this regime in a manner commensurate with how much they benefit from it, it would make sense that an excise tax regime be used instead of a levy system.
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) Catherine McCullough
Address: (street/box number) Level 3, 111 Dixon Street
(town/city) Wellington
Email: Catherine.mccullough@drugfoundation.org.nz
Organisation (if applicable): New Zealand Drug Foundation
Position (if applicable): Senior Adviser, Policy Development and Knowledge Translation

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): As a civil society organisation focussed on reducing drug-related harm in New Zealand

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

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.
About the Drug Foundation

The New Zealand Drug Foundation was established in 1989. It is an independent trust with a national focus on minimising drug-related harm. This includes social and health harms caused by legal drugs, such as tobacco and alcohol, as well as illegal drugs, such as cannabis.

The Drug Foundation advocates evidence-based policy on these issues, and provides reliable and credible information to organisations and individuals. We take a lead role in networking and cooperation within the alcohol and drug sector.

The Drug Foundation recognises that drugs, legal and illegal, are a part of everyday life experience. Drugs, and their use, impact on many of us, and on the people we care about. Harms to individuals and families include injury, disease, social, personal and financial problems and a reduced quality of life. Harms to society include unsafe communities, increased need for law enforcement, and high health and economic costs. For these reasons, the Drug Foundation is committed to reducing drug use and its harmful consequences.

This commitment to reducing harm includes ensuring that any illicit drugs, if used, are used safely. Our focus is on advocating for policies that build a healthy society where there is the least possible harm from drug use. All efforts to control or reduce the harm from drugs must be evidence based, socially just and maintain the rights of individuals and the aspirations of communities.

The Drug Foundation provides leadership and representation for our nationwide membership of organisations and individuals working on alcohol and drug issues. The Drug Foundation is a member of the International Harm Reduction Association, the Global Alcohol Policy Alliance, the Vienna NGO Committee on Narcotic Drugs and the International Drug Policy Consortium.
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Philip Siataha
Kaimahi, Waipuna Trust Community Action on Youth and Drugs, St John of God
From: Hawke’s Bay & Mokai Whanau Ora CAYADs

Re: Submission on Psychoactive Substances Regulation

The Hawke’s Bay CAYAD covers the Napier and Hastings area. We have 2 FTE with the general aim of reducing the harms of alcohol and other drugs especially amongst youth. The Mokai Whanau Ora CAYAD operates nationally and targets methamphetamine specifically with a similar harm reduction objective. It has 1 FTE. This submission is generally the same as those from other CAYAD sites but will have variances.

1. Introduction

In concert with our fellow CAYADs we wish to raise some additional considerations regarding the purpose of the Psychoactive Substances Act (“the Act”) that are not covered in detail in the consultation questions.

2. Additional Considerations

2.1 Generic Local Approved Products Policy

We support the proposal to create a Generic Local Approved Products Policy that applies as a default mechanism 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, particularly to reduce the exposure of young people and vulnerable people to the harmful effects of psychoactive products. We suggest:

- Restricting premises selling be 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.
Access to points of sale should be restricted to those 18 years and over

2.2 Local Approved Products Policies (LAPP)
These policies do not carry the same heft as the Local Alcohol Policies. We believe that the LAPP should be analogous to the LAP, be reviewed with the same regularity and contemporaneously with the LAP as, after all we are simply dealing with intoxicants.

We believe that, with the introduction of potentially many new unknown intoxicants, equally strong controls as those like those possible for alcohol and within Local Alcohol Policies should be available to local authorities managing psychoactive substances. We suggest these include:

- 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 for public places (venues) and spaces (times)
- The ability to introduce bans on the use of psychoactive substances including nicotine in public places (venues) and spaces (times)

We suggest that decision-making councillors deliberating on LAPPs

- demonstrably have no vested interest in the wholesale, manufacture or retail of psychoactive substances/products including alcohol
- have no other conflict of interest including ownership of property nor involvement in businesses within the zone of the local policy

2.3 Internet retail
We recommend the prohibition of the internet sale of psychoactive substances to achieve the intent of the regulatory framework as regards the control and supply of psychoactive substances through LAPPs. Internet sale makes products available anywhere, and with very limited oversight or connection made with purchasers of products who may be highly vulnerable individuals. The internet driven supply chain cannot ensure that the recipient, say of a courier pack, is over 18 years of age.

2.4 Research into substance or product risk levels
The trial and assessment of new psychoactive 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 and determine that they should be the only people able to provide the trial data that the Psychoactive Substances Expert Advisory Committee (PSEAC) and the 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.

2.5 Monitoring and reporting adverse reactions
In light of New Zealand’s experience with alcohol and tobacco 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 suggesting 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.

2.6 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".

Along with other CAVAD sites 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 support the suggestion that 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. AS previously noted New Zealand research has shown that recreational drugs are very often used in combination here, most commonly with alcohol\(^2\).

2.7 Tax

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

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\(^1\) 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

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

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

2.8 Drug-Driving
We recommend that, for each product that is to be approved, 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.

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

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

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

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

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

3. 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?
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 will be efficient for confirming eligibility of applications for further processing.

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 18(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.
  - Failure to report to the relevant body (ie distributor or manufacturer) by a customer or family member of adverse effects to the relevant entity.
  - 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.

Breachs 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.

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.
- Capacity to meet product testing and trial standards used internationally for medicines.

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

Yes, 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 protecting the public from 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

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

7 years to enable sufficient time for audit processes.

Research:

Record keeping for research and clinical trials should meet relevant standards for similar human trials for approval of medicines.

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 to apply generally to all retail licences. In addition, we recommend the following conditions apply generally to all retail licences:

- A requirement to seek age identification from any person who appears to be under the age of 25 years old prior to sale.
- To better protect vulnerable populations who are at greater risk of harm from use of psychoactive products, we suggest a requirement for staff training on:
  - 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
- Sale to intoxicated persons should be defined and prohibited, including intoxication by any drug including alcohol, due to risks combining use with other products or engaging in risky consumption (taking more than recommended doses).
- A restriction on the retail of products to the hours of 9am to 9pm only. This will reduce the risk of young people accessing products before school hours. The closing time also limits the opportunity for intoxicated people leaving closed venues that sell alcohol seeking to continue their recreational activities through additional purchase of psychoactive substances. The mixing of such products is likely to carry risks that won’t be assessed during product approval processes.
- Consideration of a “day off” e.g. Sunday whereby sales are banned totally. This gives an opportunity for people to break the cycle and/or will bring issues of addiction to the fore.
- Consumption of psychoactive products within a retail-licensed premise does not appear to be considered under the Act or the proposed regulations. We therefore recommend an interim requirement that licensed retail premises prohibit consumption inside their premises, at least until such time as health impacts of such supply and usage can be assessed and consulted upon, and appropriate health measures and regulations developed. For the interim, this avoids the possibility of intensive use at a party venue, where intoxicated persons may continue purchasing and taking excessive doses of psychoactive products that would be damaging to their health.

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.

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

Yes.

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.

In addition, we recommend:

- Inclusion of behavioural effects in the list above.
- A requirement to include any known data on effects of the substance on vulnerable groups such as those at risk of mental illness or who are already dependent on alcohol or other drugs.
- A specific requirement for the same data as above to be provided for the final product for which approval is sought, as the product may contain combinations of substances, psychoactive or otherwise.
- A warning not to use in conjunction with other intoxicants or prescription medicines.

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 information and data should be provided for the substance.

In addition we recommend a requirement to include:

- Any known information or data on effects of the substance on vulnerable groups such as those at risk of mental illness, young people or those who are already dependent on alcohol or other drugs.
- Data and information on the use of products when combined with use of other common drugs including alcohol, cannabis and tobacco should be provided, with reference to the effects listed at both questions 12 and 13. Poly-drug use is noted as a particularly risky and common pattern of use of recreational drugs in many studies, and recently with BZP party pills3.
- 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.
- Data on previous use in the "wider population" could include populations overseas.


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.

To ensure lack of appeal to minors, we recommend plain packaging of products. Further, imagery and slogans on packaging 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.

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’, it is possible that users will likely consider the products to be safe and of low strength, and that they may regularly take more than double recommended doses, as was the case with use of benzylpiperazine (BZP) party pills before they were prohibited (Sheridan et al., 2007). A prominent warning will remind people to consider the known risks of the substance and the recommended dosage and directions.

In addition, we suggest adding three further warnings:
- All psychoactive substances carry risk of adverse physical and psychological reactions
- Health effects of long-term, regular use of this product have not been assessed
- If smokable products are permitted, a warning that inhaling smoke will cause damage to the lungs.

Ref:

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.

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 supports the intention of the Act to protect the health of users (Chan, 2000).


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


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:

- Smokable forms - due to impact on lung function and therefore overall fitness, which is very important to protecting health.
- If smokable forms are allowed, additional regulations on product use should be applied, 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
- Approved products should not be pre-mixed with food and beverages, due to risk of accidental consumption by adults and particularly children.

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

Yes – 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.

We recommend a level of security be required to include monitored alarm systems at the least, with discretion of the authority to require other security elements as it sees fit.

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

Yes. Hawke's Bay outlets have been robbed. 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 two days of normal trade.

We recommend a level of security be required to include monitored alarm systems, with discretion of the authority to require other security elements as it sees fit.

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?

Yes - a process for disposal that can be trusted and tracked back 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 psychoactive substances/retail 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 of the Hazardous Substances and New Organisms Act.

We have seen the necessity of such a provision in the rural Bay of Plenty, where a CAYAD site has been informed of the 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 young people at much lower prices than normal retail. Should other products be recalled, such dumping could occur again and careful local planning should be put in place for such recall situations.

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

- Premises should be required to have signage indicating:
  - products will not be sold to under 18s
  - No consumption on premises
  - Details for help (which should also be available on hand out slips)
    - Where to go for emergency help
    - Reporting number to call to report adverse effects
    - Signs of addiction, dependence or health issues and ways to access help for these issues

We actually believe that points of sale should be limited to those 18 years of age and over.

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

We recommend retail should only be possible through stores where entry is restricted to people 18 years or older. This will avoid leakage of products to young people through shoplifting. In addition, sale in other premises that are frequented by young people could normalise psychoactive products to under 18s and we recommend this is avoided.

We would strongly prefer that internet sale is prohibited. However, should it be allowed, a low maximum number of internet sellers should be set, such as 10, to allow reasonable monitoring of their practices.
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.
- 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.
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) Denis O'Reilly
(street/box number) PO Box 7070
(town/city) Taradale
Email: denis@denisoreilly.co.nz
Organisation (if applicable): HB CAYAD
Position (if applicable): 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): Community Action Advocates

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

From: Dr. Chris Wilkins, Drug Research Team, SHORE & Whariki Research Centre, College of Health, Massey University

Re: Submission on Psychoactive Substances Regulation

Thank you for the opportunity to provide a submission on the proposed Psychoactive Substances Regulations.

General Comments:

As outlined in our previous public submission on the Psychoactive Substances Bill, we believe there are a number of important gaps in the new NPS regulatory regime which impair its ability to minimise harm and promote public health. These are:

1. Absence of a product tax on NPS products

The New Zealand Law Commission recommended the imposition of a product tax on NPS products similar to that which is now imposed on alcohol and tobacco products. They note alcohol studies have found price to be a ‘critical factor in moderating the demand for alcohol’ and that ‘cheap products are favoured by heavy, harmful and young drinkers’ (New Zealand Law Commission, 2012, p.138). The Ministry of Health have recently increased the excise tax on tobacco products in recent years, advocating it as an important policy tool to reduce smoking and related harm in New Zealand (Ministry of Health, 2007). It should be noted that in all places where cannabis has recently been legalised a product tax on cannabis products is planned to be imposed. A tax on approved NPS products would provide funding to agencies and services which will be required to address the harm from NPS use, including emergency, health, social services, police, customs and drug treatment. A tax would also cover the costs of operating the new Psychoactive Substances Regulatory Authority including enforcement agents.

We request that a regulatory process be introduced into the psychoactive substances regime to allow the imposition of product tax on NPS products once the demand for NPS products is known.

2. Identifying low risk products

The clinical tests required for an NPS product have previously been described as ‘broadly similar to those for new medicines’. Details of the testing have not been included in the Psychoactive Substances Act. There is no indication whether these tests will be required to meet international standards for medicines. We have identified a number of characteristics of the recreational use of NPS which may not be well addressed by a standard clinical trial for a medicine. These include the harms from excessive use (i.e. during hedonistic social occasions), poly-drug use combination with alcohol and cannabis, risky means of administration (e.g. injection), and use by vulnerable people, for example those with mental health issues, alcohol and drug dependent and risk taking young people.

We request that standard clinical trials for medicines be extended to include the specific risks from the recreational use of NPS products.
3. Who conducts the product testing?

We are concerned that the scientific testing of NPS products is conducted to the highest scientific standard. We support the decision that the industry should pay for product testing but are concerned the industry will be able to manipulate testing via direct funding of researchers and research institutes, and control the subsequent test data from these trials. The pharmaceutical industry has a long history of unethical involvement in clinical trials of medicines via direct funding of researchers and research institutes (Goldcare, 2012). This has included manipulating trials to produce favourable results (e.g. by selecting test subjects, and by determining the length of trial and who drops out), withholding the results and data from unfavourable trials, and controlling research institutions via funding contracts (Goldcare, 2012).

We recommend that the testing of products should be conducted by an independently certified research institution which is contracted by the Psychoactive Substances Regulatory Authority (not the industry) and has no funding links to the industry.

4. Controlling the black market unapproved NPS products

The authorities are likely to face challenges in suppressing the black market for unapproved NPS given unapproved NPS will look exactly likely their approved counterparts. If people can continue to use unapproved NPS products largely without penalty then this will undermine the legal market. There is a chance that legal approved NPS products will simply be more popular. However, unapproved products may be able to offer unique attractions, such as a more powerful effects, means of administration and lower price.

The task of identifying unapproved NPS products could be enhanced with the development of sophisticated product labelling (e.g. hologram watermarks, bar codes) and real-time testing technology which can be utilised by the authorities to instantly verify a product is approved. A simple confirmatory test could be used to identify approved compounds. Those products which fail would be confiscated and subjected to further more in-depth testing.

5. Monitoring NPS products

Post-approval monitoring will be important to ensuring approved NPS do not pose unintended health risks (i.e. known as pharmacovigilance). The PSA requires licence holders to report adverse effects from an approved NPS product, and the regulator has the power to withdraw a product. There are a number of instances where pharmacovigilance may fail to identify problems from a medicine including instances of rare side-effects, common complaints which can be easily associated with other illnesses, long time frames between use and adverse effects, and the low profile of a medicine. Pharmacovigilance may be particularly challenging for NPS as NPS products will often be combined with alcohol and other drugs, and the resulting ‘hang-over’ effect may reduce reporting of complaints, and further complicate the process of isolating side-effects to a specific product. Pharmaceutical companies are increasingly required to provide post-approval monitoring plans which outline how a product and any related adverse effects are to be monitored.

Legal high manufacturers should be required to provide post-approval monitoring plans which outline how their product and any related adverse effects are to be monitored.

6. Local Approved Product Policies
Local authorities should be given the power to impose a cap on the number of NPS retailers in their districts and impose restrictions on hours and days of operation (e.g. prohibiting sales after 6pm). They should also be able to provide minimum distances of NPS retail outlets from alcohol retail outlets.

7. Information on adverse effects

Some health reporting sources largely rely on self-reported information from the public, who may be reluctant to report the use of illegal drugs or neglect to report the co-consumption of alcohol or pharmaceuticals. Even hospital emergency medical cases often do not include all the information and tests required to make an accurate assessment of the safety of a product due to the time pressure of the emergency, the fact that toxicology and drug confirmation tests were not deemed necessary, the patient was not admitted to hospital, the incident largely resolved itself, or the patient voluntarily left before receiving any follow-up care. These gaps in the information available from routine emergency department cases are the reason why studies of adverse cases from NPS products in New Zealand have required the design of customized data collection instruments or refined retrospective case searches. The Hermanns-Clausen et al paper illustrates the value of having toxicology and drug confirmatory tests available to assess the toxicity of synthetic cannabinoid products. Some legal high manufacturers have raised concerns that decisions about the safety of NPS products may depend on unreliable self-reported information from users, and as a consequence, the system could be exploited by unethical operators wishing to discredit the products of rivals.

These issues suggest that the effective use of the NPS product safety assessment framework will require the commission of retrospective studies of NPS adverse cases and additional test data.

References


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?
   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.

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 Police ‘fit and proper person’ check.

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. Including:
  - 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.

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

Yes, particular with alcohol as it is not permitted to sell alcohol in the same premise as NPS products.

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 protecting the public from 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

7 How long should licence holders be required to keep records for?
RPH – 7 years to enable audit

Research:
Record keeping for research and clinical trials should meet relevant standards for similar human medical trials.

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 to apply generally to all retail licences. In addition, we recommend the following conditions apply generally to all retail licences:

- A requirement to seek age identification from any person who appears to be under the age of 25 years old prior to sale.
- To better protect vulnerable populations who are at greater risk of harm from use of psychoactive products, we suggest a requirement for staff training on:
  - 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
- Sale to intoxicated persons should be defined and prohibited, including intoxication by any drug including alcohol, due to risks combining use with other products or engaging in risky consumption (taking more than recommended doses).
- A restriction on the retail of products to the hours of 10am to 6pm only. This will reduce the risk of young people accessing products before school hours. The closing time also limits the opportunity for intoxicated people leaving closed venues that sell alcohol seeking to continue their recreational activities through additional purchase of psychoactive substances. The mixing of such products is likely to carry risks that won't be assessed during product approval processes.
- Consumption of psychoactive products within a retail-licensed premise does not appear to be considered under the Act or the proposed regulations. We therefore recommend an interim requirement that licensed retail premises prohibit consumption inside their premises, at least until such time as health impacts of such supply and usage can be assessed and consulted upon, and appropriate health measures and regulations developed. For the interim, this avoids the possibility of intensive use at a party venue, where intoxicated persons may continue purchasing and taking excessive doses of psychoactive products that would be damaging to their health.

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 (minimum distance of 500 metres from each other and sensitive sites).
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?
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.

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.

In addition, we recommend:

- Inclusion of effects from combining the product with other common intoxicants such as alcohol and cannabis (Wilkins et al., 2008).
- Impacts related to exceeding the recommended dose (e.g. +20%, +50%, +100%, +200% recommended dose)
- Impact on effects from different modes of administration to that recommended (e.g. smoking or injection)
- Assessment of the effect of the substance on vulnerable groups such as those at risk of mental illness or who are already dependent on alcohol or other drugs (Wilkins, 2014).

This data should be made publicly available.

References


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

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.

In addition we recommend a requirement to include:

- Any known data on effects of the substance on vulnerable groups such as those at risk of mental illness, young people or those who are already dependent on alcohol or other drugs.
- 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.
- Data on previous use in the "wider population" could include populations overseas.
- Impact on effects from different modes of administration to that recommended (e.g. smoking or injection).
- Inclusion of effects from combining the product with other common intoxicants such as alcohol and cannabis.
- Impacts related to exceeding the recommended dose (e.g. +20%, +50%, +100%, +200% recommended dose).
- Impact on effects from different modes of administration to that recommended (e.g. smoking or injection).

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.

In addition we recommend labels include details of:

- drug addiction and mental health support lines
- contact details for Psychoactive Substances Regulatory Authority
- All contents of the product (not only the active ingredients), grouped as psychoactive and non-psychoactive
- All 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 20%) 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', it is possible that users will likely consider the products to be safe and of low strength, and that they may regularly take more than double recommended doses, as was the case with use of benzylpiperazine (BZP) party pills before they were prohibited (Sheridan and Buttre, 2009, Wilkins and Sweetsur, 2010). A prominent warning will remind people to consider the known risks of the substance and the recommended dosage and directions.

In addition, we suggest adding three further warnings:
- All psychoactive substances carry risk of adverse physical and psychological reactions
- Health effects of long-term, regular use of this product have not been assessed
- If smokable products are permitted, a warning that inhaling smoke will cause damage to the lungs.

References


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 in advance by the Psychoactive Substances Regulatory Authority, and as stipulated in the Act be limited to objective data about ingredients and price, and not be deemed attractive to minors.

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 supports the intention of the Act to protect the health of users (Chan, 2000).

Reference

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

Reference

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 the following forms should not be approved:
- Smokable forms - due to impact on lung and cardiac function and overall health,
- E-cigarettes as they promote high dosage behaviour.
- Appeal to minors - support that product forms with appeal to minors should not be allowed (e.g. lolly-pops, sweets)
- Easily injectable forms, products should include protection against being made easily injectable
- Sachets which can easily be added to alcohol drinks
- Approved products should not be pre-mixed with food and beverages.

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 -- 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.

We recommend a level of security be required to include monitored alarm systems at the least, with discretion of the authority to require other security elements as it sees fit.

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 two days of normal trade.

We recommend a level of security be required to include monitored alarm systems, with discretion of the authority to require other security elements as it sees fit.

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?

Yes - a process for disposal that can be trusted and traced back 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 psychoactive substances/retail 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 of the Hazardous Substances and New Organisms Act.

We have seen the necessity of such a provision in the rural Bay of Plenty, where a CAYAD site has been informed of the 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 young people at much lower prices than normal retail. Should other products be recalled, such dumping could occur again and careful local planning should be put in place for such recall situations.

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

Premises should be required to have signage indicating:
- products will not be sold to under 18s
- No consumption on premises
- Details for help (which should also be available on hard out slips)
  - Where to go for emergency help
  - Where to go for advice for alcohol and drug problems, mental illness
  - Reporting number to call to report adverse effects
  - Contact number for Psychoactive Substances Regulatory Authority

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, retail should only be possible through stores where entry is restricted to people 18 years or older.

In addition, sale in other premises frequented by young people may normalise psychoactive products to under 18s.
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 restricted to objective information about ingredients and price, not be attractive to minors, and consistent with the Advertising Standards Authority's Advertising Code of Ethics
- Prohibition of endorsement of products via all media sources (including internet blogs etc). Anyone with a large online following 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.

We recommend:
- There should be a restriction on product endorsement with fines consistent with section 56(5) of the Act.

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

- Advertising on sites must be restricted to objective information about ingredients and price, not be attractive to minors
- A cap should be imposed on the number of websites which can sell approved products
- 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 the Act which restricts advertising to objective information about ingredients and price, not be attractive to minors

29 Do you agree with the proposed fees for the different licences? If not, please provide specific suggestions.
30. Do you support a fixed fee or an hourly charge for processing applications for product approvals?

No comment

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

Yes – levies should be collected to enable:
- The conduct of research studies to assess the health risk of newly approved products
- The completion of a research evaluation of the new regulatory regime to provide evidence of its effectiveness and impact on alcohol and other drug use
- Development and operation of information 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 should be collected from retailers to enable:
- Development, delivery and evaluation of standard training on safe retailing practices e.g.
  o identifying under 25 year olds and appropriately seeking identification
  o signs of intoxication, drug-related health or addiction issues
  o 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) Chris Wilkins
Address:  (street/box number) SHORE, P.O. Box 6137, Wellesley Street
         (town/city) Auckland
Email: c.wilkins@massey.ac.nz
Organisation (if applicable): Massey University
Position (if applicable): Senior Researcher, Drugs Team Leader

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): University research centre ..................................................

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.)
c.wilkins@massey.ac.nz

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
Making a submission

Submissions close on Friday 21 March 2014 at 5 pm.

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

Please detach and return this part of the document.

Consultation questions

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

2. Should retail licence applications be accompanied by evidence of compliance with a local approved products policy if one is in effect in the applicant’s area?
   Yes – we believe they the retail applications should be accompanied with evidence to demonstrate compliance with a Local Approved Products Policy (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 – we believe they the retail applications should be accompanied with evidence to demonstrate compliance with a generic LAPP or with the general legislation, in absence of a generic LAPP.
4 Are the factors the Authority should take into account when determining whether a licence applicant is a fit and proper person or whether a body corporate is of good repute in section 16(2) enough? The section 16(2) factors are:

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

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

We believe that in addition to the criteria listed for a 'fit person' or organisation, that they should be a NZ citizen not a NZ resident.

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

Yes we believe the applicant should provide these details, particularly regarding alcohol licensing and gambling, in particular pokies and TAB's.

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

7 How long should licence holders be required to keep records for?
8 Do you think there are factors or issues that the Authority should consider when setting discretionary conditions? If so, please provide details.

We would really like to see conditions for these products, if they must be sold, to only be available to over 25’s. for 3 reasons

   i) The ability to assess risk is not fully developed until youth are 25 years approx.

   ii) The brain is undergoing many changes earlier than that and taking substances such as these can seriously limit the brain developing to its full potential.

   iii) If a youth at 18 buys for their mates Under age, it will cause greater damage.

The development of a brain is a key factor that should be considered, particularly of a teenage brain. I would like to site 2 articles made known to me from the brainwave trust.

1) http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2827693/

This is an excellent scientific article from a reputable organisation which says the points you wanted to emphasise about the effect of drugs on the developing adolescent brain

2) http://preventionhub.org/training/adolescent-brain

Another reputable site that refers to the way the adolescent brain works

It is our understanding, backed up by research that the brain isn't fully developed until 25. Any access to brain altering drugs prior to that age will seriously affect the brain fully developing and reaching it’s potential.

As such, we would really like to see conditions for these products, if they must be sold, to only be available to over 25’s.

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 above

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

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

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

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

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

14 Are the proposed requirements and restrictions on labelling sufficient? If not, please make specific suggestions for further requirements and restrictions.
Yes we agree with the details sought, however request that this is detailed in plain English/commonly used language.

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

We believe that the wording of the warnings are:
- too long and not plain English
- Need to include to consume them at your own risk
- There needs to be details regarding what is in the product
- The packaging of these products should be bland e.g. brown packaging and black writing. This should be along the same lines as plain packaging of cigarettes legislation
- Should include health warnings as outlined in 16

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

Yes – but we would also submit that they should be plain/ bland packaging as per plain packaging cigarette legislation.
The packaging should be plain, and in no way designed to attract youth and young adults to purchase the product.
In addition we would like to see included on the packaging health warnings from long term studies that demonstrate the short & long term affects of these substances and products on the body.

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

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

18 Do you agree with the proposal that a dose, in whatever form the product takes, is split wherever possible?
No – we believe that splitting the dose over a number of packets, may lead consumers to believe that it is OK to consume greater numbers of pills at a time, and this is likely to lose the meaning of the dose levels. It also encourages the idea that taking more than one portion at a time is okay - which becomes dangerous when the person is unaware of dosage strength of other pills they might be given. In addition some consumers may not accurately recall the numbers of the 'split' dose they have consumed.

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 these products should be restricted to pill format only.

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

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

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

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

Also, these should not be visible to the public, should be securely locked, and potentially have some type of minimal temperature control to ensure the chemicals contained are not damaged (the chemist could set limits that would make sense).

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

6 Psychoactive Substances Regulations: Consultation document
We do not believe that the products should be on visible display within the premises e.g. similar to the constraints of tobacco.

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

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

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

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

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

Yes — we believe that the restrictions should also extend to a premises selling these products should not be within a specified distance e.g. 500 metres of a licensed premises or a TAB, school, bus stop or residential area.

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

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

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

Additionally that internet sites should not be seen to market directly at the 18-25 age group for reasons outlined in question 8.

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

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

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

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

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

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

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

8 Psychoactive Substances Regulations: Consultation document
We believe that a combination of a minimum application fee and an hourly fee on top for processing if complicated or inadequately prepared applications require this is to ensure the community is not cross subsidising potential producers.

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

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

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

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

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.
Tena Koe The Manager of Psychoactive Substances Regulatory Authority,

Thank you for the opportunity to comment on this consultation document regarding psychoactive substances regulation.

As this is Consultancy, Advocacy and Research Trust’s (CART’s) first submission to the Psychoactive Substances Regulatory Authority we would like to provide a brief introduction about the Trust.

CART is a non-profit organisation that works predominately with the ‘Nga Mokai’ population; reaching approximately 900+ whanau aged 0 to 65+ from within the South Wellington area and surrounding suburbs. Throughout this submission “Wellington City” and “Wellington City Community” refers to the South Wellington area and surrounding suburbs. The ‘Nga Mokai’ population is primarily of Maori decent who experience social and economic disadvantages which contribute to poor health and nutrition. CART’s approach is to first establish a sense of being ‘on your side’ with whanau clusters, as well as responding to immediate needs. The ethos of CART revolves around the idea that each person is full of ‘promise’. CART works towards this by helping to remove barriers and releasing the expansive potential of individuals and whanau. CART is the “umbrella” agency that supports programmes, such as Whanau Ora, E Tu Whanau, He Taumata Toa and CAYAD (Community Action Youth and Drug).

The submission being presented is supported by all of these programmes, written on behalf of CAYAD. CAYAD is a national project funded by the Ministry of Health which uses a community action approach to reduce alcohol and drug related harm to young people and family/whanau. One function of CAYAD is to increase community discussion and debate about alcohol and other drugs. Another role of CAYAD is to support the implementation of effective policies around reducing drug-related harm; hence CAYAD’s involvement in this submission.

This particular submission is of high interest to CART because working directly with the community we are aware of the negative impacts psychoactive substances have on the community as a whole.

In conclusion, our submission is supported by research (when possible) and includes real life stories and human experiences shared by individuals around Wellington City who have first-hand experiences with these substances. The aim of including these life experiences is to bring this submission “to life” and to show the human side behind the black and white.

I wish to receive updates about the development of psychoactive substances regulations at Maggie@cart.org.nz.
SUBMISSION FORM ON PSYCHOACTIVE SUBSTANCES REGULATIONS

Name: Maggie Kelly
Position: Wellington City Community Action Youth and Drugs (CAYAD) Kaimahi
Organisation: Consultancy, Advocacy and Research Trust (CART)

Address: 3 Myrtle Crescent, Mount Cook, Wellington, New Zealand

Date: 21 March 2014

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

Tena Koutou Members of the Psychoactive Substances Regulatory Authority,

PSYCHOACTIVE SUBSTANCES REGULATIONS

General Comment

Ideally CART and Wellington City CAYAD would like to see a healthy community, free of all psychoactive substances. This point of view is based on feedback and experiences directly from the Wellington Community.

- In a series of focus groups conducted from December of 2013 until March of 2014, reaching 41 youth with an average age of 16.6 "legal highs" was identified as a health concern in the Wellington Community by 100% of the participants.
  a. Direct comment from 16 year-old male: "Legal highs make you crazy".
  b. Further comment from 20 year-old female "taking drugs [referring to psychoactive substances] is more common than drinking alcohol. Sometimes it's cheaper than buying alcohol".
  c. On the 7 August 2013 local secondary school principal met with Wellington City CAYAD to discuss a recent spike in drug and alcohol related incidents. A comment was made that the number of students that have been suspended and/or excluded in 2013 exceeds the total number over the past five years combined. A number of the incidents seem to have been a direct result of using Synthetic Cannabinoids ("Legal highs").
- Furthermore, an on-line survey conducted by Wellington City CAYAD 56.4% of the participants identified "synthetic cannabis" as a health issue in the Wellington Community.

Proposed Requirements

1. In regards to the police check on the application form it would be helpful to set out what the consequences might be. For instance, if someone has a criminal record, will they not receive a licence?
2. It should be a requirement that retail licence applicants provide evidence of compliance with local approved products policy (LAPP) or General Approved Products Policy (GAPP) if LAPP is not available. CART and Wellington City CAYAD recommend that this is up to date and displayed for random and regular checks.
3. The Regulatory Authority should not grant a license to any applicant that fails to comply with the LAPP or GAPP.

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1 Focus Group conducted on the 3rd of December 2013.
2 Focus group conducted on the 11th of December 2013.
Fit and Proper

4. Additional factors the Authority should consider-
   a. A specific definition of “fit and proper”
   b. Specify “relevant offence”
   c. Recommend adding “previous non-complier” to the section 16(2), second bullet point—whether there has been a serious or repeated failure by the applicant to comply with any requirement of the Act.
   d. CART and Wellington City CAYAD suggest that retailers are compliant with the Ministry of Health regulations.
   c. What happens if a retailer is granted a license and then does not comply? Who is responsible for breaches of the Act?

5. Applicants should be required to provide details of their involvement in other regulatory regimes.
   a. Applicants should also be required to provide details of "failed licence applications".

6. It is recommended that the Authority require licence holders to keep a record of incidences (i.e. number of times a minor attempted to purchase, theft or burglary) as well as action taken (i.e. who was the incident reported to?). Additionally, we recommend:
   a. Public sales record inclusive of quantity of products or substances distributed, and quantity sold in a single transaction
   b. Purchase records inclusive of licence number of the seller from whom the psychoactive substances or products were received.

7. We recommend that the licence holders should be required to keep records in alignment with the timeframe that the Act is being reviewed.

Discretionary Conditions

8. Rather than “a declaration if Internet sales are proposed” – Wellington City CAYAD strongly recommends Internet sales is prohibited due to regulating difficulties. Alignment with the Ministry of Health’s Tobacco guidelines would be appropriate, “Anyone selling tobacco via the internet in New Zealand must not display tobacco products or any other tobacco-related information on the website or any other electronic document or media.” Furthermore we recommend penalty for breaching the display requirements.

9. CART and Wellington City CAYAD recommend the following:
   a. Age verification for any person who appears under the age of 25 - a text message conversation with a 12 year-old boy about "legals" was intercepted by Wellington Community support worker during the second week of March 2014 and reported to Wellington City CAYAD.
   b. Refusal to sell to any person who is under the influence of any substance(s) (i.e. alcohol).
   c. In agreement with Local Government New Zealand we recommend that the Authority also consider:
      • An excise 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 be 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;
      • A probationary period for new retail operators with full licenses provided after a satisfactory performance;
      • Forbidding any food, alcohol or gambling from sale at a licensed premise;
      • Ensuring sales staff are 20+ years of age;

• Requiring the provision of fact sheets setting out the health risks associated with consumption of the products;
• Ensuring premises have information on health and addiction services that people with problems related to consumption can seek help;
• Given the flexibility in many home occupation rules in district plans, the regulations should make it clear that psychoactive substances are not to be sold from any building the primary purpose of which is a residential dwelling.

Product Approval Applications

10. Yes.
11. Yes.

Determining the Risk of Harm

12. Yes. In addition we recommend a requirement to include any known data on the effects of the substance on vulnerable groups such as those with mental illness or who have a substance dependency.
13. In a meeting with reporting analyst from CCDHB Emergency Department on 04/02/2014 the following was stated: “since 2012, 15 people have presented with symptoms primarily relating to herbal high ingestion”. Based on this information CART and Wellington City CAYAD recommend additionally including medical effects and behavioural effects.
   a. In regards to reporting adverse reactions Centre of Adverse Reactions Monitoring (CARM) places the responsibility of reporting on the medical/health provider. We recommend including the retailer in the process, as well. This could possibly be tracked with regulatory licence.
   b. In agreement with the National Collaboration Group we recommend a requirement to include:
      • Any known information or data on effects of the substance on vulnerable groups such as those at risk of mental illness, young people or those who are already dependent on alcohol or other drugs.
      • Data and information on the use of products when combined with use of other common drugs including alcohol, cannabis and tobacco should be provided, with reference to the effects listed at both questions 12 and 13. Poly-drug use is noted as a particularly risky and common pattern of use of recreational drugs in many studies, and recently with BZP party pills.
      • 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.
      • Data on previous use in the “wider population” could include populations overseas.

Labelling and Packaging

14. In regards to CARM we strongly recommend a “user friendly” system that allows the general public to report an adverse reaction. As you can see throughout this submission a number of issues in the Wellington Community have been raised to our organisation. The “user friendly” system contact details should be included on every product label.
15. Additional recommendations to regulation requirements mentioned in section 11(4) of the Act:

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5 Interview with Senior Reporting Analyst, CCDHB Emergency Department, 04 February, 2014.
6 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
a. In regards to addictive potential- on the 10th of March 2014 an 18 year-old male disclosed an "addiction" to legal highs.
b. In addition to “proposed directions for use” information on the effects and risks at different levels of dosage should be provided.
c. Information regarding “drug-driving” or operating a vehicle (i.e. heavy machinery, working) under the influence
d. In agreement with the National Coordination Team submission we agree with the following:
   - 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’, it is possible that users will likely consider the products to be safe and of low strength, and that they may regularly take more than double recommended doses, as was the case with use of benzylpiperazine (BZP) party pills before they were prohibited. A prominent warning will remind people to consider the known risks of the substance and the recommended dosage and directions.

   - In addition, we suggest adding three further warnings:
     o All psychoactive substances carry risk of adverse physical and psychological reactions
     o Health effects of long-term, regular use of this product have not been assessed
     o If smokable products are permitted, a warning that inhaling smoke will cause damage to the lungs.

16. To ensure lack of appeal to minors and vulnerable populations CART and Wellington City CAYAD recommend “Plain Packaging” as outlined in “Smoke-free Environments (Tobacco Plain Packaging) Amendment Bill 2013.”

   a. We recommend including the health impacts on the packaging and only allowing harmful health, social or economic effects or other harmful effects messages when using the substance.

**Quantity and Dose Requirements**

17. Support the proposal to restrict a packet to one dose-

   a. On the 21st of January 2014 an employee at CART supported whanau in the Intensive Care Unit at Wellington Hospital whose 20 year-old daughter was experiencing seizures and then sent into a medically induced coma after taking synthetic cannabis. It is suspected that this was due to an overdose.

18. Yes. We support split doses.

19. CART and Wellington City CAYAD recommend that the following forms should NOT be approved:

   a. Smokeable- due to the impact on lung functioning and side effects of second-hand smoke. The Centre for Disease Control reports based on information from Poison Control Centres, those symptoms [artificial marijuana smoke] can include rapid heart rate, vomiting, agitation, confusion, and hallucinations.

   - On the 14th of March local police officer shared difficulties in identifying whether the substance being used is “illegal cannabis” verses “legal psychoactive”.

   b. Pre-mixed or in the substance of food and/or beverage, as this appeals to young and vulnerable populations and creates a high risk of accidental consumption.

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8 Smoke-free environments (Tobacco Plain Packaging) Amendment Bill, Parliamentary Library, Bills Digest, Digest No. 2120; 17 December 2013.
9 The Dangers of Second Hand Artificial Marijuana Smoke, [www.teenhealthfs.com](http://www.teenhealthfs.com).
Storage, Disposal and Display

20. Recommend following the Ministry of Health’s “Guidelines for Implementing the Prohibition on the Display of Tobacco Products” 2012 as a guideline.

21. Refer to 20.

22. Refer to 20.

23. CART and Wellington City CAYAD recommend a “safe disposal” following similar steps: “1. Remove them from their original containers and mix them with an undesirable substance, such as used coffee grounds or kitty litter (this makes the drug less appealing to children and pets, and unrecognizable to people who may intentionally go through the trash seeking drugs). 2. Place the mixture in a sealable bag, empty can, or other container to prevent the drug from leaking or breaking out of a garbage bag.”

a. We also suggest reporting the disposal to a reputable source (possibly a responsible and licenced retailer and/or Centre of Adverse Reactions Monitoring).

24. CART and Wellington City CAYAD recommend the following signage to be visible and displayed at all times:
   a. Products will not be sold to any person under the age of 18
   b. Any person who appears under the age of 25 is required to show verified photo identification
   c. Refusal to sell to any person who appears under the influence.

Place of Sale and Advertising

25. We recommend that retail should only be possible through stores where entry is restricted to individuals over the age of 18.

a. Further information reported to Wellington City CAYAD regarding illegal sales or “black market sales”- On the 4th of March 2014 local police officer mentioned video footage of youth exchanging suspected legal highs in front of local business.

26. We strongly recommend that the only advertising permitted involves the Ministry of Health developing a communication strategy to inform New Zealanders about the nature of the new Psychoactive Substances legislation and relative roles of the different agencies involved in its implementation.

27. Refer to response 8 under “Discretionary Conditions”.

28. Yes. CART and Wellington City CAYAD take a strong stance to prohibit sponsorship and prohibit any form of advertising -on-line/electronic/social media- that may target at-risk or vulnerable populations.

Fees and Levies

29. No comment.

30. No comment.

31. Recommends no allowance for special licence or one-off events.

32. Suggests including cost of communication strategy and educational information regarding health warnings and side effects.

Thank you for the opportunity to comment on the Psychoactive Substances Act during the early stages of implementation.

Please feel free to be in touch if you have any further queries or wish to collaborate in the future.

Yours faithfully,

Katrina Moar, CART Manager

Maggie Kelly, Wellington City CAYAD

10 U.S. Department of Health and Human Services, Food and Drug Administration, How to Dispose of Unused Medicines, updated 28/01/2014.
The Manager
Psychoactive Substances Regulatory Authority
Ministry of Health
PO Box 5013
Wellington 6145
To The Manager

21 March 2014

Re: Submission on Psychoactive Substances Regulations

Submission from: Community Action Youth and Drugs (CAYAD) National Coordination Team

1. Introduction
Thank you for the opportunity to be involved in the consultation on the Psychoactive Substances Regulations. The CAYAD National Coordination Team is based at the SHORE and Whariki Research Centre of Massey University. We provide workforce development, information sharing and planning and evaluation support for the CAYAD programme. We also provide advice to the Ministry of Health about the direction of CAYAD programme and the issues which CAYAD communities are facing.

CAYAD is a Ministry of Health funded programme operating in 25 sites in cities, towns and rural areas across New Zealand, particularly in places of high need. The CAYAD project outcomes are:

- To increase informed community discussion and debate about issues related to alcohol and other drugs;
- To support the adoption of effective policies and practices to reduce alcohol and other drug related harm;
- To increase local capacity to support young people in education, employment and recreation;
- To reduce the supply of alcohol and other drugs to young people.

This submission begins with some considerations that are not covered in detail in the consultation document, but which we believe are important for the protection of health under the purpose of the Psychoactive Substances Act ("the Act"). This is followed by our responses to the specific consultation questions.

2. Additional Considerations

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

We recommend that this generic policy establish broad restrictions on the location of retail premises in general terms, particularly to reduce the exposure of young people and vulnerable people to the harmful effects of psychoactive products. We recommend that the GLAPP includes:

- A distance restriction on 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.
- A distance restriction on premises selling approved products to a minimum of 150m away from other psychoactive product retail premises and from on-license or off-license alcohol outlets.
• Stores should not be on the main route between sensitive sites and the main residential area for a local population.
• Hours of sale limited to 9am to 9pm (see rationale under Question 8, page 7).

2.2 Local Approved Products Policies (LAPP)
These policies have few strong measures compared to the provisions 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 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 alcohol outlets (on-license and off-license)
• The ability to introduce liquor bans in public spaces

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

2.4 Research into substance or product risk levels
We seek assurance that the trial and assessment of the risk of harm of new products will 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 be required to:
• Demonstrate that they have no vested interest in the wholesale, manufacture or retail of psychoactive substances/products.
• Have no other conflict of interest that the Authority (or the Psychoactive Substances Expert Advisory Committee) considers relevant.
• Work to the same international standards required for approval of medicines.

2.5 Monitoring and reporting adverse reactions
It will be challenging both to monitor and to detect the health effects of individual products after they are approved. Wilkins\(^1\) cites several reasons for this, such as the way recreational drugs are often used in combination; that they produce effects which are similar to the effects of different substances or even of health conditions; the rarity of some effects and the long timeframes that may lapse between use and effects. In addition, product manufacturers and retailers have a financial disincentive to monitor the safety and impact of their products if the reporting of problems might mean their product will be removed from the market. 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 implementing post-approval monitoring of their product in their product application.
• Monitoring plans should include:
  o Regular collection of baseline data on emerging patterns of use and effects (short and long-term) of the use of psychoactive products
  o Detailed analysis and review by the PSRA every three years after approval of a product
  o Provision for thorough medical case events to be developed – including provision of resources for medical staff to undertake detailed testing and analysis of case events (individuals suffering acute or chronic symptoms from use of a psychoactive product).

\(^{1}\) 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
• 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 psychoactive product. We recommend investment in a user-friendly process for reporting adverse effects of psychoactive products, with relevant, customised forms.
• We suggest exploring a simple national system for collecting and providing such data to CARM through all medical facilities in New Zealand, particularly emergency departments.
• We recommend independent, University or other non-government research into the appeal of psychoactive products to vulnerable populations and assessment of trends in product use; this could be funded through levies or a tax on approved products.

2.6 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 risk of harm in combination with other common recreational drugs or psychoactive 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.

2.7 Tax
We recommend a specific tax is added to the retail price of approved products in order to:
• Cover potential expenses for government services including justice, social services, health and particularly ongoing independent monitoring and analysis of longer term effects of products. Because no psychoactive product can be entirely safe for all individuals, health interventions and social support will be required for some users.
• In addition, tax is an efficient way to make products more expensive and therefore discourage heavy, dependency-oriented patterns of use and makes it more difficult for young people under the age of 18 to access approved products.

2.8 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 driving/other activities are established. In addition, reliable and simple road-side tests for the presence of such drugs will be required.

2.9 Total product cap
We recommend a cap on the number of products that will be approved. Beyond ten additional products, for example, various difficulties and expenses will be incurred:
• Monitoring and oversight of health impacts by the PSRA will be very difficult.
• Assessment of risks of using products in combination will also be highly difficult as the number of possible combinations increases.
• Testing of users by Police to confirm intoxication while driving will become very difficult.
• Testing by regulatory bodies such as Police and Customs to confirm a product or substance is approved/unapproved will be more expensive and difficult.

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3. 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 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, this will be efficient for confirming eligibility of applications for further processing.

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 will be efficient for confirming eligibility of applications for further processing.

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 18(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.

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
- Capacity to meet product testing and trial standards used internationally for medicines.
- 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, 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 protecting the public from 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

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

7 years to enable sufficient time for audit processes.

Research:
Record keeping for research and clinical trials should meet relevant standards for similar human trials for approval of medicines.

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 to apply generally to all retail licences.

In addition, we recommend the following conditions apply generally to all retail licences:

- A requirement to seek age identification prior to sale to any person, or should this pose too great a burden, identification should be sought from anyone who appears to be under the age of 25.
- To better protect vulnerable populations who are at greater risk of harm from use of psychoactive products, we suggest a requirement for staff training on:
  - 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
- Sale to intoxicated persons should be defined and prohibited, including intoxication by any drug including alcohol, due to the risk of combined use with other products or engaging in risky consumption (taking more than recommended doses).
- A restriction on the retail of products to the hours of 9am to 9pm only. This will reduce the risk of young people accessing products before school hours. The closing time also limits the opportunity for intoxicated people leaving closed venues that sell alcohol seeking to continue their recreational activities through purchase of psychoactive substances. The mixing of such intoxicating products is likely to carry increased risk of harm.
- Consumption of psychoactive products within a retail-licensed premise does not appear to be considered under the Act or the proposed regulations. We therefore recommend an interim requirement that licensed retail premises prohibit consumption inside their premises, at least until such time as health impacts of such supply and usage can be assessed and consulted upon, and appropriate health measures and regulations developed. For the interim, this avoids the possibility of intensive use at a party venue, where intoxicated persons may continue purchasing and taking excessive doses of psychoactive products that could be damaging to their health.

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, but on the basis that this information is not made publicly available.

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.
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.

In addition, we recommend:
- Inclusion of behavioural effects in the list above.
- A requirement to include any known data on effects of the substance on vulnerable groups such as those at risk of mental illness or who are already dependent on alcohol or other drugs.
- A specific requirement for the same data as above to be provided for the final product for which approval is sought, as the product may contain combinations of substances, psychoactive or otherwise.

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 information and data should be provided for the substance.

In addition we recommend a requirement to include:
- Any known information or data on effects of the substance on vulnerable groups such as those at risk of mental illness, young people or those who are already dependent on alcohol or other drugs.
- Data and information on the use of products when combined with use of other common drugs including alcohol, cannabis and tobacco should be provided, with reference to the effects listed at both questions 12 and 13. Poly-drug use is noted as a particularly risky and common pattern of use of recreational drugs in many studies, and was recently seen in New Zealand with B2P party pills.
- 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.
- Data on previous use in the “wider population” could include populations overseas
- Data on the effects of the product on risky tasks such as driving and the operation of machinery.


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. We also 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

To ensure lack of appeal to young people under 18 years old, we recommend plain packaging of products. In addition, imagery and slogans on packaging can be considered as product 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”.

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”, it is possible that users will likely consider the products to be safe and of low strength, and that they may regularly take more than double recommended doses, as was the case with use of benzylpiperazine (BZP) party pills in New Zealand before they were prohibited. A prominent warning will remind people to consider the known risks of the substance and the recommended dosage and directions.

In addition, we suggest adding three further warnings:

- All psychoactive substances carry risk of adverse physical and psychological reactions
- Health effects of long-term, regular use of this product have not been assessed
- (if smokeable products are permitted) Inhaling smoke will cause damage to the lungs.

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.

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Yes. This can reduce the risk of overdose and supports the intention of the Act to protect the health of users.

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

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.

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:

- Smokable forms - due to impact on lung function and therefore overall fitness, which is very important to protecting health.
- If smokable forms are allowed, additional regulations on product use should be applied, 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 soluble forms to reduce risk of drink spiking.
- Injectable forms or forms that can easily be made injectable, and should not come in with injection equipment, due to the many health risks associated with this form of use.
- Approved products should not be pre-mixed with food and beverages, due to risk of accidental consumption by adults and particularly children.

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

Yes – 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.

We recommend a level of security be required to include monitored alarm systems at the least, with discretion of the authority to require other security elements as it sees fit.

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

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6 Ibid.

10
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 two days of normal trade.

We recommend a level of security be required to include monitored alarm systems, with discretion of the authority to require other security elements as it sees fit.

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?

Yes—a process for disposal that can be trusted and tracked back 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 psychoactive substances/retail licence number of the person or company it has been received from, and a confirmation that the regulatory agent (including their name, signature and that of a witness) has seen the product as described (type, amount) and disposed of it according to requirements of the Hazardous Substances and New Organisms Act.

We have seen the necessity of such a provision in the rural Bay of Plenty, where a CAYAD site has been informed of the 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 young people at much lower prices than normal retail. Should other products be recalled, we strongly recommend careful local planning amongst enforcement agencies be put in place to ensure disposal is well managed.

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

Premises should be required to have signage indicating:
- Products will not be sold to under 18s.
- No consumption on premises.
- Details for help (which should also be available on hand out slips)
  - Where to go for emergency help
  - Reporting number to call to report adverse effects
  - Signs of addiction, dependence or health issues and ways to access help for these issues
25 Do you think the regulations should specify further places where approved products may not be sold? If so, please provide specific suggestions.

We recommend retail should only be possible through stores where entry is restricted to people 18 years or older. This will avoid leakage of products to young people through shoplifting. In addition, sale in other premises that are frequented by young people could normalise psychoactive products to under 18s and we recommend this is avoided.

We would strongly prefer that internet sale is prohibited. However, should it be allowed, a low maximum number of internet sellers should be set, such as 10, to allow reasonable monitoring of their practices.

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.
- A requirement in the regulations that any advertising must be consistent with the Advertising Standards Authority’s Advertising Code of Ethics

We recommend:

- The regulations contain detail to ensure advertising in stores or on product retail websites (if permitted) is restricted to objective information only. As per Section 56(3) of the Act i.e. that advertising of an approved product must be limited to material that communicates objective information about the product.
- Under Section 56(2) of the Act, a person must not advertise an approved product in a manner, way, medium, or form that contains themes that are, or are likely to be, particularly appealing to minors. Therefore, we recommend advertising is restricted to plain text forms, to avoid the risk images being used that appeal to under 18s. This will provide simplicity certainty for the industry and the authority, removing the challenging administrative task of identifying and judging what images, logos or themes might appeal to minors in a fast-moving market place.
- For the same reasons as above, we recommend that internet retail sites (if permitted) should not be able to play music. All use of audio should be restricted to objective product information only. Use of well-known persons to voice such audio information should also be restricted.
- 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 intentions of the Act to restrict advertising and to avoid promotion to young people.

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

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

Yes. We discuss some additional fees under question 31.

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. Product approval application fees should be calculated (or increased as necessary) to cover:  
- assessment of the effects of the psychoactive product on risky tasks such as driving and the  
  operation of machinery prior to product approval, and  
- establishment of safe levels or limits for driving or other activities of high risk to others prior to  
  product approval, and  
- development of reliable and simple road-side tests enforcing relevant product safety levels for  
  drivers prior to product approval.

Fees should be collected from retailers to enable:  
- Development, delivery and evaluation of standard training on safe retailing practices e.g.  
  - Recognising 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. We suggest the collection of additional levies (if not an excise tax on approved products) to enable:

- Drug-driving enforcement operations and testing by police
- 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
  - Development of thorough medical case events by medical staff, including detailed testing and analysis of case events of individuals suffering acute or chronic symptoms from use of an approved product.
  - Newly approved products to be reviewed for evidence of emerging harms and long-term use effects 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)
- Payment for testing of products to support the public defence of individuals charged with possession of an unapproved substance. Vulnerable individuals may otherwise find themselves unable to defend such charges under the Act.

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)  PO Box 6137 Wellesley Street
           (town/city)  Auckland
Email:  
Organisation (if applicable):  Massey University
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): On behalf of the Community Action Youth and Drugs National Coordination Team.

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 and I would like to see the government service REAL ME used to verify identification as I have personal used this service and found it to be robust system that was easy to follow.

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

   Yes but only when applying for the Full retail licenses when they become available.
   I think it is unfair to expect compliance with local area product policies in the interim license period when it has been made clear to many that nothing is to change during the interim period and especially location of retail premise so therefore I submit that all LAPP's Can’t come into effect and/or compliance isn’t required during the interim period
   • This will give all retailers currently trading under interim license reasonable time to locate and obtain suitable premise that meet the L.A.P.P requirements

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 would add consistency nationwide to where a suitable location for adult shops would be or not be as the case may be
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 submit that additional factors that should be considered when considering if a applicant is a Fit and Proper Person should include whether they have had any serious criminal charges such as

- Serious Sexual Offences
- Serious Violent Crimes

Also relevant details should include any recent loss of license/s issued by the NZ or Local Government in the last 3 years for Gun Licence, Driver license etc.

And whether they have had previous Drink Driving convictions in the last 7 years.

Any Alcohol related charges in the last 3 years

Any community support they have provided or been involved in this could include Firemen, Ambulance Staff or even aged care

And any details of the applicants involvement in other regulatory regimes.

If they have been in a professional area of work or qualified in and maintained good practice for their respective profession. E.g Lawyers for example have to be a Fit and Proper Person or they could risk being stopped from practicing.

A Body Corporate application – Should be required to include in their application all Current Owners that have a controlling interest and also Directors, Operations Managers (or similar role) and all Frontline Staff should have to be a Fit and Proper Persons.

For the purposes of the act a Body corporate cannot be Fit and Proper without taking into consideration the above.

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

Yes this should be included as a track record of compliance or not as the case may be this will help in making sure only fit and proper persons can sell these psychoactive substances.

Also include there involvement with any industry where they maintain a fit and proper person compliance themselves, such as Lawyers and Doctors

For a Company it should provide any relevant details such as involvement with other regulatory regimes or compliance with legal requirements where applicable.

What records should the regulations require licence holders to keep?
License to Import
- Records to consider are Sales Records to include the license number and name of the recipient of the goods and the quantity and date of the sale
- Current stock level to be updated and accessible as required

License to Research
- Records to be kept should include any purchase/s of Active ingredients and relevant details such as date and from whom and the quantity
- Any research carried out that uses active ingredients should specify how much active was used and the purpose of the testing
- Records of any spillage, damaged product or product disposed of and how, when & why this occurred
- A percentage of wastage should be allowed e.g up to 5% may be unaccounted for loss attributed to coating of equipment and so forth
- Current quantity of any active ingredient held on site

License to wholesale
- Records to consider would be all purchase and sales records with all relevant details of the transaction and license number on each transaction.
- Any lot of damaged product and how, when & why it happened
- Current quantity of any active ingredient held on site
- Records of shipping goods too customers – Tracking number and Courier Company Used
- Records of any product Recalls to include the reason why it was issues and the date and the action taken and record of the disposal

License to Retail
- Records to be kept should include but not limited too
- All Sales to be recorded with each transaction too include the date and time, salesperson, cost of the goods, transaction number and payment method and if any discount was applied
- All Purchases to be recorded with each transaction too include the Name of the Wholesaler and there licence number along with the date, name of the person who did the sale and the quantity and cost of the product, Product Approval Number too be located within item description.
- Any damage or lost or destroyed or stolen product should be kept in a product incident folder with details on how when and why it happened with date and person/s involved in the incident and remedy/s sort to minimise the risk of this happening again
- Records of any refunds issued to include the date and Customers details and the reason for the refund and who issued it
- Problematic and Self Banned Consumers including those with mental health conditions to be registered on a National Database to ensure at risk people have no or limited access to these products.
- Employee Industry Compliance Training Records and they should include Details of Training Given To employees including the date the training occurred and acknowledged with signature by the employee and ongoing compliance checks with staff including watching them in action.
- Training should involve going through what if scenarios like Refund requests and Return policy And how to retail sensibly and how to deal with aggressive and agitated and problematic customers and a complaints process, most importantly if you look under 25 you should be prepared to show I.D and no sales too under 18 Year olds and training on forms of valid I.D
- How to deal with customers complaining of adverse reactions
- Records of all Current stock on hand and its location kept in the place wherever the goods have been stored there should be a log book to include any movement of stock to track stock movement.
- Stock order forms to restock the retail area to include the name of the product the amount taken and the date and to be checked off on receipt at P.O.S area and placed in appropriate storage

7 How long should licence holders be required to keep records for?
I submit the following points
- Financial Records should be kept for at least 7 Years
- All other records should be kept for at least 3 years
- Any Records from the last 6 months to be readily available on demand when directed by the authority without delay
- I submit that all financial records are to be electronically recorded on a suitable software

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

Yes I submit the following Discretionary conditions, factors and/or issues that should be considered to include
- Hours of Operation for retail and manufacturing premise depending on factors such as location and operation of business and in regards too retail premise consideration should be given to the type of trade occurring on site in regards to On-license and Off-license conditions similar too alcohol licenses
- Restrictions on the sale of Liquid Refreshments to be lifted when Full licensing applications begin and the consumption of water promoted
- All Retail, Manufacturing, Research license holders to Display a Copy of their current license that is visible to the public or visitors at the place specified on the license or where the trade actually takes place
- Wholesalers to Provide a Copy of their license to retail license holders when starting new accounts and too keep a current copy on site
- Retailers should be required to provide a copy of their current license to a wholesaler before the transaction can take place.
- Manufactures location to be considered in regards to proximity to sensitive sites such as churches and schools and other sensitive areas
- I submit that all licensed retail outlets applicants be a approved license or there licensee suspended with 66 day compliance notice for existing license holders that are next door to or beside or can internally access any places that the sale of psychoactive products take place but too include pharmacy/s

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 I submit that any NEW applicants for additional Retail Premises Have to put a case forward for why there is a need for another retail Outlet in a local District, City or Town where there is already existing retail outlets but only once The Full Retail Licenses have been issued to current interim license holders .
- This will avoid saturation or over exposure to the general public and especially minors
- A community impact statement and or public consultation process similar too applicants of liquor licenses

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, it should include information on manufacturing components like what device the product is used to deliver the active ingredients.

For example, anything consumed like an empty pill capsule that will be used to house active ingredients should be listed as inactive ingredients.

Any device used to deliver the psychoactive substance/s should pass health standards like those applied to food containers.

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

I submit that the following additional restrictions be placed Retail Premises:

- The inside of the store should not be easily visible from the outside.
- R18+ ENTRY ONLY signs to be a minimum font size and standard look or the outside of the building that can be seen before entering the premises and on the door.
- Also clearly displayed at the entry points and around the point of sale a standardised logo stating Anyone that looks under 25 years of age be prepared to present your I.D.

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, as I understand them in a broad sense but this should be left to the experts.

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.
- Consuming more than the recommend dose will place you at more risk of harm
- KEEP hydrated Drink Water (recommend daily consumption)
- M.O.H Approved seal for all approved Products and compounds once imported and cleared by authority's to have the Seal placed on the goods and sent on their way to and approved M.O.H facility and this processed is to be repeated until the Retailers Receive the Goods with Seals on every package or box or device used to store or transport these products.
  This will give the public more confidence when purchasing the product that is authentic and also it gives the industry security and credibility

Are the proposed requirements relating to health warnings sufficient?
If not, please make specific suggestions for further requirements (for example, advice on what to do in the case of an overdose).
- A helpline number to address any concerns from consumers like addiction and funded by industry
- Could be hazardous to your health Take at your risk

Are the proposed packaging requirements and restrictions sufficient? If not, please make specific suggestions for further requirements.
- The use of the term “inappropriate material” should be more defined for transparency as this is subjective and may be subject to a personal opinion on some grey issues that will arise.
- Packaging of any product should comply with manufacturing requirements but all transport devices used to ship products and substances should be made of suitable material to contain any possible spillage or leakage if damage was to occur while in transit or storage.
  If the substance is flammable is should be transported and stored in a suitable manner the dangerous or flammable goods are currently transported like GAS for lighters

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

No I don't agree in that format
- Alcohol consumers can buy more than one pack or bottle or even as much as you can take with you and there is no recommended dose on alcohol that I am aware of.
- There should however be a limit on the dosages per product packaged for sale.
- It would create a lot of wasted resources and extra cost on the manufacture
- Even if a limit was adopted and placed on the number of products allowed per person visit they could simply buy from another location or online or get someone else to buy for them unless a national framework was made to monitor all users and there purchase limits but this still wouldn’t eliminate the friend from buying for someone else.
- Also dosage rates can vary between person to person and there is a lot of factors to consider like Weight or mass of the consumer and there is the potential for more harm as the recommended dosage could be set too high for some users.

Do you agree with the proposal that a dose, in whatever form the product takes, is split wherever possible?
Yes but only for oral consumption such as a Pill or Vapor
From my experience with dealings with these users of legal herbs and energy pills and the like that when a recommended dosage is applied a vast majority will take more thinking this will work even better but this is often not the case so I recommend if this was to be implemented that any dosage err on the side of caution.
For example 1 dosage for pills should be split into at least 2 - 4 Pills
- Smoking products - a packaged product should not contain more than the recommend maximum daily consumption or/and daily dosage to be split up into separate packets inside a outer packaging.
- Also the format of the product should not be misleading and not be similar to packaging used with prescription medicine, alcohol, health products or kids toys.

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
- Injection should be excluded
- Inhaling vapour instead or smoke where possible

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
- They should be stored in compliance with hazardous goods requirements already in place
  Importers, Manufactures and wholesale should be required to storage excess product should do so in a secure monitored and controlled environment suitable for these psychoactive products, This could include but limited too and as required
  1) Temperature control,
  2) Humidity control
  3) Ventilated
  4) Fireproofed
  5) Waterproofed
  6) Monitored and recorded
  7) Limited access - by secure locking mechanisms such as Codes and card access and access limited to the minimal amount of Authorized staff only to maintain daily operations
  8) Limited quantity’s stored to no more than a year’s supply

21 Do you think restrictions or requirements should be set for the storage of approved products? If so, what should they be?
<table>
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<td>1 Temperature control,</td>
</tr>
<tr>
<td>2 Fireproofed</td>
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<tr>
<td>3 Monitored and recorded</td>
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<tr>
<td>4 Limited access - by secure locking mechanisms such as Codes and card access and access limited to the minimal amount of Authorized staff only to maintain daily operations</td>
</tr>
<tr>
<td>5 Limited quantity's stored to no more than a year's supply</td>
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<tr>
<td>- Retailers should have suitable storage behind there P.O.S similar to what retailers of cigarettes have - e.g lockable Cabinets that are not transparent but you can display the products in a lockable cabinet or on a menu.</td>
</tr>
<tr>
<td>- Manufactures Should have limited numbers of dangerous or hazardous goods stored in a single location to eliminate the potential for excessive damage if tragedy should strike in regards to a fire mainly</td>
</tr>
</tbody>
</table>

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

Yes all products to be displayed in a lockable display cabinet not accessible to the public but ideally located on a menu like in a restaurant on a display board and/or to hand in person and small thumb sized pictures to be allowed next to each product.

- But regardless of the form of delivery the product details should be limited to the Name, Size and retail price and what the registered active and non active ingredient's are
- There should be the requirement to include a Standard health warning –
- E.g. These products may be hazardous to your health purchase at your own risk
- A recognisable R18+ emblem to be included on all literature on display

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

Yes the disposal of products to coincide with the disposal of hazardous or dangerous goods procedures already in place for other such products containing potentially environmentally damaging product's if disposed of as common rubbish.

Containment procedures for any spilt or unstable or damaged product

- To be placed in a suitable device that will keep the product out of harm’s way until it is picked up and disposed in the manner required by a qualified person/s or company
- Keep a incident report of any disposals and include why, how and when and also the number disposed of

24 Do you think there should be signage requirements in the regulations? If so, please give specific suggestions.
- Yes – The inside of the store should not be easily visible from the outside
- R18+ ENTRY ONLY and maybe a minimum font size and standard look on the outside of the building that can be seen before entering the premises and on the door
- Also clearly displaced at the entry points and around the point of sale a standardised logo stating Anyone that looks under 25 years of age be prepared to present your I.D
- The number for a national help line for dependency and general concerns from consumers (help and advice on where to get help if they cannot help)

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

Yes
- They should not be sold within 200 metres from where medicines and health products are sold otherwise some people will assume that are health product or can be trusted like prescribed medication and even give the perception that prescription medicine is for recreational use.
- Should not be should where visible from or within 100 metres of any educational facility where under 18’s attend

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

Yes should be modelled from tobacco laws on advertising
Advertising should be defined not too include mass emailing to a prescribed group or posting on Social media groups or pages where no general public access to content is allowed and when asking to join said groups Age verification shall be required as well a disclaimer regarding content similar to the suggested process for internet sites

27 Do you think the regulations should prescribe restrictions or requirements on internet sales of approved products? If so, please provide specific suggestions.
Yes and I suggest the following:
- There needs to be on the entry point too verification process of age for access to website content of any psychoactive substances
- Only sold by a approved and licensed retailer
- R18+ only clearly stated on entry page
- Copy of license on the front page or a link to it
- No Product details on entry page
- Entry Page to clearly state that this website is for the sale of Psychoactive products and content may offend
- I.D verification and registration could be 2 stage process
  1. To gain entry to web content potential customers may fax, email a copy of of their valid I.D and are required to register their personal details
  2. Once inside they cannot purchase product unless there 18+ verification process has been continued which could include a Credit card with the users name on it and or a bank deposit from the person/s bank account, if they have verified their age through REAL ME then this number should be used
- Product information should be factual and informative AND NOT MISLEADING OR FALSE CLAIMS OR statements
- Limit the number of products that can be purchased per transaction per visit this will reduce on selling and stockpiling and overuse
- Before the transaction is complete the purchaser should have to tick a box next too the statement that they – Agree to purchase this product for my personal recreational use and I will not supply anyone under the age of 18 and personal details given are true and correct and anyone breaching this will be liable for prosecution

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

   Yes
   - Should comply with the advertising standards authority with some additions
   - Advertising of psychoactive products in a retail store should be acceptable if entry to the store is R18 only and the inside of the store is not visible from the outside
   - All advertising limited to factual information on the product e.g Name, active and non active ingredients and retail price Package size and dose
   - Also clearly displayed at the entry points and around the point of sale a standardised logo Stating Anyone that looks under 25 years of age be prepared to present your I.D
   - The number for a national help line for dependency and general concerns from consumers ( help and advice on where to get help if they cannot help) to be displayed at the exit points and near POS at least
   - Advertisement if age control is in place should be allowed in private groups or pages or via subscribed email that has subscribed and signed up to the content
   - Allowed to where company branded clothing as long as it complied with the standard

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

   Yes I agree

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.

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): ______________________________________________________

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?
- The inside of the store is not easily visible from the outside
- R18+ ENTRY ONLY and maybe a minimum font size and standard look on the
  outside of the building that can be seen before entering the premises and on the door
- Also clearly displaced at the entry points and around the point of sale a standardised
  logo Stating Anyone that looks under 25 years of age be prepared to present your I.D

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.
Psychoactive Substances Regulations
A consultation document

Submission to the Ministry of Health
Date: 21 MARCH 2014

Contact
Marilyn Head, BA, DIP TCHG,MSC, SENIOR POLICY ANALYST
DOI 04 494 6372 OR 0800 283 848 | E-MAIL MarilynH@NZNO.ORG.NZ | www.nzno.org.nz
NEW ZEALAND NURSES ORGANISATION | PO BOX 2128 | WELLINGTON 6140
About the New Zealand Nurses Organisation
The New Zealand Nurses Organisation is the leading professional and industrial organisation for nurses in Aotearoa New Zealand, representing over 46,000 nurses, midwives, students, kaimahi hauora and health workers on a range of employment-related and professional issues. Te Rūnanga o Aotearoa comprises our Māori membership and is the arm through which our Te Tiriti o Waitangi partnership is articulated.

NZNO provides leadership, research and support for professional excellence in nursing, negotiates collective employment agreements on behalf of its members and collaborates with government and other agencies throughout the health sector. Nurses are the largest group of health professionals comprising half the health workforce.

The NZNO vision is "Freed to care, Proud to nurse". Our members enhance the health and wellbeing of all people of Aotearoa New Zealand and are united in their professional and industrial aspirations to achieve a safe, sustainable and accessible system of public health care for all New Zealanders.

INTRODUCTION

1. The New Zealand Nurses Organisation (NZNO) welcomes the opportunity to comment on the consultation document on psychoactive substances regulations.

2. NZNO has briefly consulted its members and staff in the preparation of this submission, including professional nursing, policy, and legal advisers, and members of our specialist Colleges and Sections, in particular, the Mental Health Nurses Section (MHNS), Nurses for Children & Young People Aotearoa (NCYPA), the College of Emergency Nurses (CENNZ) and the College of Primary Health Care Nurses (CPHCN).

3. NZNO supported the Psychoactive Substances Bill (NZNO, 2013) and made a number of recommendations to help achieve its purpose.

4. As noted then, and in a more recent submission to the Ministry of health (NZNO, 2014), the failure to protect young people in particular from the predictable and serious health risks of legalised "highs" (party pills), should be acknowledged as a singular and devastating failure of the national drug policy: the supply control was negligible, lack of education and appropriate labelling, packaging and pricing, increased rather than reduced demand, and early intervention and treatment was not consistently available from health or social services.
5. That the harm has been disproportionately borne by the young and already disadvantaged, exacerbating rather than reducing health disparities and inequity, is evident, so NZNO is somewhat disappointed that the consultation document does not link education, a critical element in protecting the health of and minimising the harm to individuals who use these substances, to the two main regulatory controls proposed: ensuring products are low risk and controlling access.

6. The national drug policy advocates integrated action on the three 'pillars' supporting it - supply control, reduced demand, and problem limitation. Since each pillar is integral to the effective management of drug use in Aotearoa New Zealand, it is important that all parts of the strategy are developed together.

7. As health professionals, nurses are aware of the wide range of health impacts any product/factor can have on individuals. Their concern is to ensure a continuum of regulation and health care i.e. not only limiting access to dangerous products, but also ensuring access to appropriate education, information and services to prevent and minimise harm.

8. While we welcome restricted sales sources, labels displaying effective health warnings (previous 'warnings' were dangerously confusing) and listed agreements we would like to see the Psychoactive Substances Regulatory Authority (the Authority) and the Ministry being charged with taking a more proactive role in coordinating strategies to reduce demand for, and harm from, these substances.

9. Providing information for consumers on product contents, dose and potency is not enough, for example, if that information is meaningless to the intended audience. Nor will it protect those who may have an adverse reaction (including addiction) unless there are the support and treatment services in place.

10. NZNO submits that there is a particular obligation to provide 'remedial' education specifically for psychoactive substances because of how young people were lulled in to a false sense of security by their legal sale in outlets that were primarily community based and easily accessed via the internet.

11. NZNO and the MHNS support the approach and recommendations of the Declaration from the Wellington national drug policy summit, 27-28 August 2013 Reshaping New Zealand's Alcohol and other Drug Policy.

12. Our responses to the consultation questions that are relevant to us follow. In general NZNO supports:

- strengthening community input into and control of decisions governing local activities, including retail outlets opening hours and what can be sold;
- regulation aimed at prevention and minimisation of harm, including clear and appropriate evidence-based information and education to inform healthy choices, and access to health care services.

Consultation questions

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

   Requirements should be at least as rigorous as those applying to the Sale of Alcohol Act
   Suggest verified identity
   Support consent to undergo a police check.

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

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

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

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

Yes

6. What records should the regulations require licence holders to keep?
All those proposed in the consultation document, including additional sales record keeping under the regulations.

| 7 How long should licence holders be required to keep records for? |
|---|---|
| No comment |

| 8 Do you think there are factors or issues that the Authority should consider when setting discretionary conditions? If so, please provide details. |
|---|---|
| Apart from those identified, we would suggest that the Authority be able to consider community concerns and factors such as proximity to schools. We note the difficulty most communities have had in preventing licensed retailers to locate alcohol outlets in highly sensitive/vulnerable areas, for dairy owners to completely disregard community concerns about selling psychoactive substances etc. Consequently the most vulnerable communities end up being exposed to the most harm. |

| 9 Should the regulations prescribe other matters the Authority must take into account when deciding on an application? If yes, what should these matters be? |
|---|---|
10. Do you agree a product approval application should include information on proposed manufacturing methods and how they will comply with the Psychoactive Substances Code of Manufacturing Practice?

Yes

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
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 - though previous use may be difficult to comply with, with novel compounds?

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

Note our previous comments about labelling - they must be directed to, and meaningful for, the target consumer group.
Country of origin should be included
Should be explicit that it is a potentially dangerous substance <not> a healthy, safe 'herbal high.'
Suggest a warning graphic or distinctive colour could be used.

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).

R18?
Products that are meant to be smoked, as some of psychoactive substances like the now banned Kronic were, should have to meet the tobacco labelling and packaging requirements.

16 Are the proposed packaging requirements and restrictions sufficient? If not, please make specific suggestions for further requirements.
We suggest that packaging be required to suit labelling/health requirements; the product size does not have to be related to the package as is evidenced by many consumer goods and it is important that the messaging is clear and that important information is not relegated to an insert.

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

Yes. It is a direct and unambiguous means of conveying a 'correct' dose.
We assume this applies to products that are intended to be smoked as well i.e. enough for one cigarette.

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

There are mixed feelings about this. Though nurses certainly appreciate the child safety aspect, there is some concern that split doses will lead to taking higher doses as it makes it easier for the strength to be modified.
It is also difficult to gauge the effect on individuals. E.g. split doses do allow a 'half' dose to be taken, which may make it easier to introduce and give a false impression of safety.

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?
Tobacco-like products that have to be smoked should be excluded.

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?
Yes. They should be the same as the restrictions on tobacco displays.

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

No comment

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

Yes - as above - the same restrictions as apply to tobacco.
Additionally, NZNO strongly recommends that the regulations should require display of public health messages to prevent and minimise harm, e.g. signs of adverse reaction/addiction, where to seek help if an adverse reaction occurs, or an addiction problem to address etc.

25 Do you think the regulations should specify further places where approved products may not be sold? If so, please provide specific suggestions.
26 Do you think the regulations should prescribe restrictions or requirements for advertisements of approved products? If so, please provide specific suggestions.

Yes. They should not be able to be advertised in magazines, radio or television or the internet, or 'fliers'. They should not be able to be offered with other products, or discounted in the way that supermarkets use alcohol as a loss leader.

The principles of the Standard Authority's Advertising Code of Ethics do not embrace public health and are therefore not rigorous enough to cover psychoactive substances.

The principle that All advertisements should be prepared with a due sense of social responsibility to consumers and to society is vague and arguable. The regulations should be able to prescribe restrictions or requirement that prevent advertising of products as 'healthy', or that encourage use that is likely to be unhealthy.

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

NZNO is very pleased to see this proposal as our supplementary submission on the Psychoactive Substances bill indicated that nurses' experience is that patients regularly purchase products through the Internet using YouTube or Google with taglines such as "Buy research chemicals" or "Buy MD 2200" were concerned that for the legislation to be effective internet sales had to be addressed.

We support restrictions on designing to appeal to minors, R18 access and mandatory health warnings, though we are aware of the limitations of these tools. We suggest restrictions on the quantity that may be bought might be useful and would recommend that agencies familiar with internet risks for children, e.g. NstSafe, Police, InternetNZ and the New Zealand Māori Internet society would be better able to advise on workable solutions.

28 Do you think the regulations should prescribe restrictions or requirements on the advertising of approved products? If so, please provide specific suggestions.
29 Do you agree with the proposed fees for the different licences? If not, please provide specific suggestions.

No comment

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

No comment

31 Should fees be set for other specific functions? If yes, please state what they should be set for.
32. Do you agree with the proposed list of items and process for setting levies? If not, please provide specific suggestions.

No comment

Marilyn Head
Senior Policy Analyst

REFERENCES
18 March 2014

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

By email: psychoactives@moh.govt.nz

Dear Sirs,

Re: Psychoactive Substances Regulations: A consultation document

Safer Whanganui welcomes the release of this consultation document as the issue of psychoactive substances is one of much interest and concern within our community. We thank the Ministry of Health for providing this opportunity to comment on and provide input into the development of the psychoactive substances regulations.

Introduction

Established in 2009, Safer Whanganui is a Council led community owned collaborative and co-operative framework between community organisations, local government and central government agencies within the Whanganui region. Safer Whanganui achieved the World Health Organisation International Safe Community accreditation in 2010 and is globally benchmarked. The central tenet of a Safe Community is the idea that safety is a universal concern of all peoples and the responsibility of all peoples. Safer Whanganui and its member organisations work within the Whanganui community striving to continually make it a safer community, where everyone feels safe to be in and move around all of the time.

At the Safer Whanganui meeting held on 26 February 2014, a resolution was passed to action a submission to the draft Local Approved Products Policy (LAPP) regulations.

SUBMISSION

• Identification

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

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

- **Fit and proper person test**

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

- **Inspection of premises**

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

- **Compliance with Local Approved Products Policy**

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

- **Changing premises**

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

- **Record keeping**

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

- **Display of licence**

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

- **Restricted trading hours / products**

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

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

- **Labelling and packaging**

  Safer Whanganui considers the proposed requirements and restrictions with respect to the labelling of psychoactive products need to be strengthened. Included within the health warning on packaging should be wording advising consumers not to mix the use of psychoactive products.

  Additionally, Safer Whanganui believe that included within the regulations should be a requirement that all occurrences of adverse effects reported to health officials must also be forwarded to the Authority so that accurate numbers of such occurrences and where such occurrences are happening can be recorded. Going forward, such information will be invaluable when developing and implementing health and/or social programmes to
combat adverse individual, family, whanau and community impacts derived from the availability and use of such products; and also in the event that it becomes necessary to seek the removal of an approved product from the market.

Safer Whanganui believe that it is important that the packaging of psychoactive products be kept plain and non-descript, be child proof and tamper proof, and not designed using images/words associated with youth culture.

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

- **Quantity**

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

- **Storage**

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

- **Generally**

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

On behalf of Safer Whanganui and its membership:

<table>
<thead>
<tr>
<th>Name</th>
<th>Position</th>
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<tbody>
<tr>
<td>Mayor Annette Main</td>
<td>Chairperson</td>
</tr>
<tr>
<td>Charmaine Matihaia</td>
<td>Safer Whanganui Co-ordinator</td>
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<tr>
<td>Bernie Rush</td>
<td>New Zealand Fire Service Wanganui</td>
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<td>Gary Ward</td>
<td>New Zealand Fire Service Whanganui</td>
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<td>Jemal Weston</td>
<td>New Zealand Fire Service Whanganui</td>
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<tr>
<td>Deanna McKay</td>
<td>Wanganui Primary Schools Association</td>
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<td>Stephen Mastrovich</td>
<td>New Zealand Police</td>
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<tr>
<td>Heather Williams</td>
<td>ACC</td>
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<tr>
<td>Danny Jonas</td>
<td>Sport Wanganui</td>
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<tr>
<td>Ian Lowe</td>
<td>Horizons Regional Council</td>
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<tr>
<td>Cr Jack Bullock</td>
<td>Councillor – Wanganui District Council</td>
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<tr>
<td>Jan Dunphy</td>
<td>Community House</td>
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<tr>
<td>Mike Ward</td>
<td>Community House</td>
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<tr>
<td>Julie Patterson</td>
<td>Whanganui District Health Board</td>
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<tr>
<td>Lauren Tamehana</td>
<td>Whanganui District Health Board</td>
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<tr>
<td>Marian Dean</td>
<td>Whanganui Disability</td>
</tr>
<tr>
<td>Meg Hansford</td>
<td>Child, Youth and Families</td>
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<tr>
<td>Sam Burroughs</td>
<td>Child, Youth and Families</td>
</tr>
<tr>
<td>Melanie Heron</td>
<td>Wanganui District Council</td>
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<tr>
<td>Sally Patrick</td>
<td>Wanganui District Council</td>
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<td>Rae Karipa</td>
<td>Ministry of Education</td>
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<tr>
<td>John Maahi</td>
<td>Whanganui Iwi</td>
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<td>Shelly Harkness</td>
<td>Restorative Practices Whanganui</td>
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<td>Tim Metcalfe</td>
<td>JigSaw Whanganui</td>
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Reference Group Representatives:

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<tr>
<td>Alcohol and Other Drugs</td>
<td>Julie Herewini</td>
<td>Nga Tai O Te Awa</td>
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<td>Safety and Wellbeing</td>
<td>Te Ora Nyman</td>
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<td>Emergency Planning</td>
<td>Matthew Smith</td>
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<td>Road Safety</td>
<td>Glenda Leitao</td>
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21st March 2014

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

Consultation on Psychoactive Substance Regulations

Thank you for the opportunity for the Auckland Regional Public Health Service (ARPHS) to provide consultation on the Psychoactive Substance Regulations.

The following submission represents the views of the Auckland Regional Public Health Service and does not necessarily reflect the views of the three District Health Boards it serves. Please refer to Appendix 1 for more information on ARPHS. Throughout this document where the term 'we' or 'our' has been used it is referring to ARPHS.

We understand that all submissions will be available under the Local Government Official Information and Meetings Act 1987, except if grounds set out under the Act apply.

Yours sincerely,

[Signature]
Dr. William Reigner
Service Manager
Auckland Regional Public Health Service

[Signature]
Dr. Shanika Perera
Medical Officer of Health
Auckland Regional Public Health Service
Specific Comments

Role of Enforcement Officers

1. In addition to our response to the consultation questions, ARPHS would like to highlight the importance of defining the role of enforcement officers. Enforcement officers appear to be involved in the following areas: site inspections for applications; site inspections and auditing of licence holders post-approval; response to complaints (either reported by members of the public or referred by the Authority); and involvement in Controlled Purchase Operations (CPOs).

2. We recommend that the Psychoactive Substances Regulatory Authority (the "Authority") define the specific role of public health enforcement officers in the Regulations and ensure that the provisions to be enforced align with the enforcement powers as described in the Act. We request that the Authority considers what action is required and how this action will be carried out by enforcement officers.

3. If there are to be set time-frames for processing applications in the Regulations, we recommend that these time-frames realistically incorporate any site inspections to be conducted by enforcement officers. Ideally, time-frames should retain some flexibility as multiple applications may be received concurrently. Also, estimating the time required to conduct site inspections may be difficult when the Regulations initially commence.

4. Inspection of manufacturing premises is beyond the usual role of public health enforcement officers, so we recommend that any assessment involving manufacturers be devolved to other authorised personnel with the appropriate professional background. If public health enforcement officers are expected to assess manufacturing premises, we would expect appropriate training and resources to be provided by the Authority.

5. In a geographic area the size of the Auckland region, there will be numerous CPOs conducted in retail premises in multiple police districts. It is important that the role of enforcement officers in CPOs be clearly defined to ensure resources are used efficiently and effectively. We recommend that public health enforcement officers be involved in CPOs of licensed premises only as this directly relates to assessing compliance.

6. We suggest that CPOs of licensed premises should be conducted by both Police and Public Health in partnership to cover any illegal activities identified. If a programme of routine CPOs is to be considered, the frequency of CPOs should be based on available resources.

7. Any matters, including CPOs, that involve unlicensed premises will involve illegal activities exclusively and as such should be referred to the Police with support from Public Health if required. We recommend the Regulations should define when the Authority, Police or Public Health (on behalf of the Authority or otherwise) is responsible for prosecutions.
8. We support the Authority's role in assessing applications on a national basis in order to provide consistency throughout the country.

Consultation questions

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

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

9. There is the potential for applicants to provide a 'front' for others parties who would otherwise be unable to apply successfully for a licence, for example overseas parties or individuals who would fail the fit and proper person test.

10. We recommend that more information is required for licence applications to assess any criminal or gang affiliations of the applicants due to the potential for criminal misuse of the Act.

11. We recommend that applicants should declare any associations or relationships they may have with individuals convicted of a "relevant offence" as specified in section 19(3).

12. Information on criminal associations could be used to assess if an applicant is a fit and proper person. If this information cannot be used as part of the fit and proper person test, it still may assist the NZ Police if there is future suspected criminal activity associated with a particular licence.

13. If there is a requirement for applicants to declare any criminal associations, this may deter individuals with no criminal history applying for licences on behalf of known criminals.

14. We recommend all applicants should provide (and operate from) a registered business street address and not a residential premises unless that premises is a registered and approved by the local authority for this type of activity. The use of residential premises could compromise the ability of enforcement officers and constables to conduct inspections under the provisions of the Act.

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

15. We support that retail licence applications include evidence of compliance with the local approved products policy (LAPP) for the area because compliance with the LAPP is an essential part of processing applications. The onus would be placed on the applicant to show evidence of compliance rather than the Authority determining compliance, which would enhance the efficiency and decrease the cost of processing applications.

16. We recommend that the Regulations include a process for dealing with licenced retail premises that do not comply with a newly adopted or reviewed LAPP.
17. **We recommend** the Regulations stipulate that the Authority and the Territorial Authority provides sufficient access to a generic LAPP to enable applicants to comply with the policy.

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

18. **We support** that retail licence applications be accompanied by evidence of compliance with a generic LAPP if none is in effect in the area.

19. We assume that licenced retail premises will be reassessed if a specific LAPP is later introduced by the Territorial Authority.

20. **We recommend** the Regulations stipulate that the Authority provide sufficient access to a generic LAPP to enable applicants to comply with the policy.

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

*Prior criminal record and pending prosecutions*

21. As previously highlighted, there is a potential for criminal misuse of the Act, therefore the assessment of whether an applicant is a fit and proper person is extremely important.

22. **We support** that the Authority has the discretion to decide whether an applicant is a fit and proper person. **We support** the involvement of New Zealand Customs and New Zealand Police in the fit and proper person check.

23. **We recommend** that additional offences be considered as part of the fit and proper person test over and above those listed as a "relevant offence" under section 16(3). **We recommend** that serious criminal offences involving custodial sentences be considered, as well as overseas criminal offences.

24. **We recommend** that pending prosecutions should also be considered as there could be significant charges awaiting adjudication.

*Gang affiliation*

25. Research shows that individuals and groups affiliated with gangs are more prone to commit to crime and various abusive anti-social behaviours including illicit drug intake, than unaffiliated individuals and groups.\(^1\) **We recommend** that gang affiliation be considered to assess whether a person is a fit and proper person or whether a body corporate is of good repute.

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

26. We support that a history of compliance with other regulatory regimes, such as alcohol licensing and smoke-free environments, should be used to provide an indication of the applicant’s future compliance with the Act and the Regulations.

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

27. We support the proposal that records should be kept of all sales transactions including the quantity of products received and distributed. We recommend that records be retained for both domestic and international sales transactions. This information will not only be useful to determine "product leakage" (pg. 9 of the consultation document), but will also be useful to trace any batches of product that needs to be recalled or investigated. This information could also be used as part of epidemiological surveillance.

28. We recommend that delivery details, destinations, quantities despatched and batch/lot identification should be recorded for wholesalers, manufacturers, importers and exporters.

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

29. We recommend records should be kept for seven years as minimum requirement to align with existing financial and commercial legislation such as the Companies Act 1993 and the Tax Administration Act 1994.

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

Trading hours

30. The Sale and Supply of Alcohol Act 2012 has provisions for permitted trading hours (sections 43 to 46) and restrictions related to trading hours (sections 46 to 49). A review of international literature relating to hours of alcohol sales by Stockwell et al. (2009) demonstrate even a slight change of earlier closing hours of retail premises can equate to less assaults in a community.²

31. As the Psychoactive Substances Act 2013 does not have any provisions related to trading hours, we recommend that the Authority should consider trading hours when setting discretionary conditions.

Maximum limit of product purchased at retail premises

32. For retail premises, we recommend the Authority should also set a maximum amount of psychoactive product that can be sold to an individual during a single transaction over a defined time period, for example 24 hours.

Question 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?

Demonstration of applicant’s knowledge of Act

33. Part 6 of the Sale and Supply of Alcohol Act 2012 requires a certified manager to be on duty when alcohol is being sold or supplied to the public on any licensed premises. The general manager’s certificate requires a "prescribed qualification", which is defined as the "Licence Controller Qualification" in the associated Regulations. This qualification requires the completion of NZQA accredited unit standards to demonstrate knowledge of the Sale and Supply of Alcohol Act and host responsibility.

34. The Psychoactive Substances Act 2013 does not contain provisions that require the demonstration of knowledge by applicants. However, we recommend that the Regulations include the requirement for retail licence applicants to demonstrate their knowledge of the Act, the Regulations and the associated responsibilities. Ideally, this should be based on applicant tested knowledge using NZQA unit standards.

History of unsuccessful licence applications

35. We recommend that the Authority consider whether the applicant has made previous licence applications that were not granted and the associated grounds. If an applicant has provided false or misleading information in the past, this should be considered depending on the extent and the frequency.

Question 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?

36. We support product approval applications including information on proposed manufacturing methods and how they will comply with the Psychoactive Substances Code of Manufacturing Practice. This would place the onus of the on the applicant to show evidence of compliance rather than the Authority determining compliance, and demonstrate the applicant’s knowledge of the Code.

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

37. We assume that every psychoactive product approval relates to a specific manufacturing site whether in New Zealand or overseas. If this is not currently the case, we recommend that a product approval cannot be transferred to another manufacturing site. This would prevent domestic production being transferred overseas without evidence of compliance with the Psychoactive Substances Code of Manufacturing Practice.
38. We assume that all imported psychoactive substances will need to comply with the New Zealand Psychoactive Substances Code of Manufacturing Practice. If a licence to import psychoactive substances is used to import final packaged psychoactive products, we recommend that the Regulations contain a process for the inspection of these imported products to ensure compliance with the psychoactive product approval and the Code prior to being released into the domestic market.

**Question 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?

**39. We support** that product approval applications contain specific data on toxicity, pharmacology and related clinical effects. This would place the onus on the applicant to provide sufficient and appropriate evidence to the Authority and the Psychoactive Substances Expert Advisory Committee.

**Question 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?

**40. We support** that the Regulations require product approval applications to contain information and data as specified above.

**41. We support** the provision of guidelines by the Authority to ensure manufacturers are aware of the information and data requirements for product approval applications.

**42. We assume** that product approval applications will include proposed labelling and packaging of the product and that this will be assessed to ensure compliance with the Act and Regulations.

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

**43. We support** the proposed requirements and restriction on labelling. We recommend that the Regulations contain a prescribed font size for lettering to ensure that all labelling is legible.

**Question 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).

**44. We support** the four compulsory warnings proposed.

**45. Section 48 of the Psychoactive Substances Act 2013 restricts persons under 18 years from buying or possessing psychoactive substances, however, this does not cover consumption. We recommend the additional health warning 'do not consume if aged under 18 years'.**
46. We recommend labelling specifying any known allergic reactions related to any component substance or excipient contained in a psychoactive product.

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

47. We support the proposed packaging requirements and restrictions. In addition, we recommend that the packaging should not indicate any association to food such as fruit.

48. We recommend that all inserted material should only relate to details of the product (as per labelling requirements) and health warnings. No other inserted material should be allowable, including promotional or advertising material.

Standardised plain packaging

49. Following Australia’s policy of plain packaging cigarettes, smoking in public places such as cafés, restaurants, and bars declined. A cross-sectional study from Victoria supports plain packaging have the effect to lower the appeal of smoking. We recommend all packaging of psychoactive products should be plain and standardised in appearance.

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

50. We support the proposal to restrict a packet to one dose as this will reduce the risk of possible overdose. Also this would provide greater exposure of health warnings on products to potential consumers.

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

51. We support the proposal to split the dose wherever possible.

Question 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?

52. We recommend products should be restricted to non-smokeable products only. This would avoid the additional health risks associated with smokeable products, issues with passive smoking, and risks of substitution of smokeable psychoactive products for tobacco. This would support and align with Smokefree New Zealand 2025.

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

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It must be duly noted plain packaging as an instrument to discourage smoking was complimented by large pictorial warnings and legislation restricting smoking areas.

53. Due to the profit associated with psychoactive substances and products, stores may be the target of theft. We recommend the regulations should include specifying minimum security measures for any premises where psychoactive substances are stored and an assessment of security measures as part of the application process. We recommend restricting storage volumes in order to limit the impact of any potential theft.

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

54. We recommend specifying minimum security measures and restricting storage volumes for any premises where psychoactive products are stored as per our response above.

55. We recommend that the type of premises be considered when setting security measures or storage volumes. It is unlikely that security measures at a retail premises can replicate those of a manufacturing, research or wholesale premises. Therefore, it is particularly important that retail premises should only be allowed to keep a maximum amount of stored psychoactive products on-site.

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

56. We recommend the Regulations note the display of approved products should not be easily visible from outside of the premises in order to align with section 56(3)(c) of the Psychoactive Substances Act, which relates to the advertising of an approved product.

57. We recommend that the display of approved products should not appeal to youth in order to align with labelling and packaging requirements.

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

58. We support restrictions and requirements relating to the disposal of approved products to ensure there is no harm to the community as a result from unsafe disposal. Options available to dispose the products include incineration at an approved facility and burial at an approved landfill.

59. An alternative model for disposal is the current process for the surrender of non-compliant graphic materials to the local Public Health Unit with a Health Protection Officer witnessing the destruction at a refuse transfer station after verification of the quantity. In these circumstances, satisfactory destruction is achieved by driving the digger over material to pulverise the contents with immediate loading of the crushed residue into the transfer vehicle to avoid any chance of scavenging. The resource requirements for such a service would need to be considered such as a standard charge.

60. We recommend the regulations include a restriction on export or of psychoactive substances or products that are requiring disposal.

Question 24: Do you think there should be signage requirements in the regulations? If so, please give specific suggestions.
61. We recommend there should be signage requirements in the regulations. Signage should not appeal to youth to align with labelling and packaging requirements. Signage should prominently state the health warning and that the product cannot be sold to a person under the age of 18 years.

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

62. We recommend that the sale of approved psychoactive products should be prohibited at the following places:
   - Dance venues without liquor licences
   - Video hire premises
   - Gaming facilities without liquor licences
   - Tertiary education providers
   - Healthcare providers
   - Alternative medicine providers

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

63. We recommend that the Regulations prohibit:
   - Flyers (whether delivered to letterboxes, distributed in public places etc)
   - Poster advertising in public places and on hoardings
   - Direct to consumer marketing including letters or text messaging
   - Catalogues and newsletters that promote the use psychoactive products.

64. We recommend that the Regulations stipulate that advertising should not contain misleading information is not misleading.

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

65. Based on evidence related to internet sales of medicines, it is likely that internet sales will result in illegal transactions based on age and unregulated products. Medsafe signalled the dangers of buying medicines online as a result of a joint operation from Medsafe and Customs on substandard, illegal and counterfeit medicines. In 2013, medicines originating from 32 different countries were contained due to the absence of labels and undeclared ingredients.

66. We recommend that the Authority consider how to manage internet sales of psychoactive products from international websites as these websites may not be required to comply with the Regulations.

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7 Ibid.
67. **We recommend** that any retail licence holder intending to sell approved products on-line, should be required to pre-register any purchaser in order to verify identification and payment details.

68. **We recommend** internet sites offering psychoactive products for sale within New Zealand should include the following advertising and interface requirements:

- No appeal to youth
- A maximum amount of product that can be sold in a single transaction to a single consumer over a defined time period (for example, 24 hours)
- An entry page to verify age
- A declaration by the purchaser not to on-sell or supply the products to any person under the age of 18
- Utilisation of the RealMe service to verify age prior to every purchase online
- Publication of the licence on the website.

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

69. **We support** the limitations placed on the advertising for an approved product as outlined in section 56(3) of the Psychoactive Substances Act 2013.

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

70. **We support** the proposed fees for the different licences in cases where processing applications are straightforward. However, some applications may require additional assessment and processing, for example, additional site visits to proposed premises and requesting additional information for incomplete applications.

71. **We recommend** that cost associated with additional processing should be recoverable from the applicant. This would also encourage applicants to file complete applications.

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

72. We do not have a preference for either a fixed fee or an hourly charge for the processing of applications for product approvals. However, if a fixed fee approach is used, we recommend that the Authority maintain the right to charge an additional fee to reflect any additional work required.

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

73. **We recommend** fees will need to be set for specific functions including enforcement officer activities such as enquiries, controlled purchase operations (CPOs), audits and inspection visits.
74. We also recommend fees for processing imported consignments.

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

75. We support the proposed list of items and process for setting levies. We recommend levies should not only be based on the type of licence, but should also be based on the size of the proposed business using sales records.
Appendix 1 - Auckland Regional Public Health Service

Auckland Regional Public Health Service (ARPHS) provides public health services for the three district health boards (DHBs) in the Auckland region (Auckland, Counties Manukau and Waitemata District Health Boards), with the primary governance mechanism for the Service resting with Auckland District Health Board.

ARPHS has a statutory obligation under the New Zealand Public Health and Disability Act 2000 to improve, promote and protect the health of people and communities in the Auckland region. The Medical Officer of Health has a delegated enforcement and regulatory role under the Health Act 1956 and other legislative designations to protect the health of the community.

ARPHS' primary role is to improve population health. It actively seeks to influence any initiatives or proposals that may affect population health in the Auckland region to maximise their positive impact and minimise possible negative effects on population health.

The Auckland region faces a number of public health challenges through changing demographics, increasingly diverse communities, increasing incidence of lifestyle-related health conditions such as obesity and type 2 diabetes, outstanding infrastructure needs, the balancing of transport needs, and the reconciliation of urban design and urban intensification issues.
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?

   Only for new applications. Already existing licences should have the option to move to a more suitable location.

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 for new applications. Already existing licences should have the option to move to a more suitable location.
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?

Sales records, negative and positive feedback, problems. Some basic user/Buyer stats could also be useful.

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

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

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

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

11 Do you think any further particulars, information, documents or other material should be prescribed in the regulations? If yes, what should these be?
Nothing I can think of right now.

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.

More effects info, what effect is product intended to have.
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.

In theory I believe people need to learn to read the label. In reality this is not always the case. It would depend on the substance. For low risk products I believe people are generally capable of safely using a product containing more than one dose. Also, everyone is different. Still, some upper limit may be good. If someone consumes the whole pack they should not come to real harm, however if they misuse a product some negative effects such as nausea should be expected.

C

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

Where possible, but not always. It depends on product.
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, smoking and oral (blotter tab, pill, capsule) only, not snorted or injected.

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

Child and animal proof unit, which is locked or stored in a locked room.

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

Child and animal proof unit, which is locked or stored in a locked room.

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

7 units max of any product. Not visible from street. For non-R18 shops out of sight of under 18 customers.
23 Do you think restrictions or requirements should be set regarding the disposal of approved products? If so, what should they be?

Burning would ensure products do not end up on the black market.

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

R18 signs, conditions of sale signs, inside store or only

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

no

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

Yes, in store or on website only. Limits on marketing that may confuse products with natural cannabis.
Do you think the regulations should prescribe restrictions or requirements on internet sales of approved products? If so, please provide specific suggestions.

Keep the products, advertising, blogging etc all limited to the one approved website. List all product info such as ingredients, warnings, usage on site.

---

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

Yes, similar to alcohol.

---

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

I find them somewhat excessive, considering the products are recreational drugs, not health products.

---

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

Hourly charge.
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)

- [ ] yes 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

(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.

- [ ] yes I do not give permission for my personal details to be released under the Official Information Act 1982.

- [ ] yes I do not give permission for my name to be listed in the published summary of submissions.

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10 Psychoactive Substances Regulations: Submission form
21 March 2014

Donald Hannah
Manager
Psychoactive Substances Regulatory Authority
Ministry of Health
PO Box 5013, Wellington

By email: psychoactives@moh.govt.nz

SUBMISSION REGARDING THE PSYCHOACTIVE SUBSTANCES REGULATIONS - CONSULTATION DOCUMENT

INTRODUCTION

1 Stargate Operations Limited ("Stargate") welcomes the opportunity to submit on the Psychoactive Substances Regulations Consultation Document ("the Consultation Document"). Stargate is available to answer any further questions the Psychoactive Substances Regulatory Authority ("the Authority") may have regarding the Regulations.

2 Stargate's role, both in New Zealand and internationally, includes:

(a) The development and bringing to market of safer, legal alternatives to addictive and dangerous drugs;

(b) The development and introduction of nutritional biochemistry solutions for existing or recovering alcohol and drug users;

(c) Advocating for more effective, evidence-based drug policy through the political process;

(d) Representing the interests and issues of those communities most affected by drug use to government and the public;

(e) Developing and providing innovative drug education programmes; and
(f) The development of ‘on the ground’ harm minimisation strategies to provide physical help for people experiencing drug related difficulties.

3 Stargate’s interest in the Psychoactive Substances Act 2013 (“the Act”) Regulations (“the Regulations”) is as a licenced importer, manufacturer, and retailer of psychoactive substances.

SUMMARY OF RECOMMENDATIONS

4 Stargate makes four overall submissions:

(a) Regulations must meaningfully support the purpose and principles of the Act. The only legitimate basis for Regulations under the Act is that they meaningfully support the purpose and principles of the Act. Stargate is aware of a number of submissions which have proposed Regulations that appear to be for improper purposes. For example, it would be improper for Regulations to be made for the purpose of making it more difficult to obtain approved products, to make it easier to prohibit approved products, or to enable local authorities to interfere with the licenced sale of approved products. Stargate submits that every Regulation should have a clear and direct link with the purpose and principles of the Act.

(b) Consultation on draft Regulations. Stargate notes that a number of the proposals contained in the Consultation Document are not fully developed, or are ambiguous. This significantly limits the effectiveness and adequacy of the consultation process in a number of areas. Stargate recommends that further consultation should be undertaken on draft Regulations. This further round of consultation would take into account policy decisions made after this consultation.

(c) Importance of creating clear and unambiguous requirements. Stargate submits that the Authority should pay particular attention to ensuring that regulations are clear and certain. Forms and guidelines should be utilised to clarify requirements where possible. Where certainty is of particular concern to Stargate this has been noted in the body of this submission.

(d) Ensuring regulations are necessary and created through the appropriate mechanism. The Act creates a full suite of regulatory mechanisms. These include:

- requirements and restrictions that are in the Act itself;
- licensing administered by the Authority (including licence conditions);
- product approval (including packaging, dosage and mode of delivery) administered by the Authority;
- Local Approved Product Policies ("LAPPs") created by territorial authorities;
- Code of Manufacturing Practice administered by the Authority; and
- Regulations created under the Act by Order in Council.
Given the full range of tools, Stargate submits that the Authority should be mindful of the need to ensure restrictions are created through the appropriate mechanism. It is detrimental to the coherency of the regime if the Regulations double-up restrictions that are applied elsewhere, especially where there are subtle or non-subtle differences in how the restrictions are worded or applied. This is consistent with the Government's emphasis on reducing the amount of regulations, and ensuring new regulations are necessary for their purpose. Where this is of particular concern is Stargate – it has been noted in the body of the submission.

The specific recommendations made in this submission can be summarised as:

(a) **Implementation of retail licensing must be brought forward.** The implementation of the retail licence regulations should be brought forward to the middle of 2014. This is to avoid the unreasonable and damaging extension of the interim retail licensing period.

(b) **Include a transitional period for packaging requirements.** The requirements relating to packaging will take time to implement and require a lead-in period.

(c) **The Regulations should not provide for a “generic” Local Approved Products Policy (“LAPP”).** A generic LAPP is unnecessary and inconsistent with the regulatory scheme of the Act. [Consultation Question 3].

(d) **Licence holders should keep records about manufacture, disposal, sale, purchase, and importation.** The record-keeping requirements should allow the Authority to track the full life-cycle of a substance or product. [Consultation Question 6].

(e) **Discretionary conditions applied to licences should be necessary for achieving the purpose of the Act and should be applied on a case by case basis.** There should be no mandatory “discretionary” conditions. [Consultation Question 8].

(f) **Public interest and demand should be considered in determining licence applications.** This should include the public interest in having a competitive and diverse regulated market. [Consultation Question 9].

(g) **Product approval applications should not need to include information about Code of Manufacturing Practice compliance.** The proposed requirement to provide information relating to the Code is superfluous, imposes additional compliance costs and could lead to delays. [Consultation Question 10].

(h) **Product approval applications should include the full details of the product.** This includes its packaging, mode of delivery and dosage. [Consultation Question 11].

(i) **The process for considering applications and determining priority should be clear and tightly controlled.** For example, the Regulations should prescribe timelines for the Authority to notify whether an application is complete.
(j) There should be a process for modifying complete applications. Such a process is necessary and would greatly assist the Authority in meeting its goals efficiently.

(k) Labelling and packaging requirements should be dealt with as part of product approvals. In order to ensure certainty, the Authority should verify compliance with labelling and packaging restrictions during the product approvals process.

(l) Dose, split dose, and mode-of-delivery requirements do not require regulations and should be dealt with as part of product approvals. The Regulations should not fetter the discretion of the Authority to approve products which are established to pose no more than a low-risk of harm. The proposed regulations are unnecessary, as these issues can be dealt with during the product approval process. The Authority could develop guidelines which provide guidance to manufacturers on these matters without fettering discretion completely. [Consultation Questions 17, 18 and 19]

(m) Consider regulating the disposal of psychoactive products. [Consultation Question 21].

(n) Fees and levies must be justified based on an actual estimate of the Authority's costs. Stargate has not been given sufficient information to make an informed contribution as to fees. The proposed fees and levies appear to be unjustified based on the latest available estimate of the Authority's costs.

PROPOSED TWO-PHASE IMPLEMENTATION

6 Stargate makes two submissions regarding the proposed two-phase implementation timeframe. First, Stargate submits that the retail licensing regulations must be brought forward. Second, Stargate submits that the Regulations relating to packaging and labelling must provide for a transitional period.

Retail licensing

7 Stargate believes that the proposed implementation timeframe unreasonably extends the interim retail licensing period. The full retail licensing process should be implemented as soon as possible, and no later than the middle of 2014, for the following reasons:

(a) During the interim period, new retailers are not able to apply for licences. This means, if Local Approved Product Policies (“LAPPs”) lead to retailers closing — there could be substantial gaps in the market, and effective prohibition in certain territorial areas. That situation would be inconsistent with the purpose of the Act, and potentially undermine its core objectives. Stargate notes that this is already the case after a number territorial authorities have passed highly restrictive LAPPs.
(b) The proposed delay poses an unreasonable barrier to entry to the retail market—undermining competition. Stargate recommends seeking the advice of the Commerce Commission before moving further with such a delay.

(c) The delay is unjustified as territorial authorities do not need until the middle of 2015 in order to develop LAPPs. Territorial authorities have been in a position to develop LAPPs from the middle of 2013, and two years would be an extraordinary lead-in period. A number of territorial authorities have already implemented LAPPs, and more are in the process of consulting on them. It is clear that one year from the enactment of the Act is a reasonable and sufficient amount of time to give territorial authorities to develop LAPPs if they wish to do so.

(d) Delaying the implementation of retail licensing will not resolve the situation where a new or amended LAPP affects an existing retail licence. Even if the Authority was to give territorial authorities a full two years to develop LAPPs before implementing retail licensing—territorial authorities would still be free to develop new LAPPs or amend existing LAPPs after retail licensing is implemented. Therefore, the Authority will not be able avoid having a process for the situation where a new LAPP affects existing licences—which appears to be the reason for the delay.

Transitional period for packaging regulations

8 The Regulations relating to packaging and labelling will take time to implement and require a transitional period. Giving effect to packaging and labelling requirements will require manufacturers to purchase the necessary equipment. Manufacturers are not in a position to purchase equipment before knowing the specifications required by Regulations and this equipment can take up to six months to source.

9 Stargate submits that the Regulations should provide that the packaging restrictions come into effect six months after the Regulations come into force. Alternatively, the Regulations could apply only to full product approvals, and not to products with interim approval.

LICENCE APPLICATIONS

Information requirements

General information requirements

10 Stargate submits that the proposed general information requirements for licence applications are comprehensive and reasonable. There is no further information that should need to be provided.

Evidence of compliance with LAPP

11 Stargate agrees that retail licence applications should be accompanied by evidence of compliance with a LAPP if one is in effect in the applicant’s area. This is an appropriate
and efficient way of monitoring compliance with LAPPs — and ensuring that the retail licence process and LAPP process are well integrated.

However, Stargate notes that the Consultation Document implies that retail licences will be issued for a particular address. Stargate submits that this requires some careful consideration and justification.

Section 14 of the Act outlines the grounds for granting a licence (including a retail licence). It provides that the Authority must grant a licence where:

(a) the application is in the correct form, and does not contain materially false information; and

(b) the applicant is a fit and proper person (in the case of an individual), or of good repute (in the case of a body corporate);

There is no reference to the Authority considering whether the location of the retail outlet is appropriate. Stargate submits that as a matter of policy the Act creates a division of responsibility between the regulatory purpose of retail licensing (implemented by the Authority) and LAPPs (implemented by territorial authorities):

(a) Retail licensing is a mechanism for ensuring retailers are fit and proper, or of good repute. This allows the Authority to monitor and ensure compliance with the Act and regulations.

(b) LAPPs are a mechanism for local communities to regulate the location of retailers.

The Act shows an unambiguous preference that restrictions relating to the location of retailers are to be set by local communities (after mandatory local consultation), and that the Authority's role is to ensure retailers are fit and proper.

Nothing in the Act specifies that retail licensing should also be another mechanism for regulating the location of retailers. Issuing retail licences for a particular address will create further compliance and regulatory processes, and Stargate submits that this would require active justification by the Authority.

Evidence of compliance with generic LAPP

Stargate opposes the proposal to develop a generic LAPP. A generic LAPP would be unnecessary, and inconsistent with the scheme of the Act.

As explained above, the Act creates a division of responsibility between retail licensing and LAPPs, and shows a clear preference that restrictions relating to the location of retailers are to be set by local communities.

Pursuant to section 69 of the Act, the adoption, amendment, review and revocation of a LAPP must be undertaken in accordance with the special consultative procedure set out in section 83 of the Local Government Act 2002. That strong theme of local consultation on LAPPs means it would be inappropriate to set “default” rules, subject to just one generic and undetailed consultation. There is no need for the Authority to undertake
the role of regulating the location of retailers nationally, other than as required by the Act.

*Fit and proper person test*

20 Stargate submits that the factors to be taken into account when determining whether an applicant is fit and proper (or of good repute) prescribed in section 16(2) of the Act are sufficient. Stargate agrees that the New Zealand Customs Service and New Zealand Police should be involved in this check.

21 Other matters which the Authority may consider relevant should be determined on a case by case basis. The applicant’s involvement in other regulatory regimes, such as alcohol licensing, may be relevant and the Authority should consider that case-by-case.

22 Stargate opposes fettering the discretion of the Authority so that any particular factor would be treated as an automatic disqualification.

*Licence conditions*

*Record keeping*

23 Stargate submits that licence-holders be required to keep records of all substances and products:

(a) manufactured (note that this information is required to be kept under the Code of Manufacturing Practice);

(b) destroyed or disposed, including the method and date of destruction or disposal;

(c) sold wholesale, including the person who the goods were sold to, and the method and date of delivery;

(d) sold retail, including the total number of products sold of each type in a given time period, although Stargate would strongly oppose a requirement that a retailer record the name of the person who purchased a product, as this would act as a significant deterrent to purchase, and is out of step with the regulation of other products such as alcohol;

(e) purchased, including who the goods were purchased from, and the address and date of delivery;

(f) imported, including who the goods were imported from, when the goods passed through customs and the address and date of delivery; and

(g) bought or held as research samples.

24 The purpose of the records-keeping regime should be that the Authority has the ability to “track” all products and substances through the regulated market.
Stargate submits that the record keeping requirements should be aligned with the provisions of the Tax Administration Act 1994 in terms of the period for which records must be kept.

Stargate submits that the Regulations should clearly set out the form of records to be kept.

**Discretionary conditions**

Stargate submits that discretionary conditions should not be imposed unless they are necessary to further the purpose of the Act. Stargate strongly believes that all discretionary conditions should be made on a case-by-case basis, exercising the discretion of the Authority. It would be inappropriate and inconsistent with the intention of the Act for the Regulations to prescribe any mandatory “discretionary conditions”.

For example, Stargate opposes the proposed blanket prohibition on the sale of food, confectionary, soft drinks and other household goods at licenced locations. First, such a condition double-ups the place of sale restrictions already contained in the Act. Second, making this an inflexible and mandatory condition would prevent the Authority from considering the reasonable sale of minor ancillary products. Stargate is aware of a number of responsible retailers who currently sell other products in a way for which there is no evidence of harm. The Authority could specify in guidelines what their default conditions are, without fettering their discretion completely.

**Any other matters the Authority may consider**

Stargate submits that the Regulations should prescribe these other matters that the Authority must take into account when deciding on a licence application:

(a) public interest in having a competitive and diverse regulated market for low-risk psychoactive products;

(b) public demand for access to a diverse range of low-risk products in a regulated market;

(c) whether declining an application will substantially reduce competition in the market; and

(d) New Zealand ownership and control of the market for the manufacture, retail and wholesale of substances and products.

**PRODUCT APPROVAL APPLICATIONS**

**Information requirements**

Stargate submits that any information requirements should be prescribed as precisely as possible so, in the interests of certainty and efficiency, it is clear what is required to be provided.
**Code of Manufacturing Practice information**

31 Stargate submits that a requirement to provide information about compliance with the Code of Manufacturing Practice ("the Code") is unnecessary and superfluous. All manufacturers must comply with the Code anyway, and requiring them to provide information at an earlier stage increases compliance costs and could cause unnecessary delays.

32 The Act creates an appropriate separation between product approval (which ensures products are low-risk) and the Code (which ensures good manufacturing practice). These are distinct regulatory functions, and are appropriately dealt with separately, at their respective times. It is unnecessary to create further compliance requirements. Manufacturing processes, for example, may change with new technology or as new methods are developed.

**Information submitted in product approval applications relating to risk of harm**

33 Stargate supports the proposal that the Regulations require applications to contain information and data on the toxicity, pharmacology and related clinical effects of the psychoactive product they are seeking approval for.

34 Stargate agrees that product approval applications should include data on the psychoactive potential and related behavioural effect of the substance; the addictive potential; the proposed directions for use; and previous use, including use in clinical trials and in the wider population.

35 Stargate submits that the Regulations should also prescribe that product approval applications include **full details of the product**, including information about:

(a) the substance, including the active ingredients, excipients and form of the substance (such as size, shape, and appearance);

(b) the packaging of the substance (both external and any internal packaging);

(c) the mode of delivery of the substance;

(d) the dosage, the number of dosages contained in a single product and whether they are split; and

(e) anything else contained in, or sold with the product (such as any delivery device that would be sold with the product, or any information or leaflet contained in the package).

36 The application should be able to provide supporting information as to the appropriateness of, and risk associated with, each aspect of the product.

37 Stargate submits that the information requirements should be specified as clearly and precisely as possible – to minimise any ambiguity in what information the Authority is seeking.
Process for considering applications

Determining priority

38 Stargate understands that the Authority intends to process applications in the order in which a completed application is received. Given the importance of having clear and fair rules about the priority afforded to applications, Stargate submits that the Regulations should prescribe a robust and controlled process.

39 In particular, Stargate submits that the Regulations should prescribe:

(a) A period in which the Authority must notify an applicant that it considers an application to be complete or incomplete. Stargate submits the period should be ten working days from the date of the original application.

(b) The form and contents of the notice that the Authority must give an applicant in the case of an incomplete application. This should include the reasons for deciding that an application is incomplete, and specify the particulars of the additional information that is required to complete the application.

(c) That once the Authority has received additional information, the same time and notice requirements apply to the Authority notifying an applicant that their application is either complete or still requires further information.

(d) That once the Authority considers an application to be complete, the application is afforded priority based on the date that the complete application or any additional information which completed the application was provided to the Authority.

Modifying completed applications

40 Stargate submits that the Regulations should prescribe an additional process for modifying a completed application. This should allow an applicant to modify details of their application without prejudice to the priority attached to that application.

41 Stargate anticipates that such a modification process is necessary, efficient and would greatly assist the Authority in achieving its goals. For example, where the Authority determines that they are concerned about a particular aspect of a product (for example, its packaging or potency) – it is appropriate that the applicant is able to modify its application to address these concerns, especially where they are minor. Without such a process, there could be an unacceptable amount of time and money wasted on small and easily changed issues, and both the Authority and applicant are likely to be considerably more reluctant to modify proposals to better achieve the purpose of the Act.

42 Stargate submits that the Regulations should provide:

(a) the Authority may suggest that an applicant modify its application, either before, during or after the application is assessed by PSEAC;

(b) the Authority may accept reasonable and technical modifications to the details of an application, without prejudice to the priority attaching to the application; and
(c) the Authority may request additional information in response to an applicant modifying their application.

**Additional products**

43 Stargate supports the proposal that products containing the same mix of active ingredients marketed in different size packages or with different flavours should require approval as “additional products”. It would be unreasonable and disproportionate to require these products to go through a full application process (with associated fees).

**LABELLING AND PACKAGING**

**Labels, health warnings and packaging**

44 Stargate supports the proposed requirements relating to labelling, health warnings and packaging. However, Stargate notes the importance that these requirements be precisely prescribed – to avoid uncertainty or ambiguity about compliance with any restrictions.

45 Stargate submits that certainty could be achieved through approving or verifying labelling and packaging as part of the product approval process.

**Quantity and dosage**

**Dose restriction**

46 Stargate is concerned about the proposal to limit a package to one dose. Our concerns are that the restriction would:

(a) Reduce the average price of psychoactive products available on the market – and be inconsistent with tobacco control regulations. Stargate note that the Smoke-free Environments Act 1990 prohibits the sale of tobacco products with less than 20 cigarettes. This is in order to increase the price of purchasing a product, and discourage low-value *on a whim* purchases. Some of this logic applies to psychoactive products, and Stargate would not recommend enforcing one-dose sales across the board.

(b) Encourage the sale of higher-potency dosages. Manufacturers would be encouraged to increase the potency of a single dose – instead of selling several low-potency dosages in one package.

(c) Be unnecessary for some products (the proposed restriction is rigid and there may be no purpose served in creating this restriction for some products).

(d) Be impractical or uneconomic for some products.

(e) Reduce consumer choice.

(f) May not achieve any change in consumer behaviour – as consumers can purchase more than one package.
47 Given these concerns, Stargate recommends that the Authority deal with dosages as part of the product approval process.

*Split-dose requirement*

48 Stargate submits that split-dose requirements can be dealt with appropriately at the product approval stage, instead of through regulations.

49 We agree that a dose should be split wherever possible. This reduces the risk that an individual will consume more than the recommend dose, and mitigates the impact of accidental consumption.

50 It is appropriate to deal with this during the product approval process. This will avoid ambiguity; such as would occur if a split-dose was required "wherever possible". Guidelines could assist manufacturers in preparing approvals.

*Restrictions on form of product*

51 Stargate submits that the Regulations do not need to prescribe any restrictions on the "form of products". The "form" and "mode of delivery" of a product will form part of the assessment about whether a product poses no more than a low risk of harm. It would be unhelpful and unnecessary to fetter the discretion of the Authority to approve products which are established to pose no more than a low risk of harm.

52 For example, Stargate agrees with the Authority that products that are intended for injection are very unlikely to meet the low-risk threshold at this stage. However, it is appropriate and consistent with the scheme of the Act that the onus is on manufacturers to prove otherwise.

*Storage, disposal and display*

*Psychoactive substances*

53 Stargate agrees that the Regulations should not include further restrictions or requirements regarding the storage and disposal of psychoactive substances. This is dealt with appropriately under the Hazardous Substances and New Organisms Act 1996, and manufacturing practice requirements.

*Approved products*

54 Stargate agrees that the Regulations should not include further restrictions or requirements regarding the storage or display of approved products.

55 However, Stargate believes that the Authority should give consideration to regulating the disposal of psychoactive products. There is potential for harm to occur if products are disposed of in an irresponsible manner. For example, precautions should be taken to ensure that members of the public cannot extract expired products from the disposed rubbish of retailers.
**Signage**

56 Stargate agrees that the Regulations should not include further restrictions or requirements regarding signage. Existing advertising, place of sale and packaging restrictions are sufficient to ensure that signage is not irresponsible or misleading, and that consumers have access to necessary information.

**PLACE OF SALE AND ADVERTISING**

**Place of sale restrictions**

57 Stargate agrees that the Regulations should not include further place of sale restrictions. These are dealt with comprehensively in the Act.

**Advertising**

58 Stargate submits that the Regulations should not include further restrictions or requirements relating to advertising. These are dealt with comprehensively in the Act, and further restrictions would be disproportionate and unnecessary.

59 We are not opposed to the proposal that advertisements must be consistent with the Advertising Standard Authority’s Advertising Code of Ethics. However, Stargate are concerned that the Code of Ethics is reasonably vague and general – and there is considerable scope for competing interpretations. As such, this requirement may not meet the necessary “certainty” desired by the Authority for its Regulations.

**Internet sale restrictions**

60 Stargate agrees with the proposed restrictions or requirements on internet sales of approved products. In particular, Stargate agree with the following:

(a) requirement for an entry page to verify the age of the person accessing the site;

(b) publication of the licence of the website;

(c) requirements for health warnings; and

(d) regular audits so that sales can be tracked.

61 We are concerned that there is a degree of ambiguity and uncertainty about the details of the proposed requirements. Stargate submits any regulations in this area should be as specific as possible.

62 Regarding “regular audits so that sales can be tracked”, Stargate supports the Authority collecting data on retail sales – so that it can track the full life-cycle of a product. However, Stargate note that this data should be sought from all types of retailers – not merely websites.
FEES AND LEVIES

63 Stargate submits that a mixture of fees and levies is appropriate for meeting the cost-recovery goal provided in the Act. Stargate agrees broadly with the proposed categories of fees and levies.

64 However, Stargate notes that the Authority has not provided information in the consultation about its projected costs. Therefore, Stargate are only able to assess the proposed fees and levies on the basis of the estimated costs of the Authority provided to Cabinet in 2013 (which estimated that the Authority would cost $3.74 million in its first four years). Based on that estimate, the fees and levies appear to be unjustifiably high.

65 Given the cost-recovery approach, Stargate submits that the Authority needs to justify its fees and levies based on an actual estimate of its costs. Further, the fees and levies should be periodically reviewed to ensure that they are not set too high or too low.

Licence applications - set fee

66 Stargate agrees that there should be a set fee for all licence applications based on an estimate of the actual time and resources required to process the application.

Product approvals

67 Stargate submits that there should be a set fee for both main product and additional product applications based on an estimate of the actual time and resources required to process the applications.

68 Stargate submits that the indicative $180,000 fee for main product applications is unreasonably high. Stargate notes that $180,000 was the fee recommended by the Hon Peter Dunne to Cabinet, and at that time it was based on the fee needed to recover the full costs of the Authority. The Minister estimated that the total cost of the Authority for its first four years would be $3.74 million, and that there would be 24 product applications in that time (generating $4.32 million revenue, and an overall surplus around $500,000).

69 The Minister's proposed fee is unable to be relied on by the Authority now. First, as the Consultation Document says – the fee is meant to recover the costs of processing applications, not the full cost of the Authority. A new calculation is needed. Second, there is very likely to be more than 24 applications in the first four years of the scheme. Finally, the Authority has proposed additional fees and levies which were not anticipated by the Minister – and logically these should reduce the product application fees if a cost-recovery approach is taken.

Levies

70 Stargate agrees that levies should be used to recover all other costs incurred in the administration of the Act. The proposed types of levies appear reasonable and
complete. However, Stargate is concerned that the process and justification for setting the levies is not clear.

71 Stargate submits that the Authority should give consideration to a levy mechanism that recovers costs based on actual market share and data. That is:

(a) manufacturers would pay a levy per unit weight of psychoactive substance manufactured;

(b) wholesalers and retailers would pay a levy unit weight of psychoactive substance sold; and

(c) those holding a product approval would hold a levy based on the sales data for that product.
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?

   In addition to the proposed information, we suggest the following:
   - A current phone number be supplied by applicants
   - A website address for individuals or corporate bodies where available
   - A photo be supplied by applicant as part of the application process.
   - Verification that the license applicant is a New Zealand citizen or the corporate body has a New Zealand base to ensure any compliance costs will be minimised.
   - A face to face interview (in person or via telecommunications) to be conducted by the licensing body to interview and verify applicant details, with any costs being paid by the applicant.

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- evidence of compliance with all local government policy and regulations should be provided by the applicant prior to any consideration of retail license applications and at their own cost.
   
   We further suggest that given the nature of the product that all retail license applicants should also publicly declare their intention to apply for a license to operate a retail outlet for the sale of psychoactive substances via advertisements in all local newspapers, as is required for alcohol liquor licenses. This would inform, consult and enable local communities to register any objections to the proposed license application prior to consideration.
   
   In addition, all license application processing costs and any related compliance costs should be paid by the applicant. This would in some small way offset the inevitably increased costs to our local communities in relation to harm reduction efforts and service provision to local substance users and their families.

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?
In Southland, we have a number of smaller rural townships and communities that would be disadvantaged by reference to a generic policy without consultation which would be unjust given the relative impact the sale of psychoactive substances would have on a smaller community.

We suggest that where a local approved products policy is not available, that a consultation process for establishing such a policy needs to be undertaken before any license applications can be considered or approved. This would allow people the opportunity to provide input into proposed retail outlets being established in their communities.

The Authority could set out guidelines for the consultation process and reasonable timeframes for completion of any required local policy development (in response to any retail license application)

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 powers of the Authority to investigate the good character and reputation of applicants, including police checks, signed declarations and provision of evidence of any prosecutions or convictions for criminal offences, whether in New Zealand or overseas, especially for drug or alcohol-related offences, dishonesty and any violent crime, including family violence offences.

However, we are also aware that less than 80% of family violence incidents are reported to police and even less result in convictions. Therefore, we suggest that applicants be required to present at least three non-family character referees, one of which must be a person of good standing from the local community in which the licensed retail outlet is intended to be located. Likewise, corporate body applicants must also be subject to investigation in relation to any previous prosecutions or convictions for compliance failure, fraud and a history of failed or unethical business practices, whether New Zealand-based or overseas.

5 Should the regulations require applicants to provide details of their involvement in other regulatory regimes, such as alcohol licensing processes?
Yes—where relevant, the declaration and investigation of any issues related to compliance or regulation breaches for liquor license holders should be an indicator as to the likelihood of compliance in the sale of psychoactive substance, especially breaches related to the sale of alcohol to minors.

However, license applications from holders of liquor licenses should not be given any preference in the application process to ensure that current circumstances and any recent breaches are considered.

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

As with the sale of any potential harmful substance, we suggest that license holders be required to keep comprehensive and updated records that are to be made available for any ongoing compliance and/or auditing purposes. These include:

- Record of product sales – including date sale, weekly volumes,
- Batch numbers (for product recall purposes)
- Complaints regarding their products, including reported adverse effects

As with track and trace of codeine-based medications, we would like to suggest that customers be required to provide identification which would be recorded at point of sale as this would allow investigation of resulting harm or offences to be investigated.

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

Records of sales and product information should be provided to the Authority on an annual basis and kept for a period of seven years consistent with financial business practice.

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

Approved retailers should be required to display their retail license in their premises, along with any additional notices (e.g. no sales to people under 18 years). In an effort to reduce harm we also suggest the following conditions to limit accessibility:

Licensed retail outlets be restricted to the sale of psychoactive substances only or are not permitted to sell other products that would be attractive to younger clientele, children or youth.

That promotion of products not be permitted where they can be viewed by underaged people (e.g. shop windows, billboards, local community noticeboards, newsletters)

That there should be restrictions on the permitted trading hours, consistent with or less than the local alcohol plan policies. All Liquor Bans and Smokefree policies and regulations should also apply to the sale and use of psychoactive substances within selected public areas, especially within school boundaries, parks and other public areas.

9 Should the regulations prescribe other matters the Authority must take into account when deciding on an application? If yes, what should these matters be?
The Authority should consider the social and economic costs to our families/whanau, our young people, in our workplaces, on our roads and in our communities when assessing license applications.

Funding of services and programmes to deal with the inevitable increase in addiction rates, crime rates, family violence offences, theft, drug offences and other services required to reduce or mitigate the harm caused by the use and misuse of unregulated psychoactive substances should be considered an integral responsibility of the Authority and of the license applicants.

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 - even minor changes to the manufacturing process should be subject to revision.

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

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?

As with any drug provided at a pharmacy, the client should be fully informed of any interactions with other medications they might be taking. This information should be provided at point of sale and inside the packaging and retail staff required to be trained on this product information so they can also inform customers of any potential hazards.

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.

Yes- comprehensive and needed.

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).

Information about possible side effects and safety plans related to psychoactive substance use should be provided by pamphlets at point of sale and on and in product packaging.

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

We suggest similar restrictions to cigarette products, that they be placed in plain packaging and be kept in locked cupboards for security reasons. We also suggest that the packaging to child-proof to reduce the likelihood of accidental or deliberate ingestion by children within the home environment. (Tamper proof bottles)

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

Yes- to restrict possibility of overdose

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

Yes- also to reduce harm or overdose

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?

Not in coloured, powdered or candy form or any other form that would be attractive to children.

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

They should be stored in locked cupboards as they will likely be subject to theft.

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

Appropriate and sufficient security measures should be required for all manufacturing and retail outlets.
22 Do you think restrictions or requirements should be set regarding the display of approved products? If so, what should they be?

Behind plain locked doors please.

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

Display should not be where children or young people could be enticed or encouraged to try to access.

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

No advertising or promotion in public places or spaces or events.

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

Yes- not in dairies or food outlets or restaurants.

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

Yes

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

Yes- sale of products to minors is difficult to restrict with online sales so we suggest these products not be made available for order online.

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


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

6 Psychoactive Substances Regulations: Submission form
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) Karen Ave
Address: (street/box number) 70 Victoria Avenue  
(town/city) Invercargill
Email: karen@stopviolence.org.nz
Organisation (if applicable): Invercargill-Southland Family Violence Focus Group
Position (if applicable): Project 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:  
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.