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. It is unclear how the information requirements apply to corporations. All retailers should be registered on the Companies Register and show this. It is unclear how and when will 'fit and proper' be checked. Will this be part of the information requirement to accompany an 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

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

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

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

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

What is the process for checking corporate applicants are "fit and proper" etc?
- They must be registered at companies house also
- It should include non-indictable (summary) offences
- A certificate proving "fit and proper" should have to be obtained, as must always be checked PRIOR to granting of licence not just "assumed" until someone challenges it.

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?

All financial records pertaining to the business for at least 6 years.
- Including records of quantities of each product sold (by licensed name) per day.
- Plus records of products recalled, returned, etc
- Records of any negative side effects reported to them including the product's licensed name and batch code for 5 years.
- A complaints register (for at least 5 years).

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

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

Yes, operating hours needs to be in there immediately. These should be stipulated on the licence. This will prevent retailers 'opening the shop' at any hour when someone calls them on the telephone.

Also separation distances needs to be defined. Otherwise these regs will not comply with the 'certainty' principle

Type of packaging. This needs to be tamper proof. All products should be sold whole in security tamper proof packs so that they cannot be split or added to.

Prohibiting sale with 'Other household goods' is too vague and will allow the authorities too great a power. There is no need or proven benefit in restricting the items that can be sold alongside psychoactive products.

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

yes

How proficient and reliable local Police are in being able to ensure that the legitimate retailer suffers no sort of intimidation or 'protectionism' from less desirable parties who are not 'fit and proper' persons.

It is all very well stating it would be a Police matter but we all know some forces/individuals are less 'proactive' in dealing with such complaints from retailers.

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

yes

11 Do you think any further particulars, information, documents or other material should be prescribed in the regulations? If yes, what should these be?
12. Do you agree with the proposal that the regulations require applications to contain information and data on the toxicity, pharmacology and related clinical effects of the psychoactive substance they are seeking approval for?

Yes

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

Partially. I do not believe that the criteria should be any more rigorous than that applied to pharmaceutical products and 'herbal/alternative medication' products as that would be unfair. Some of the above criteria are very hard to get data on, a lack of data should not automatically preclude a product from approval.

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

Yes
Include emergency services number (111) as many visitors may not be aware and once in a 'confused' state may not remember it
And in a font size that can be easily read (ditto re colour schemes – no green writing on blue background etc)
Tamper proof seals
Childproof caps?
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, include advice on what to do in event of overdose/severe adverse reaction

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

Yes esp tamper proof packs
But we do not want 'excessive packaging' or 'poster blindness' (overwhelming information so none of it is read)
Remove 'inappropriate connotations'? to whom? This is far too vague and open to abuse and does not follow the 'certainty' principle

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

No
Why? We do not do this with any other 'legal' product.
Consumers should be able to choose.
Childproof caps will prevent accidental overdose by children. It is excessive nannying.
(While I am a health professional I am submitting as an individual member of the public)

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

No
Why? We do not do this with any other 'legal' product.
Consumers should be able to choose.
Childproof caps will prevent accidental overdose by children. It is excessive nannying.
(While I am a health professional I am submitting as an individual member of the public)
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 more than there is (no injectable though you can't ultimately stop people doing so at home as they have done with pharmaceuticals)

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?

Not quantity.
Only location and security (and temperature etc) as per other goods (which the retailer will want to ensure anyway to maximise their profits).

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

Not quantity.
Only location and security (and temperature etc) as per other goods (which the retailer will want to ensure anyway to maximise their profits).

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

No
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 other chemical disposal or hazardous substances and pharmaceuticals. Also disposal should be free or it will encourage dumping, possibly in water courses or upstream of drinking water intakes or in sensitive habitats, all with potentially catastrophic effects.

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

C

No

Except for age restriction and where to find additional information (eg re side effects etc)

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

C

No

It is already too restrictive.

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

Yes, as indicated in Act (re not advertised and comply with SAACode of Ethics) plus billboards, sports stadium hoardings and signboards, road signs, building sides, scaffolding etc.
27 Do you think the regulations should prescribe restrictions or requirements on internet sales of approved products? If so, please provide specific suggestions.

Yes, as specified in the Act. Ticking an 'entry box' to say over 18 serves no point. It proves and verifies nothing. The other proposals are sound.

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

Yes, factual and objective information only (including expected effects plus side effects)

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

Assuming proper research has actually been done and there is evidence to support the proposed fees. The research fee seems far too low. Has the person who came up with this ever done any decent research? It takes many hours to get it correct and reliable. What about the Police checks/fit and proper person checks?

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

Hourly
Different products may require vastly different levels of investigation and research
31 Should fees be set for other specific functions? If yes, please state what they should be set for.

Yes
Inspections

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

I do not have enough information or knowledge on this to be able to comment

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

This submission was completed by: (name)
Address: (street/box number) (town/city) Blenheim
Email:
Organisation (if applicable):
Position (if applicable):
Are you submitting this:
(Tick one box only in this section)

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

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

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

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

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

Please put ‘Regulations Consultation’ in the subject line.

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

☒ I do not give permission for my personal details to be released under the Official Information Act 1982.
☒ I do not give permission for my name to be listed in the published summary of submissions.
Submission on Psychoactive Substances Act Regulations

Introduction

My concern is in minimising the harm caused by psychoactive substances, rather than complete prohibition (which is outside the brief of this process anyway).

I agree with the overall purpose of the Act which is to ensure only low-risk products are on the market, and that there are strict controls on how and to whom psychoactive products may be sold and who is allowed to sell them.

As an individual, I agree with the overall intent and content in the proposed regulations but would like to make comments on some aspects which I would like added or emphasised.

License applications: who should be allowed to import, manufacture or sell these products?
Retail licence applications should be compliant with the Local Approved Policy and if anything is further required from a council to substantiate or negate this, it should be fully cost recoverable so the potential licensee rather than the ratepayer will pay for it.

Fit and Proper Persons
I believe that anyone licensed to sell psychoactive substances – and their shop staff - should undergo full police checks and if they have any offenses concerning selling alcohol or tobacco to underage customers then the licence will be declined. Very stringent controls should be required to classify a person as being “fit and proper”. Comparisons with requirements to become a licensee or duty manager in an on-licence premise are appropriate.

As with on-licence premises, no person should be allowed to sell psychoactive substances to intoxicated or “high” customers.

Any breaches of these (or other) conditions should result in the retail licence being suspended or cancelled.

License conditions
Retailers should keep full records of all sales, invoices, which product and the quantity of product sold in each transaction. Lists of employees, all receipts, so that transactions are traceable. These should be kept for 7 years.

As well, there must be signage visible to all, showing the licence, the name of the Duty Manager, health warnings, limits of how many products that can be bought at once, and contact numbers for medical help or to report breaches of the licence conditions.

Discretionary Conditions
The location must be in keeping with the Council’s policies if they have one. There should be a default regulation from Central Government, outlining location requirements such as the need to be away from schools, churches, mental health institutions, children’s playgrounds etc. No store in a residential area should be allowed to sell.

As part of the application to sell, there should be a site visit by an enforcement officer (DHB) to ensure the potential retailer meets all requirements.
At present, Two Dollar and 1 – 2 – 3 shops are legally allowed to sell psychoactive substances, and that should be removed as children can enter those shops. Only shops allowing over-18s in the store should be licensed to sell.

Psychoactive substances should not be sold right next door to a dairy, or with a separate entrance to separate them.

**Hours of selling**
The Regulatory Authority should set restrictions on opening hours, and that this should be at time when young people are unlikely to be around – so not before 8:30 am and from 3 – 5 pm. Retailers should clearly display their hours of sale (so there are not a lot of people hanging around outside).

**Advertising and sponsorship**
These products should be sold as cigarettes are now – kept in a cupboard out of sight. Customers can read a list of products, which lists all the ingredients of each package, dosage size, contraindications and possible side effects.

There should be no sponsorships allowed.

**Labelling and Packaging**
These substances should be sold in plain packaging, tamper-proof packs. On the outside, there should be a full list of ALL ingredients, and a health warning (similar to that on tobacco) which is product-specific. Somewhere there should also be advice on overdosing, and where to go for help.

**Restrictions on form of product and storage and display**
In the case of party pills, these should only be sold in single doses. With any of these products, the substance should not be sold mixed with food or drink. To restrict customers buying these and on-selling, there should be limits of how many products can be sold to each customer at any one time. As well, there needs to be limits in the amount of items that can be stored at any time, to minimise the risk of theft.

**Internet sales**
Internet licences should be separate from other licences – and use the same stringent controls as betting at the TAB online requires, not just the use of a credit card. Internet sales must be done only from licensed premises, not from residential addresses.

Only retailers with a retail licence are to be allowed to purchase the products from the wholesaler.

**Product approval applications – information requirements**
Product approval application should include information on proposed manufacturing methods and how they comply with the Psychoactive Substances Code of Manufacturing Practice. Products manufactured overseas should have the same requirements and be verified as genuinely complying.

**Determining the risk of harm**
I agree with requiring applications to contain all the information needed to show it is safe for consumption. This information should be accessible and understandable by clinicians who may be dealing with the effects of consumption.
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 an individual ______________________________________________

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

1. Is the list of proposed information requirements for licence applications comprehensive enough?
   If not, what else should be required, and why?
   Yes. We additionally support the proposal to include consent to undergo a Police check being included on the application form.

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

3. Should retail licence applications be accompanied by evidence of compliance with a generic local approved products policy if no policy is in effect in the applicant’s area?
   Yes, applications for retail licenses should contain evidence of compliance with generic policies.

4. Are the factors the Authority should take into account when determining whether a licence applicant is a fit and proper person or whether a body corporate is of good repute in section 16(2) enough? The section 16(2) factors are:
   - whether the applicant has been convicted of a relevant offence
   - whether there has been a serious or repeated failure by the applicant to comply with any requirement of the Act
   - whether there are other grounds for considering that the applicant is likely to fail to comply with any requirement of the Act
   - any other matter that the Authority considers relevant.
   If you think these factors are not enough, please give examples of additional factors the Authority should consider.
We support:
- The proposal to include the New Zealand Customs Service (regarding importation compliance) and the Police in the fit and proper person check.

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

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

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

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

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

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

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

To this end, we recommend all licence holders be required to keep

- Purchase records - including licence number of the seller from whom the psychoactive substances or products were received
- Sales records, including quantity of products or substances distributed, and quantity sold in a single transaction,
- Records of disposal of any product or substance and the reason for doing so

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

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

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

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

As such, we recommend research licence holders retrain records of

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

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

7 years to enable audit

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

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

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

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

In addition, we recommend for retail licences:

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

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

For retail licences, we recommend:
In the absence of an LAPP or generic LAPP, physical proximity to premises regularly used by young people and vulnerable groups should be considered by the authority.
Likely impact on the character of an area.
10 Do you agree a product approval application should include information on proposed manufacturing methods and how they will comply with the Psychoactive Substances Code of Manufacturing Practice?

Yes

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

No comment

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

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

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

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

- the psychoactive potential and related behavioural effects of the substance
- the addictive potential
- the proposed directions for use
- previous use, including use in clinical trials and in the wider population?
Overall yes, this information and data should be provided for the substance.

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

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

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

In addition we recommend:

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

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

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

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

In addition we recommend labels include details of:

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

15 Are the proposed requirements relating to health warnings sufficient? If not, please make specific suggestions for further requirements (for example, advice on what to do in the case of an overdose).
We recommend that a bold, short and simple title “HEALTH WARNING” be prominent (covering at least 10%) of the exterior product packaging, and the exterior of any sub-units of packaging, followed by the four compulsory warnings proposed.

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

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

Ref:

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

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

See question 14 regarding support for plain packaging.

The other requirements proposed appear sufficient.

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

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


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

Yes, please see above.

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

Yes. We believe products in the following forms should not be approved:
- Additional regulations should be applied for smokeable products, covering any public indoor or other confined space. Non-consumers should not be subject to second hand smoke from such products.
- Appeal to minors – support that product forms with appeal to minors should not be allowed.
- Liquid or other easily injectable forms, and should not come in/with Injection equipment.
20 Do you think there should be restrictions or requirements on the storage of psychoactive substances? If so, what should the restrictions or requirements be?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Yes

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

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

Yes – levies should be collected to enable:
- The establishment of data collection and monitoring systems including:
  - Regular collection of baseline data on emerging patterns of use and effects of the product
  - Detailed analysis and review by the PSRA every three years after approval of a product
  - Enable thorough medical case events to be developed - including provision of resources for medical staff to undertake detailed testing and analysis to case events (individuals suffering acute or chronic symptoms from use of a product).
  - Newly approved products to be reviewed for evidence of harms every three years
- Development and operation of systems for reporting adverse effects of psychoactive products (e.g. CARM, and systems for relevant medical facilities such as emergency departments, GPs and mental health clinics)

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

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

No comment
You do not have to answer all the questions or provide personal information if you do not want to.

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

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.
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?

   If not already covered, there should be an exclusion for:
   - Mental Health patients,
   - Bankruptcy

   Premises for licence should not be mobile e.g. A 'Mr Whippy' type van, or Coffee Cart
   Exclude Night Clubs, Churches, Hairdressers, Pharmacies, Food Outlets such as Fish & Chip shops
   Exclusion zones around schools, Children Entertainment Centres, Picture Theatres

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

   Yes

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

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

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

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

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

- Definitely full disclosure of all activities/involvement with other regulatory regimes
- Also full disclosure of other activities in other Companies involved with Psychoactive Substances such as importing company, manufacturing and retail.
- Disclose Internet presence – websites promoting Company’s product

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

- At least equivalent to other medicine or health remedy regulations

7 How long should licence holders be required to keep records for?
Records should be kept for perpetuity.
- if 10 years later, people develop major health issues, need to be able to track back to the actual ingredients in the product at the time and the amount of the product produced / sold.
- Batch and individual component batches

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

Consider whether there should be a positive for the applicant manufacturer such as a patent which would stop other Companies from "copying" a successful product and replicating it in the same way that a Pharmaceutical Company has a patent which excludes other Companies from copying until a set period of time has passed.

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?

Retail Staff – age limit – Over 20

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?

Definitely agree

11 Do you think any further particulars, information, documents or other material should be prescribed in the regulations? If yes, what should these be?
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
There should also be a requirement for absolute specifications to be provided to the National Poisons Centre so that Centre can provide appropriate advice re poisoning

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

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

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

Need to include the necessary but not so much that it won't be read or so much that the printing is too small to be read.

Do these products have an Expiry Date / Use By Date / Best Before Date?

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

Not sure how many doses should be in a packet but each dose should be individually presented.

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

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

Storage should be appropriate to the active ingredient in relation to temperature, safety (should the product be stored in a locked cabinet if potent)

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

Consider requirements for Cigarettes – storage of these substances should be relational to comparative ‘Risk of Harm’.

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

Yes - Consideration needs to be given to the limitations placed on display of Cigarettes. If these have to be hidden behind closed doors than should a more potent product be permitted to be blazoned across the front window of a retail premise.
23 Do you think restrictions or requirements should be set regarding the disposal of approved products? If so, what should they be?

Should be appropriate to the active ingredient and the potential for harm if large amount of product is disposed of in a public accessible place – eg. Rubbish bin in park.

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

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

Yes
Should not be sold from a mobile unit eg. A ‘Mr Whippy’ type van, or Coffee Cart
Exclude Night Clubs, Churches, Hairdressers, Pharmacies, Food Outlets such as Fish & Chip shops
Exclusion zones around schools, Children Entertainment Centres, Picture Theatres, Playgrounds

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

Yes – Internet sales for any products should not be allowed – approved and not approved – this is to protect young people as the Internet does not ‘see’ the purchaser and cannot verify age.

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

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

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

Yes
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.

I believe people are purchasing these products under the knowledge they are legal forms of cannabis and therefore less harmful than cannabis. How do they rate against the illegal form of cannabis from a Harm perspective?

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) Janelle Ashton
Address:  (street/box number) P O Box 913
          (town/city) Dunedin
Email:  Janelle.ashton@otago.ac.nz
Organisation (if applicable):  NZ Pharmacovigilance Centre
Position (if applicable):  Manager Information Systems
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): national agency for monitoring adverse events to 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:

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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.
20th March 2014

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

Dear Sir/Madam

RE: PSYCHOACTIVE SUBSTANCES REGULATIONS – CONSULTATION DOCUMENT

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

Background
Waipa District Council adopted a draft Psychoactive Substances Policy (Local Approved Products Policy [LAPP]) for consultation on the 3rd December 2013. The draft Policy was open for consultation between 14 January and 17 February 2014. Seventy-three submissions were received and 21 spoke in support of their submissions at a hearing that was held on 4th March 2014. The Policy is due to be adopted by Council on 25th March 2014.

Following the hearing that was held in March Council discussed issues that they wished to include in a submission on the proposed regulations, and these have been included in this submission. A number of Waikato councils have also been drafting submissions on the regulations, and this submission reflects a collaborative approach while also focussing on points that are of most concern to our Council.

The consultation document on the regulations has a broad scope and deals with a number of matters that extend beyond the normal focus of councils, such as manufacturing, labelling and importation. Council has a view on a number of these issues, for example place of sale, which we raise as appropriate throughout this submission.

General Comment
Council would first like to express our concern over the short period of time provided to make a submission to the proposed regulations. This makes it difficult for elected members to have meaningful input to the submission document. This is especially so as many councils are currently involved in submission analysis or hearings for their LAPPs at this time.

Making policies without knowing the full extent of council’s powers or the range of national regulations that the Authority itself might apply, such as hours of operating, has made the local policy making process more difficult than perhaps it needed to be. The result is that councils are in something of a 'catch-22' because the regulations that are meant to guide the development of LAPPs are yet to be designed and notified (expected in early 2015). On the other hand policies need to be in place before the regulations are notified otherwise they may not be able to influence the location of shops once licenses cease to be interim licenses.

Consequently councils have been obliged to take a pragmatic response and face the risk that once regulations are notified the LAPPs might need to be amended to conform to the new regulations.
The consultation document has been used as a guide for this submission. Council will focus its response on the following areas:

- Generic policies
- Interim licences
- Licence requirements
- LAPPs
- Fit and proper person test
- Discretionary conditions
- Health warnings
- Place of sale
- Advertising
- Fees and levies
- Other matters.

**Licence applications**

**Generic Policies**

Council agrees that generic policies should apply in jurisdictions where councils have not adopted LAPPs. Council is of the view that applications for retail licenses should contain evidence of compliance with generic policies on the grounds that the desired effect of restrictions in one area that has a LAPP will be reduced if a neighbouring area/s does not have a LAPP in place. Council considers a generic policy to be a good idea to avoid a retailer setting up on the boundary between a Council with a policy and one without so they can easily reach both markets.

**Interim Licences**

The consultation document raises the issue of how retail premises operating in areas that are outside the provisions of an adopted LAPP should be dealt with. It is assumed that these are premises operating under an interim license prior to the notification of retail regulations in 2015. The options appear to be that they:

1. Continue to operate outside the legal zone in a council’s LAPP until the interim period concludes and permanent licenses within the designated area are secured, at which point the licensed premises shifts in order to comply with the policy;
2. Retain the license to operate but are obliged to shift the premises to a position within the designated zone while still under an interim license, presumably within a defined period;
3. To close down until the end of the interim period and apply for a permanent license within the appropriate zone when that option becomes available.

It appears that most councils expect that option three will apply where premises with an interim license finds itself outside the designated LAPP zone once a policy is adopted but before the regulations are notified.

Council recommends that interim licenses should be subject to an adopted LAPP, noting that interim licenses holders who cannot continue to operate will be able to apply for a full license in a designated area once regulations are notified.

**Licence Requirements**

Council agrees that applicants for a retail licence must show that their licence application complies with the relevant LAPP.

The proposal is for retail licence applications to be accompanied by some information showing compliance with a Council’s LAPP. Council envisions 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 a LAPP in force, licence applications should be incomplete without the document from the TA, and be unable to be lodged with the Psychoactive Substances Regulatory Authority or progressed until the document is provided.

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

c) Council submits that when licences come up for renewal every three years, that each application is treated as a new application and has to undergo the same process of assessing alignment with relevant LAPPs in the district as well as all the other licence application requirements.

Local Approved Products Policies (LAPPs)
An additional matter is the status of a LAPP that has the unintended result of effectively banning sales by preventing the location of a retail outlet within a particular jurisdiction. This could occur, for example, in a smaller community where there are multiple places of a particular kind (sensitive sites). We recommend that the Ministry ask Crown Law for a view on the legal status of any policy that inadvertently results in such a situation.

In an ideal world councils would know the full extent of their authority, that is the matters they can take into account, before beginning to consult on and adopt a regulatory plan, such as a LAPP. The problem is that some councils may over-prescribe and expose their policy to legal challenge on ultra vires grounds, while others may under-prescribe and fail to fully meet community expectations. Both may face a policy amendment process once the final regulations are announced - a costly process for both councils and communities.

Fit and proper person test
Council agrees with the proposal in the consultation document that the Authority should consider the following factors when assessing the fitness of a retail applicant:

- Whether the applicant has been convicted of a relevant offence;
- Whether there has been a serious or repeated failure to comply with any requires of the Act;
- Whether there are grounds for considering the applicant is likely to fail to comply with the requirements of the Act; and
- Any other relevant matters.

However the factors that the Authority should take into account when determining whether a licence applicant is a fit and proper person is not considered to be comprehensive enough. The Authority should consider any conviction not just a ‘relevant offence’. Any conviction provides an indication of reputability.

Any information on record from other regulatory regimes should be provided by the applicant and considered by the Authority. This might also include IRD information. This will help build a fuller picture of the applicant’s history and repute.

When determining whether there might be additional matters, or whether there are other grounds for believing an applicant might not comply with the Act’s requirements, Council recommends that the Authority consult with the relevant TA to ascertain the nature of any relevant experience the council might have with the applicant. It is possible that applicants will have a history of contact with a local authority that either shows them to be either good corporate citizens or, at the other extreme, serial non-compliers.
Council submits that all licences should be made to an individual not a body corporate. This is to ensure proper accountability. The personnel of a body corporate can change over time and there is no mechanism to apply the fit and proper test retrospectively.

Council submits there should be a zero tolerance approach to comply with the requirements of the Act, one mistake should be enough to take action to suspend and/or revoke licenses rather than relying on serious or repeated failure. One failure can cause significant harm.

**Discretionary Conditions**
Council believes that the statutory tools in the Act may not go far enough to meet community expectations for the regulation of retail sites. Council would like to see any licence applications that are filed within the district publicly notified within the district that it would apply to. This could mean that there be a requirement in the regulations for the applicant to demonstrate that they have consulted with the community or communities they wish to establish their business/es in as a compulsory part of the application process, akin to the local alcohol licensing process.

Council has had a number of submissions asking that opening hours of stores be limited to inside school hours to ensure that school age children are not affected. This may include trading hour restrictions (for example to protect children travelling to school between 7.30am and 8.45am and again from between 2.45pm and 4.00pm Monday to Friday). Council would fully support this requirement being imposed on licences.

Council would also support the requirement for a store to provide security staff and CCTV surveillance if there are security issues associated with the store.

Council is also strongly of the view that the regulations should specify a maximum amount of an approved substance that might be purchased in a single sale to restrict the on-selling of the product.

**Labelling and Packaging**

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

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

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

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

d) Health warnings should include the warning that prolonged use can lead to psychosis.

**Place of sale and advertising**

**Place of sale**
The consultation document suggests that the regulations could place further restrictions on the types of places where approved products can be sold. Council supports any mechanism that restricts the availability and “normalisation” of approved products, or where the provision of other goods and services may be used to mask the sale of products to otherwise prohibited persons. Council would suggest adding the following places to those prohibited:
a) Cafes / restaurants
b) Takeaway food outlets.

Advertising
Council is supportive of the requirement that on-site advertising is restricted to the inside of premises where approved products are offered and limited to communicating only product information, such as active ingredients.

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

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

Other matters
Council would strongly suggest raising the age of purchase of psychoactive products from 18 to 25 as it is felt that the younger age group is more vulnerable to harm.

Council would like to see the details of manufacturers of these products made public, for example the names of company directors.

Council strongly suggests that the addition of a marker that will show up in urine tests be compulsory in manufacture of these products. Council understands that at present these products are not detectable in the tests used to detect other types of drugs. In the event of car accidents or illegal activity, it would be useful to detect whether there was evidence of usage of these products. It would also show any relationship to 'harm'.

Conclusion
Waipa District Council would like to thank you for the opportunity to provide feedback on the proposals. We hope that these comments are useful in your deliberations.

Yours sincerely

[Signature]

Gary Knighton
MANAGER STRATEGY
Consultation questions

1 Is the list of proposed information requirements for licence applications comprehensive enough?
   If not, what else should be required, and why?
   Yes. We additionally support the proposal to include consent to undergo a Police check being included on the application form.

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

3 Should retail licence applications be accompanied by evidence of compliance with a generic local approved products policy if no policy is in effect in the applicant’s area?
   Yes, applications for retail licenses should contain evidence of compliance with generic policies.

4 Are the factors the Authority should take into account when determining whether a licence applicant is a fit and proper person or whether a body corporate is of good repute in section 16(2) enough? The section 16(2) factors are:
   - whether the applicant has been convicted of a relevant offence
   - whether there has been a serious or repeated failure by the applicant to comply with any requirement of the Act
   - whether there are other grounds for considering that the applicant is likely to fail to comply with any requirement of the Act
   - any other matter that the Authority considers relevant.
   If you think these factors are not enough, please give examples of additional factors the Authority should consider.
We support:

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

For all licences, we recommend

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

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

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

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

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

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

Yes, please see above.

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

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

To this end, we recommend all licence holders be required to keep:

- Purchase records - including licence number of the seller from whom the psychoactive substances or products were received
- Sales records, including quantity of products or substances distributed, and quantity sold in a single transaction,
- Records of disposal of any product or substance and the reason for doing so

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

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

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

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

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

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

This data should be collated and made available to health services and other relevant stakeholders.

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

In addition, we recommend for retail licences:

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

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

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

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

No comment

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

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

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

13 Do you agree with the proposal that the regulations require product approval applications to contain information and data on:
   • the psychoactive potential and related behavioural effects of the substance
   • the addictive potential
   • the proposed directions for use
   • previous use, including use in clinical trials and in the wider population?
Overall yes, this information and data should be provided for the substance.

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

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

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

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

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

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

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

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

15 Are the proposed requirements relating to health warnings sufficient? If not, please make specific suggestions for further requirements (for example, advice on what to do in the case of an overdose).
No. We recommend that a bold, short and simple title “HEALTH WARNING” be prominent (covering at least 10%) of the exterior product packaging, and the exterior of any sub-units of packaging, followed by the four compulsory warnings proposed.

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

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


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

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

See question 14 regarding support for plain packaging.

The other requirements proposed appear sufficient.

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

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


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

Yes, please see above.

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

Yes. We believe products in the following forms should not be approved:
  • Additional regulations should be applied for smokeable products, covering any public indoor or other confined space. Non-consumers should not be subject to second hand smoke from such products.
  • Appeal to minors – support that product forms with appeal to minors should not be allowed.
  • Liquid or other easily injectable forms, and should not come in/with Injection equipment.
20  Do you think there should be restrictions or requirements on the storage of psychoactive substances? If so, what should the restrictions or requirements be?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Yes

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

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

Yes – levies should be collected to enable:

- The establishment of data collection and monitoring systems including:
  - Regular collection of baseline data on emerging patterns of use and effects of the product
  - Detailed analysis and review by the PSRA every three years after approval of a product
  - Enable thorough medical case events to be developed - including provision of resources for medical staff to undertake detailed testing and analysis to case events (individuals suffering acute or chronic symptoms from use of a product).

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

Fees or should be collected from retailers to enable:

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

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

No comment
You do not have to answer all the questions or provide personal information if you do not want to.

This submission was completed by: (name) Douglas Sadlier
Address: (street/box number) 
(town/city) 
Email: douglas.sadlier@aucklandcouncil.govt.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): .................................................................................................................................

Do you wish to receive updates about the development of the psychoactive substances regulations?
☐ Yes  ☐ No 
(If yes, please make sure you provide an email address.)
Please return only one copy of your submission no later than 5 pm on Friday 21 March to:
The Manager 
Psychoactive Substances Regulatory Authority 
Ministry of Health 
PO Box 5013 
WELLINGTON 
Email: psychoactives@moh.govt.nz

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

Please put ‘Regulations Consultation’ in the subject line.

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☐ I do not give permission for my personal details to be released under the Official Information Act 1982.
☐ I do not give permission for my name to be listed in the published summary of submissions.
19 March 2014

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

Email: psychoactives@moh.govt.nz

Dear Sir / Madam

REGULATIONS CONSULTATION - PSYCHOACTIVE SUBSTANCES REGULATIONS

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

The Hawke's Bay District Health Board (HBDHB) takes an active interest in all areas that impact on the health and well-being of the residents of Hawke's Bay and the Chatham Islands and seeks to improve health outcomes in our communities through the reduction of health inequalities. In Hawke’s Bay we have worked collaboratively on the management and regulation of Psychoactive Substances within the HBDHB across our, community mental health, health promotion and health protection units and also with external stakeholders including the Eastern Policing District, Ngati Kahungunu Iwi, a number of non government organisations and at the community level.

Psychoactive substances have been proven to have considerable negative health and social impacts on the Hawkes Bay community. Many of the negative issues facing our Hawkes Bay communities are intrinsically influenced by psychoactive substance abuse and its misuse, and the associated negative impacts that their usage has on our babies, children and young people is especially critical.

We note the regulations play an integral role in ensuring the Psychoactive Substances Act (2013) achieves its purpose, to regulate psychoactive substances before they reach the consumer market. The overarching objective that underpins our submission is the reduction of harm from the misuse of psychoactive substances particularly by young people. We aim to achieve this objective through our submission which is as follows.

Licence Applications

1 Is the list of proposed information requirements for licence applications comprehensive enough?
   If not, what else should be required, and why?
A definition of responsible person is required and previous convictions including under the Sale and Supply of Alcohol Act and the Smoke-free Environments Act. The regulations also need to ensure there is a clear distinction between the owner and people who are selling. Under the Sale and Supply of Alcohol Act a duty manager is required to be named and we believe this should be mirrored in this act. This should extend to include company and trading name details where available.

Products should be able to be identified from the manufacturer, importer, wholesaler, to retailer and ultimately to consumer, not dissimilar to medicine batch tracking or "cradle to the grave" system.

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. An applicant should be able to demonstrate that they comply with their Council's LAPP. This could be provided for by the Regulations requiring a written statement from the Council that the applicant meets these conditions.

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

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

**Fit and proper person 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?

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.

HBDHB recommend that the Fit and Proper person test should be tested as to whether or not the applicant has been convicted of a relevant offence in another piece of legislation with particular reference to the Smoke free Environments Act and the Sale and Supply of Alcohol Act.
Rationale: A person who meets the threshold for a conviction under the Smoke-free Environments Act and/or the Sale and Supply of Alcohol Act; with particular reference to operating outside permitted trading hours or sale to minors; poses a risk of selling psychoactive substance to youth (<18yo) and is therefore not a suitable person to be selling psychoactive substances.

We agree with the previous proposals to require applications to undergo a Police check, this should include Infringements notices.

Applicants who have been in breach of a Local Approved Products Policy, including warnings provided.

The fit and proper person should include those working on the premises, not just the licence applicant. Within the liquor industry there are duty managers who are required to have a “bar licence”

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

Yes. This enables fit and proper person information to be more readily gauged if this information can be shared and made available at the application or renewal stage. If an applicant has been refused a licence under another approval regime this will enable the authority to explore the reasons behind this when deciding if they meet the fit and proper person test.

**Licence conditions**

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

HBDHB agree with the proposed comments regarding sales records. In addition for retail sale the following records/policies should also be kept:

- Records of purchase i.e., invoices
- The quantity of products sold within each transaction
- Batch number of products (to assist identification of manufacturer and wholesaler)
- Recall policy including how product is disposed when requested by the authority
- Adverse reaction reporting
- Policy regarding the sale to under age consumers
- List of employees
- Name of Courier number/receipts

We would suggest aligning these requirements to other legislation e.g. Sale and Supply of Alcohol and Smoke-free Environments Act. Records should be able to be readily retrieved when requested.

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

This should be aligned to other pieces of legislation for guidance. Seven years appears to be a common timeframe for auditing purposes.
Discretionary conditions

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

HBDHB recommend that additional restrictions need to be made on opening hours for retailers of Psychoactive Substances and secondary restrictions on where they can be sold. We recommend that restrictions around hours of sale need to be structured so that these products are sold when youth (<18yo) are less likely to be in the vicinity of these retailers; or less likely to be at risk of receiving psychoactive substances illegally either from retail sale or via an adult purchasing for them on their behalf.

We also recommend that the regulations request retailers clearly display hours of sale

HBDHB recommend a limit of stock on premises to reduce risk of theft/burglary.

Each retail outlet must be set up as one entity, reducing the risk of split premises.

There needs to be a clear limit to the quantity sold to individual customers by retail to reduce the risk of on selling. I.e. wholesaling or supplying others

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?

HBDHB recommends a site visit report from an enforcement officer to accompany an application in order to provide context to the application for the regulatory authority. This pre-inspection (at cost) could be similar to that of a Food Hygiene pre-inspection prior to licensing in order to demonstrate that the applicant meets all pre-set conditions required of them.

If a retailer is applying to sell online we recommend that they have to apply for a second licence. Online licence applications should contain a different set of requirements that include processes to validate the purchasers age and ensure that the product is only delivered to them, to reduce the risk of underage use. There would need to be a tracking system to allow access across the country by authorities investigating the substance purchased. Along with similar check to those outlined above.

Product approval applications

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

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

Requirements for imported products to have met manufacturing standards which would be the equivalent in New Zealand.

Offence for non-compliance with Code of Manufacturing.

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 proposal. We also believe that Material Safety Datasheets should be produced especially for clinicians.

Labelling and packaging

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

Yes the HBDHB agree with the proposals outlined including having plain packaging, restrictions on labelling design so it is less appealing to minors etc.

Additional labelling should include a full list of ingredients rather than just a requirement for ‘active ingredients. Non active ingredients may pose a risk to those with allergies.

We also have concerns about customers buying off retail outlets in bulk and then repacking them. Please see previous comments regarding having a definition for retail and wholesale.
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 agree with the proposed requirements including advice on what to do in case of an overdose and how to report adverse reactions.

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

HBDHB agree with the proposals outlined but would like to see restrictions around how psychoactive products are consumed or delivered.

The packets need to be tamper proof to prevent additional substances being added to the packages e.g. (other drugs). We also recommend that products are packaged in plain packaging to reduce their visual appeal.

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

To reduce risk of overdose we agree with the proposal to split the dose wherever possible. We do have a concern that this could increase affordability of products.

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

Yes, we agree with this proposal. We believe that the dose should be specified on the products packaging together with information outlining what is the maximum safe dosage permissible at any one time.

This is so that the consumer of the product is pre-informed about what is a permissible dose for the usage and they can adjust their intake accordingly, and therefore reduce the risk of overdose or excessive use of a psychoactive substance in a single sitting.

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 restrictions on the form of products containing tobacco, taking into account the health risks of tobacco consumption and our current national strategy to reduce tobacco harm. We believe that psychoactive substances should not be delivered with tobacco due to the increased risk of addiction and dependency from the consumption of both products to the consumer.
We also feel that approved products should not be able to be pre-mixed with food and beverages as this poses a risk of accidental or un-intended consumption of psychoactive substances by children and youth, and may also encourage the attractiveness of these products to minors and at risk groups.

Finally we believe that any decisions made to regulate the form that products take should be focused around the potential to overdose or exceed maximum permissible dosages in one sitting. Therefore it is not suitable for psychoactive substances to be able to be delivered through means such as nasal sprays, or atomisers where the permissible dose can readily be exceeded by both intentional and unintentional usage.

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 believe that there should be restrictions around the maximum amount of psychoactive substance stored at a premises at any one time and transported in a vehicle at any one time. There is uncertainty around the chemical content and stability of these products therefore exposure to large amounts of product in a confined space may have unintended health effects.

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

We believe product should not able to be stored on residential property for wholesale or retail sale via the internet etc. They should only be able to be stored on licensed premises. Therefore it may be suitable to adopt minimum quantity thresholds for the storage of psychoactive substances. For example being in possession or storing >500g of synthetic cannabinoid products would require a wholesale or retail licence.

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

This should mirror the requirements of the Smoke-free Environments Act including product not being visible and advertising not permitted at the point of sale. We feel that customers should be provided at the point of sale with a product list which provides information on the product name, price, full list of ingredients and the anticipated effect and the known potential side effects.
23. Do you think restrictions or requirements should be set regarding the disposal of approved products? If so, what should they be?

Good documentation needs to be kept of any disposal of approved products, especially when requested by the Authority. This will then ensure the process can be audited by enforcement officers.

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

We do believe there should be signage requirements in the regulations. These could include:
- Display of the licence
- Name of the “Duty Manager”
- ID required
- No sales to under 18 years.
- Health warnings

Place of sale and advertising

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

Yes the regulations should specify further places where approved products may not be sold. This needs to include discount shops and other similar type retail outlets where children and young people under the age of 18 are likely to be present. This is to help prevent the normalisation of the product to those under the age of 18.

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

The HBDHB agree that the Advertising Standard Authority’s Advertising Code of Ethics needs to be adhered to. We also recommend prohibiting the use of sponsorship.

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

We largely agree with the proposed requirements in the consultation document. However we are of the opinion that internet sales should be restricted to wholesale purchasing only by licensed retailers.
The rationale for this is that internet sales of psychoactive substances create difficulties around the traceability and control of where and to whom these products are sold. Online purchasing of psychoactive substances increases the risk that minors and youth are able to more easily access these products as the checks and balances that apply to restriction of sale at retail outlets are far less stringent for sales over the internet.

However if online purchasing of psychoactive substances by consumers are to be permitted then we believe that the verification of age is an important step in this process and we would recommend looking at other areas which require this (e.g. TAB sites- that require verified copies of Driver's Licences and/or Passports to verify age prior to an account being setup) to ensure it is as robust as possible.

Enforcement Officers need to have ready access to records. All sales, including internet sales should be from licensed premises and not residential premises. The rationale for this is that it's not suitable for these products to be stored and traded from residential premises over the internet where children and young people are at risk of accessing and using these products.

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

We agree with the proposals in the consultation document.

Fees and levies

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

We believe that all costs associated with enforcing that Act and its associated regulations and guidelines should be met fully by the licence holders. Any proposed fees regime set by the authority needs to be flexible to reflect previous, current, and future costs associated with the establishment and future enactment of this legislation so that full cost recovery is achieved.

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

No comment.

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

No comment
32 Do you agree with the proposed list of items and process for setting levies? If not, please provide specific suggestions.

No comment.

Thank you again for providing us with the opportunity to present this written submission.

Yours sincerely

[Signature]

Dr Kevin Snee
CHIEF EXECUTIVE OFFICER
You do not have to answer all the questions or provide personal information if you do not want to.

This submission was completed by: (name) Dr. Caroline McElnea
Address: (street/box number) corner Omahu Road and McLeod Street
(town/city) Hastings
Email: Caroline.mcelnay@hbdhb.govt.nz
Organisation (if applicable): Hawke’s Bay District Health Board
Position (if applicable): Director of Population Health

Are you submitting this:
(Tick one box only in this section)
  □  as an interim licence holder
  □  a person or body corporate intending to apply for a licence
  ✔ other (please specify): The Hawke’s Bay District Health Board

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

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

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

Submissions close on Friday 21 March 2014 at 5 pm.

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

Please detach and return this part of the document.

Consultation questions

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

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

   I am happy with proposed requirements, all I would add is that current interim licence holders of good repute and who already have good, responsible businesses and who have not encountered any issues with local councils and the police, should be retained as permanent licence holders, as there are only approximately 140 of these outlets currently selling psychoactives and I would imagine that moving forward, this amount of retailers would be insufficient for adequate spread of distribution across New Zealand. Local councils, as seen by the recent policy adopted by the Hamilton City Council, has acted in a way to effectively prohibit the sales within the Hamilton city by imposing unnecessary constraints! One would think that the council would be happy that the government have already reduced the retail activity from 4000 to 140 but does not appear to be the case! Why force existing good operators to potentially have to move premises when they are already established and have a customer base in the area that we currently exist in. In addition, we have leases in place, staff who live close to work, all the logistics and cost of potentially moving and then, because of the media sensationalism, no landlord will want anyone selling psychoactives from their premises as I have discovered whilst enquiring about possibilities in the council’s proposed zones. The councils will make a mockery of the act if this is allowed to continue.

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 am the owner of 5 retail shops around the upper north island, of which one is on the LAPP from the Hamilton Council, where effectively all current licence holders have been banned selling these products, due to the draconian way in which it was implemented. I am a responsible retailer on the fringe of the city and have a regular clientele of approximately 3000 customers per month for psychoactive product at the Hamilton store. I pride myself on my exemplary record in terms of selling these substances, I have been continuously subjected to police stings like everyone else and have not been prosecuted for selling to under 18 years of age, I am strictly r18, have a clean broth store with all the necessary infrastructure to support selling these products. I have been told by the Hamilton Advertiser they are not from the Hamilton store and research that my store is in a different class to other stores selling these products. In addition, a Hamilton city councilor chairing discussions on the LAPP policy, commented that my store is the kind of store she would like to see in the city and would make mention in her submission to government that my "model" should be adopted as the council and police have had no issues with me, in fact very few people are aware of the fact that I sold them, as was evident in a recent newspaper article were people surveyed said they did not want these products sold in which was one of the options the council put forward, retailers on either side of my business were opposed to having the products retail in and were totally unaware that I sold them, that's how low key my business is! The media has created the negativity and got people's emotions running high, not to mention that there were 4000 plus outlets selling them previously and now there were only a handful in Hamilton and nationally. I believe the secret to success of a retail outlet selling psychoactive products is the blended nature of the product offering, which in my case is tobacco and psychoactive products, which complement each other very well. This, to my mind, eliminates the opportunity for the public to target the store as a dedicated psychoactive outlet, and rather with a blended model, the public have no idea whether you are a tobacco customer or a psychoactive product customer and thus diffuses any negative impact on the licenced retailer and any negative image for government. This is evident in Hamilton, where the one outlet receiving all the negative press, was the only retailer exclusively selling psychoactive products.

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?

I strongly oppose revising or suspending any good and responsible operators with interim licences, for the reasons already explained. We have put a tremendous amount of effort into compliance and are currently not acknowledged for that, but I support having good strong policies surrounding any future licences issued and their locations. Once again, 140 current interim licence holders are not a lot but is a distribution base to grow from with policies put forward by councils to apply to new outlets. Here again, I believe the authority has to take the lead and direct local councils to act in a responsible manner, rather than adopting policies that counter the essence of the act, and in the process negatively affect a responsible retailer who has had no issues and is currently nowhere near any sensitive sites. If I had to be in the CBD, I would be much closer to sensitive sites than I currently am. Logic should prevail in this instance!

With the current 140 interim licence holders, you know what you are working with and can root out any rogue operators as has been the case over the past few months and build on a solid existing base of outlets. If this decision is left to local councils, as to where the retailers should be located, they will find every loophole to find ways to gain political points with the minority of vocal people who have issue with psychoactive, and effectively ban the sale of these products through their policy. The fact that 10's of thousands of these products are sold each month in each council precinct bears testimony to the need for these products to be available in a safe and regulated form through well managed responsible and blended outlets.

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 agree with the above, but would include some compulsory training in dealing with R18 products as part of the licensing regime.

From what I have witnessed over the past few months in terms of media coverage, is the fact that the media target the psychoactive product retailers who only sell synthetic products, whereas when you are selling R18 products like Tobacco and or adult theme products, you are up with a blended customer base which in my experience creates a harmonious flow of customers and does not draw any unwanted attention to the business.

Typically, the stores that were not in existence prior to the new act and popped up are the outlets that are drawing the attention and those operators are the ones with little or no experience in dealing with R18 products.

This scenario will be replicated when existing good operators are forced to cease selling these products in favour of individuals applying for the first time when the permanent licensing regime kicks in in 2015, and they are able to open in council demarcated areas, whereas we as good current operators have leases in place, staff who are being paid well to deal with the increase in responsibility and workload, additional security in place, our livelihoods at risk, and all of this favouring people and retailers who were not pioneers in this industry and who have committed their business to this industry!

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

Yes, at least you will know that they have had exposure to dealing in an R18 environment, which will aid their ability to retail responsibly.

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

C

Psychoactive Substances Regulations: Submission form
I think full audit documents should be provided annually to determine what was purchased from suppliers and what was sold by retailers. A full vertical integration audit should be randomly available to police and the authority to determine sales volumes through the distribution chain and to determine sales per transaction. This will eliminate bulk sales to individuals who could be on selling these products to minors. This process will also facilitate the police in determining peak times of customer flows and sales.

I don't understand the need for wholesalers as all retailers currently purchase direct from manufacturers, one should have one licence or the other, not both.

I have noticed that some retailers also have wholesale licences, which results in these retailers buying in bulk from manufacturers at discounted prices and ultimately competing with the manufacturer of the specific products. I find this counterproductive as any of the suppliers will meet competitive pricing, hence nullifying the purpose of the wholesaler. This also results in the retailer selling at discounted prices through their own retail outlets and results in some retailers becoming a lot more prominent than others, because they have a wholesale licence and a price advantage over other retailers. This also gives them the excuse to sell bulk, which potentially will reach minors, hence the need for full distribution chain audits!

The other point that needs consideration is the fact that the wholesalers only have a retail base of 140 outlets currently and the need for wholesalers has been bypassed as all these retailers purchase product direct from suppliers.

In terms of retail records, my recommendation is that all retailers should be compelled to have proper retail point of sale systems with scanning ability, this will provide the authority with the number of transactions made in any given period, the number of sales per transaction, what stock is in the system, what was purchased, and what stock is on hand. This data is then married to the sales from wholesalers and suppliers and any anomalies identified, further reducing the risk of product getting into the hands of ilicit traders and hence into the hands of minors. I would also recommend a limit be placed on the number of products being sold per transaction and a minimum size product is limited to a 2.5 gram pack size.

My experience has been that the smaller denominations or pack sizes are the ones that are more affordable and hence attract the majority of the unwanted attention by younger anti-social types, so where we have experienced this situation, we have ceased selling this product denomination and the situation is normalised immediately.

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

Normal company financial records are kept for seven years, but point of sale systems usually hold data of this nature for up to 5 years, however annual sales reports should be provided and copies kept annually and filed for 3 years, which is the duration of the permanent licence.

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

I think it would be advisable to have a licence on hand if requested by the authority. Because I sell tobacco and synthetics, this creates a blended customer base, so I would prefer if licences were available on request and not on display as this could draw attention and thus possible negativity by customers who don't use synthetics. Customers currently supporting my stores would not know who is purchasing tobacco or synthetics as we do the transactions discreetly and place the product in a brown bag after scanning and concluding the transaction. This, I believe is the key to the success of my business model, as the public cannot determine who is purchasing what and hence any negativity is diffused or eliminated.

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?
Besides the person applying being of good character, I think it is essential that a training regime be put in place by a governing body, for example the star trust, or similar, to ensure the correct lock and feel of the retail premises is adhered to and doesn’t look like a drug outlet. The staff is well trained in dealing with a variety of situations eg intoxicated customers and what advice to offer, the removal of other drug paraphernalia, eg bongs, which under the current act would be regarded as a “household good” as they are sold as vases to get around the law. These items really pull the image of the stores down and send a clear, but negative message to the public of being a dirty and unscrupulous industry.

Without all these negative identifiers that are associated with many of the current outlets, I manage to do good business through word of mouth and happy customers who make their purchase with a level of dignity.

Customers, I must stress come from all walks of life! And enjoy the experience of making their purchase in my stores.

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, this will ensure that shortcuts in the process are averted and safety remains the priority.

C

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

- Retailers should have a company policy relating to the sale of these products to consumers of an R18 age and above
- Code of conduct which ties in with the employees employment contract

C

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 follow the lead of the Tobacco act, i.e. health warnings

C

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, possibly the amount that should be used at any one time and recommended time between usage to ensure safe usage.

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

All product must be barcoded for scan data purposes.
I would suggest that, considering you cannot advertise the product, that all products have their individual brand names, but are packed in a generic packaging, which are also the primary packaging resulting in no outer branding being discarded randomly by customers and annoying the public and attracting the attention of minors.
All products should carry a prominent R18 sticker in a prominent and consistent colour.

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).

Health warnings should be of a consistent proportion to the size of the packaging and placement should also be consistent on the face of the pack as per tobacco products.

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

All packaging should be generic and be the primary packaging as per above comments

17 Do you agree with the proposal to restrict a packet to one dose? Please give reasons for your answer.
I have found that the most popular dose is the 2.5 gram as this product is set at a price which limits the attentions of unwanted customers. The cheaper the pack and the smaller the pack size, is what attracts negativity in this industry. I would also limit pack sizes to the 2.5 gram only, as bigger pack sizes also have the possibility of being reduced to smaller pack sizes and be sold to minors potentially.

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

Yes, it's a good idea to split according to the amount required per dosage.

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

The form the product takes is not a consideration for me, rather the correct dosage for each use to ensure safety of the product and the same delivery per dose in whatever form.

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

Considering the basis of the products is predominantly herbal, they could be hygroscopic in nature, which means they can absorb smell/odour from other products. In this case I think it is more important to ensure that each product is sealed in a foil packaging which will result in odour from one product not contaminating another. Currently, some suppliers use plastic bag-style packaging which allows the odour to permeate through the bag and can potentially contaminate other product around it.

21 Do you think restrictions or requirements should be set for the storage of approved products? If so, what should they be?
All products should be stored in metal stock bins, this approach is currently used by smoke to ensure security and keep the insurance premiums in check.

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 should be kept out of sight and a product menu offered on request as we currently do!

23 Do you think restrictions or requirements should be set regarding the disposal of approved products? If so, what should they be?
All expired product should be returned to the respective suppliers to be destroyed in a responsible manner. We, as retailers would return expired product for credit, so the responsibility for destroying the expired product would best lie with the supplier.

24 Do you think there should be signage requirements in the regulations? If so, please give specific suggestions.
No signage or any form of advertising is recommended.

25 Do you think the regulations should specify further places where approved products may not be sold? If so, please provide specific suggestions.
I am fully supportive of the sale of the synthetic products through outlets that are appropriate, i.e. R18 stores, which are of a BLEND nature, like mature adult theme stores and Tobacco specialists. This approach is covered in earlier comments.

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

Yes, most definitely, this will pre-empt any operators drawing unnecessary attention to these products. Word of mouth is sufficient, the customers find us as retailers, without having to put the products in the public domain.

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

I think internet sales are useful for customers in remote parts of the country, but although every effort is made to ensure these products are delivered to the intended recipient, it’s not often the case when courier companies do not follow the procedure for delivering R18 products. There should be more responsibility on the courier companies to comply with internet sales as once the product leaves a premises, it’s out of the hands of the retailer! Even though the internet procedure is according to the law in terms of R18 disclaimers etc.

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

Covered in earlier comments.

29 Do you agree with the proposed fees for the different licences? If not, please provide specific suggestions.
The fees proposed for retail licences are high considering the costs associated with gearing a business to sell these products in the first instance. I would suggest $10,000 per licence for a new permanent license initially and as the retail environment grows exponentially, any renewal of a permanent licence is reduced as the costs are amortised across a bigger universe of outlets.

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

I would support a fixed fee as this gives a business certainty in terms of budgeting and cash flow forecasting.

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

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

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

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

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

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

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

Alternatively, electronically complete the submission form available at the back of this document, add your comments and email to:
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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?

   It is our position that synthetic cannabinoids should be controlled in a similar fashion to the current controls applied to alcohol and we therefore believe that the interim licences should be granted to the individual licencees rather than the business premises. Also retailers should be able to move if leases expire.

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

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

We think that maintaining the Retail price point at or above $20.00 will form a deterrent against the bulk purchase of product and limit ability to supply underage persons.

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

18 Do you agree with the proposal that a dose, in whatever form the product takes, is split wherever possible?
27. Do you think the regulations should prescribe restrictions or requirements on internet sales of approved products? If so, please provide specific suggestions.

It is our position that Synthetic Cannabinoids should not be sold on the internet. Recent events show easy access to Alcohol via the internet.

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

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

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

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

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

This submission was completed by: (name) 
Address: (street/box number) (town/city)
Email: 
Organisation (if applicable): 
Position (if applicable):
Are you submitting this:
*(Tick one box only in this section)*

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

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

- ☐ Yes
- ☐ No

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

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

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Please detach and return this part of the document.

Consultation questions

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

   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.

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?

   Daily records of every sales transaction pertaining to psychoactive substances which must correspond with the purchaser’s contact details and proof of 18+ ID

7. How long should licence holders be required to keep records for?
5

Five years

8 Do you think there are factors or issues that the Authority should consider when setting discretionary conditions? If so, please provide details.
A limit on the amount purchased per transaction i.e. one dose per customer per day

9 Should the regulations prescribe other matters the Authority must take into account when deciding on an application? If yes, what should these matters be?
Consistent hours of trading
The nature/type of surrounding businesses and the impact on them
Host responsibility

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

11 Do you think any further particulars, information, documents or other material should be prescribed in the regulations? If yes, what should these be?
12. Do you agree with the proposal that the regulations require applications to contain information and data on the toxicity, pharmacology and related clinical effects of the psychoactive substance they are seeking approval for?

Yes

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

Yes

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

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

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

Yes.
By doing this it would prevent bulk purchasing and potential on-selling. It would be inconvenient for users to make daily trips and as a result could potentially result in decreased uptake. In addition, it would reduce the incidences of excessive inhalation / overdosing by users.

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?

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?

The same as applies to the sale of cigarettes - stored in nondescript, lockable, non-branded cabinets with limited/restricted visibility.

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

As above

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

The same as applies to the sale of cigarettes - stored in nondescript, lockable, non-branded cabinets with limited/restricted visibility.
23 Do you think restrictions or requirements should be set regarding the disposal of approved products? If so, what should they be?

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

Yes.
Highly visible and in large print.
Should contain a graphic warning/s and statistical information about the detrimental effects of usage.

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

Yes.
Near businesses that attract:

a) young families and children e.g. toy shops, baby clothing and other related merchandise
b) tourists e.g. accommodation providers, public art and any other attractions that tourists seek out
c) public leisure areas e.g. parks/reserves, cafes

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

Yes.
In the event that advertising cannot be prohibited altogether, then advertisements should contain a graphic warning and statistical information about the detrimental effects of usage.
27. Do you think the regulations should prescribe restrictions or requirements on internet sales of approved products? If so, please provide specific suggestions.

Yes.
Legally internet sales should be restricted to 18+ yrs of age, but this is difficult to monitor. However, product should be signed for and proof of ID sighted at the time of delivery.

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

As per answer to Q. 25

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

C

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

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

Given that alcohol and tobacco are excisable goods, psychoactive substances should be too. The cost to purchase the latter currently serves as an incentive rather than a deterrent. Monies raised through excise could be earmarked for redress of specific social costs commonly associated with the product e.g. government anti-psychoactive substance use campaigns.

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

C

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

This submission was completed by.  (name)  Meg Rodel
Address:  (street/box number)  PO Box 526
          (town/city)  Napier
Email:  info@napierinthecity.co.nz
Organisation (if applicable):  Napier Inner City Marketing
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): as an organisation on behalf of our members

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

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Your perfect travel companion

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

March 11, 2014

To Whom It May Concern

Re: Submission regarding Psychoactive Substances

We are writing to voice our concerns over the sale of Psychoactive Substances on Dickens Street, Napier. Firstly, we would like to see an ultimate ban on the sale of all such substances and will continue to support any steps taken to make this the final result.

In the interim, we would like to propose the following restrictions:

Limited Opening Hours:

As a neighbour of the Adult Shop on Dickens Street, we have noticed a vast increase in loitering since the shop became the sole retailer of synthetic cannabis in Napier. We open prior to 7.00am each morning and have noticed there are already many vagrants hanging around the street in front of our hospitality venue. They block the stairs for our guests and are loud and at times abusive. We feel a clear and concise opening hour regulation will assist in ensuring that people do not loiter and only turn up at the nominated opening hours.

We propose hours of 8.00 am to 6.00pm. These are sufficiently long hours for people to purchase the product. In addition to this we would like to propose that the shop selling the product must be obliged to put up a clear sign stating these opening hours as is expected of a venue selling alcohol.

Limit on sale of items and sign-in

We would like to see that there is a daily limit of 2 items per person and that each purchase must be signed out. The purchaser would have to present their 18+ ID and sign their name and address. This would address the problem of on-selling large quantities to others (possibly including minors).

This would also help control the amount sold and the revenue it generates.

Duty Manager Requirements

As a detrimental substance as much as alcohol (if not more) we think the strict regulations regarding the sale of alcohol should be applied to synthetic substances. This would include a registered Duty Manager and their obligations and a sign displayed stating this. The licensing of a Duty Manager should also apply to shops selling Psychoactive Substances.
The fee for the license should be in line with a Liquor License fee and a yearly renewal process would apply. The process for applying for a License should be as onerous and time consuming as it is for any venues selling alcohol.

Excise Tax

Whilst we cannot fathom why this is already **NOT** in place, the substances should be immediately subject to excise taxes of the same severity as applied to alcohol and tobacco. There is no reason why the product currently being sold for $20 not have a 100% tax placed on it to fund all the detrimental health problems it is creating and will continue to create while it is still being sold.

Tourist Area Considerations

Currently the Psychoactive Substances in Napier are being sold in the heart of this Art Deco city that relies heavily on tourist revenues to bolster the Council’s revenues. We find this deeply insulting to all tourism businesses and an insensitive move by the Council to allow this venue a license.

We request again that if an outright ban is not to be considered then at least Tourism considerations be taken into account when a shop is granted a license. The impact on surrounding businesses has been immense.

Again we stress, particularly as parents of 2 teenage sons, that it is our end goal that an outright ban be placed on the sale of Psychoactive Substances.

Yours Sincerely

Fiona Simon
Franchise Director
**QUEST NAPIER**

Ruben Simon
Franchise Director
**QUEST NAPIER**

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Quest Napier trades as an independently owned and operated franchise of the Quest Group
The Sale of Psychoactive Substances in Napier City

To Whom It May Concern

As a business owner in Dickens Street Napier which is situated opposite and a few metres down from the Licensed Adult Shop selling psychoactive substances. We have in recent months observed a greater volume of traffic visiting the outlet. Since the City Council placed a camera opposite the Shop we have also observed many vehicles parking out of camera range near our business. The drivers who are clearly over the age of 18 go across the road to purchase and return to hand out packets to young teenagers well under 18 waiting on the footpath. During the day some of the regular users sit in front of the Dickens Street south car park smoking and leaving their empty packets on the footpaths.

This kind of activity is clearly not a good look for our central business district. We have regularly also observed many cases of antisocial behavior from these people. Examples, using foul and offensive language to passing pedestrians also when tourists are going past in the deco train they are often receive the same offensive language together with rude hand gestures.

I believe the Government should require the licensed operators to be required to limit the purchases and to purchaser to sign a register with valid ID, similar to pharmacies dealing with restricted medicines, as well as shorter trading hours.

The government has sent out a mixed message to the drug users of this country referring to the psychoactive substances (chemical cocktails) a quote "LEGAL HIGHS" compared to the green leafy plant, Cannabis which is NOT legal.

The Councils have stopped the sale of these products in suburban areas and restricted the sales only in the City CBD. I personally do not believe that our country needs to have these products for legal sale. They clearly do not have any benefit to our communities and only downgrade the parts of our city where the shops are located, making businesses suffer because of their proximity to where these psychoactive substances are sold.

Recommendations:

Limiting Hours of trading 9am to 5pm Monday to Friday. Strict Limit on purchases one pack per customer per day with weekly limit of four. To make it harder for on selling to others. Introduce higher tax in line with cigarettes and alcohol with increases on an annual basis.

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

March 11, 2014

To Whom It May Concern

C

Re: Submission regarding Psychoactive Substances

We are writing to voice our concerns over the sale of Psychoactive Substances on Dickens Street, Napier. As with our previous petition presented to Parliament, in February, We would like to see an ultimate ban on the sale of all such substances and will continue to support any steps taken to make this the final result.

In the interim, we would like to propose the following restrictions, and see regulations aligned with both the Sale of Liquor Act, and Sale of Tobacco, immediately.

Limited Opening Hours:
In alignment with businesses selling alcohol, and licensed premises, we ask that trading hours and appropriate signage be the same, and regulated, not at the discretion of the owner, which currently, can be hours to supply that suit.

C

Limit on sale of items and sign-in

We would like to see that there is a daily limit and that each purchase must be signed out. The purchaser would have to present their 18+ ID and sign their name and address. This would address the problem of on-selling large quantities to others (possibly including minors).

Duty Manager Requirements

As a detrimental substance as much as alcohol (if not more) we think the strict regulations regarding the sale of alcohol should be applied to synthetic substances. This would include a registered Duty Manager and their obligations and a sign displayed stating this. The licensing of a Duty Manager should also apply to shops selling Psychoactive Substances.

The fee for the license should be in line with a Liquor License fee and a yearly renewal process would apply. The process for applying for a License should be as onerous and time consuming as it is for any venues selling alcohol.

Excise Tax
The substances should be immediately subject to excise taxes of the same severity as applied to alcohol and tobacco. There is no reason why the product currently being sold for $20 not have a 100% tax placed on it to fund all the detrimental health problems it is creating and will continue to create while it is still being sold.

Tourist Area Considerations

Currently the Psychoactive Substances in Napier are being sold in the centre of the city. We request again, as with our previous petition, that if an outright ban is not to be considered then at least Tourism considerations be taken into account when a shop is granted a license.

Yours Sincerely

Shayne Jeffares
Together Napier
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?
   
   Referee checks, further step in verifying the applicants suitability and information provided by the applicant.
   Applications should go through the local boards as well given their interest.

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 agree this would save time regards further processing the application.

3. Should retail licence applications be accompanied by evidence of compliance with a generic local approved products policy if no policy is in effect in the applicant’s area?
   Yes if no localise policy there should be a standard generic one that covers the basic exclusion by any council regards an 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.

All offences should be considered including those the applicant has been charged with. This will take into account where there are current charges active for the applicant but yet have been determined by the court. Relevance offence should include offences under the Liquor licensing act.

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

Yes as above applicants should provide information on any alcohol licences they have or links to and any liquor establishments.

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

- Records should be kept that can be checked at any time by Ministry of Health officials and Police under the act.
- The identity of the person who purchased the item. Identification (driver’s licence/passport/Work & Income Community card). This will verify age and give officials better ideas or those purchasing the products.
- Description of the article, including its serial number or any other unique identifiers.
- The quantity and type of product purchased
- Date of transaction

(This will give officials and more accurate reading on the quantity and type been sold on a daily basis and any patterns that are developing regards the trade of psychoactive substances.)

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

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

No I believe all licence applications should be subject to discretionary conditions, and that any proposed licence should require a joint visit by the local Ministry of Health representative and a member of police prior to the application processing to recommend what discretionary conditions should be implemented.

C

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

Proximity to church/medical centres/educational facilities and centre of a CBD area.

C

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

Yes all packaging should contain what has been proposed under the regulations.
11 Do you think any further particulars, information, documents or other material should be prescribed in the regulations? If yes, what should these be?

Penalties for breaching regulations should be clearly displayed including potential health risks

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

Agree on the recommendations as outlined in the 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 as previously mentioned any harmful effects should be clearly shown on the products.

14 Are the proposed requirements and restrictions on labelling sufficient? If not, please make specific suggestions for further requirements and restrictions.
That the health warning should be on the front of the packaging not in small print at the back.

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).

Preventative information such as pamphlets and posters in the shop should be in place as a means of clearly giving side effects of taking synthetics cannabis but also outlining where help can be obtained for those wanting assistance in coming off the addiction to synthetic cannabis.

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

Like cigarette packaging there should be clear labelling, of the possible side effects of taking synthetic cannabis which should be on the front of the packaging.

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

Yes. Recommendation will limit the quantity smoked or taken, which should reduce the ability to on sale or split which is currently occurring after purchase.

- Number of packages sold to any one person be limited to maximum of two packets. Would stop people bulk buying or on selling.
- There should be no discounting products which is currently happening. No 2 for 1 deals that is occurring. All prices should be regulated for all the stores.
18 Do you agree with the proposal that a dose, in whatever forms the product takes, is split wherever possible?

Current trend is the product is split once purchased to either smoke the synthetic cannabis by itself or increasing the amount of hits by doing a mixture of tobacco and synthetic cannabis.

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?

Shouldn't allow.
- No direct links aimed at attracting youth
- All packaging should come in the same size regards diameter width.

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

- If the synthetic cannabis is stored on site, they should be kept a safe or similar lockable secure facility. (Already the shops have been targeted for burglary regards the synthetic cannabis.)
- Alternative is storing it off site and bringing it into the store on daily basis. (Already one store does this to prevent being targeted for burglary.)

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

An auditable itinerary should be kept on site as to how many products and what products are contained on site.
22. Do you think restrictions or requirements should be set regarding the display of approved products? If so, what should they be?

- Only display packets should be on display under a glass cabinet that is located next to the front counter. Products being sold should be obtained from a secure lockable safe or similar.
- These items on display should not be visible from the street and in an area that is restricted to those 16+.

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

- They all should be disposed per the Hazardous Substances Act and through Institute of Environmental Science and Research Ltd.

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

- Yes, signage should clearly state the law in relation to on selling the synthetic cannabis and also selling or giving to those under 18 years.
- It should clearly state a health warning to those purchasing.

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 a 100 metre radius of an educational facility, church, medical centre.
- Retailers shouldn't be selling anywhere near where children frequent or where people require medical help.
- On religious grounds no retailer should be selling synthetic cannabis in or near a church facility.
- No retailer should be allowed to set up on any main street of a CBD.
26. Do you think the regulations should prescribe restrictions or requirements for advertisements of approved products? If so, please provide specific suggestions.

- Agree with the current recommendation of the proposal and no advertising should be shown on the frontage of the stores.

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

- Don't agree with internet sales and even the proposed requirements would be in my view insufficient barrier to stop someone under 18 purchasing the product.
- There would have to be in place a very strict auditing process for on line sales, but would recommend no sales to be conducted on line.

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 in any newspaper or internet which attracts those under the age of 18.
- All advertising as proposed should carry a health warning and a warning stipulating offences under the act particular selling or supplying to those less than 18 years of age.

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

Yes though I believe the fees for retailers to low compared to what they earn from sales. Retailers that I have had dealings with alone would earn $25,000 a week on product sales. The fee for retailers should be similar to that of the manufacture for not only the application but the annual renewal.
30. Do you support a fixed fee or an hourly charge for processing applications for product approvals?

No just a straight fee

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.

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): New Zealand Police

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): Enforcement 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.
Consultation questions

1. Is the list of proposed information requirements for licence applications comprehensive enough?
   If not, what else should be required, and why?
   Yes. We additionally support the proposal to include consent to undergo a Police check being included on the application form.

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

3. Should retail licence applications be accompanied by evidence of compliance with a generic local approved products policy if no policy is in effect in the applicant’s area?
   Yes, applications for retail licenses should contain evidence of compliance with generic policies.

4. Are the factors the Authority should take into account when determining whether a licence applicant is a fit and proper person or whether a body corporate is of good repute in section 16(2) enough? The section 16(2) factors are:
   - whether the applicant has been convicted of a relevant offence
   - whether there has been a serious or repeated failure by the applicant to comply with any requirement of the Act
   - whether there are other grounds for considering that the applicant is likely to fail to comply with any requirement of the Act
   - any other matter that the Authority considers relevant.
Product Recall
The Psychoactive Substances Act provides for recall of a product if “the product poses more than a low risk of harm to individuals using the product”. We are concerned that this definition may not allow for recall of a new product that could be causing serious harms when used in combination with another product or drug. We suggest the regulations or the Act include a power for the authority to recall a product if evidence shows it poses more than a low level of risk in combination with products legally available before the date of its approval. New Zealand research has shown that recreational drugs are very often used in combination here, most commonly with alcohol.

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 established. In addition, reliable and simple roadside tests for the presence of such drugs will be required.

Tax
We recommend a tax is applied to approved products in order to:
- Cover potential expenses for government services including justice, social services, health and particularly ongoing independent monitoring and analysis of longer term effects of products. Because no psychoactive product can be entirely safe for all individuals, health interventions and social support will be required for some users.

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

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

For all licences, we recommend:

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

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

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

For research licences, we recommend:

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

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

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

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

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

To this end, we recommend all licence holders be required to keep:

- Purchase records - including licence number of the seller from whom the psychoactive substances or products were received
- Sales records, including quantity of products or substances distributed, and quantity sold in a single transaction,
- Records of disposal of any product or substance and the reason for doing so

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

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

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

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

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

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

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

7 years to enable audit

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

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

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

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

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

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

For retail licences, we recommend:
In the absence of an LAPP or generic LAPP, physical proximity to premises regularly used by young people and vulnerable groups should be considered by the authority. Likely impact on the character of an area.
10 Do you agree a product approval application should include information on proposed manufacturing methods and how they will comply with the Psychoactive Substances Code of Manufacturing Practice?

Yes

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

No comment

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

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

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

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

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

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

Determining the measure of ‘low risk’ will be difficult to define and potentially be scientifically inaccurate due to trying to translate the skewed distribution of harm among users into an overall concept of ‘low risk’. Thus the baseline measure for determining ‘low risk’ should be assessed against the scheduled substance that evidences ‘lowest risk of harm’ to the individual consumer. Regulations should stipulate that clinical trial methods examine the NPS in question in relation to other substances and risk factor mentioned above.

In addition we recommend:

- Data on the same factors listed at ‘12’ and ‘13’ should be provided not only for the substance for which approval is sought, but for the final product for which approval is sought, as the product for which approval is sought may contain combinations of substances, psychoactive or otherwise.
- Information on effects and risks at different levels of dosage of the final product should be provided
- The intended quantities and dose-quantities per package of the final product, alongside directions regarding suitable dosage and use, should be included in the product approval application, in order to evaluate effects and risk levels at the recommended dosage.
14 Are the proposed requirements and restrictions on labelling sufficient? If not, please make specific suggestions for further requirements and restrictions.

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

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

In addition we recommend labels include details of:

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

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

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

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

In addition, suggest adding two further warnings:

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

Ref:

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

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

See question 14 regarding support for plain packaging.

The other requirements proposed appear sufficient.
17 Do you agree with the proposal to restrict a packet to one dose? Please give reasons for your answer.

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


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

Yes, please see above.

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

Yes, we believe products in the following forms should not be approved:

- Additional regulations should be applied for smokeable products, covering any public indoor or other confined space. Non-consumers should not be subject to second hand smoke from such products.
- Appeal to minors – support that product forms with appeal to minors should not be allowed.
- Liquid or other easily injectable forms, and should not come in with injection equipment.

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

Yes – level of security should be high.

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

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

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

We recommend taking steps to reduce the likelihood and impact of burglary by limiting amounts kept in retail stores, which are obvious and highly visible targets, to a sufficient quantity for 2 days of normal trade.
22 Do you think restrictions or requirements should be set regarding the display of approved products? If so, what should they be?

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

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

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

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

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

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

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

To avoid leakage of product to young people through shoplifting, the premises where products are sold should have entry restrictions to persons 18 years and older.
26 Do you think the regulations should prescribe restrictions or requirements for advertisements of approved products? If so, please provide specific suggestions.

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

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

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

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

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

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

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

Yes

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

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

Yes – levies should be collected to enable:
- The establishment of data collection and monitoring systems including:
  - Regular collection of baseline data on emerging patterns of use and effects of the product
  - Detailed analysis and review by the PSRA every three years after approval of a product
  - Enable thorough medical case events to be developed - including provision of resources for medical staff to undertake detailed testing and analysis to case events (individuals suffering acute or chronic symptoms from use of a product).
  - Newly approved products to be reviewed for evidence of harms every three years
  - Development and operation of systems for reporting adverse effects of psychoactive products (e.g. CARM, and systems for relevant medical facilities such as emergency departments, GPs and mental health clinics)

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

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

No comment

This submission was completed by: (name) Puamiria Maaka
Address: (street/box number) PO Box 18033, Glen Innes
           (town/city) Auckland 1743
Email: ceo@twp.org.nz
Organisation (if applicable): Te Waipuna Puawai Mercy Oasis Limited
Position (if applicable): Chief Executive

Are you submitting this:
(Tick one box only in this section)
☐ as an interim licence holder
☐ a person or body corporate intending to apply for a licence
☑ other (please specify): ........................................................................................................................................................................
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 licences should be given unless the product has been proved beyond doubt not to cause harm in the long or short term. The licence holder is to be held responsible for any harm caused in the selling of the product.

2. Should retail licence applications be accompanied by evidence of compliance with a local approved products policy if one is in effect in the applicant’s area?
   The retail licence needs to be approved by the local authority in which the product is to be sold. A yearly review and renewal would be required with submissions from the community sort.

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?
   The licence application needs to be approved by the local authority in which the product is to be sold. A yearly review and renewal would be required with submissions from the community sort.
As 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 licence holder is to be held responsible for any harm caused in the selling of the product which would include personal harm, psychological harm and any damage to property and or the environment.

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

Full disclosure of all business involvement.

What records should the regulations require licence holders to keep?

Full detailed accounts of products sold including product type, amount sold.

How long should licence holders be required to keep records for?
The licence holder would be required to keep records for a minimum of 2 years with records sent to the local authority annually.

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 no discretionary conditions.

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 along with information on resulting harm from using the product. Possible consequences to the mind and body of the person using the product.

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?

Along with cost to the individual physical harm, psychological harm focusing on the short term and long term effects. The responsibility on the licence holder for creating the environment for this to happen and to put right any damage caused.

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?

Clinical trials on any psychoactive product to be based on a 5 year human trial.

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

If this product is harm free to the individual who is using then labelling would be sufficient.
15  Are the proposed requirements relating to health warnings sufficient?
If not, please make specific suggestions for further requirements (for example, advice on what to do in the case of an overdose).

The product should not be sold if harm to the individual and or the environment is a concern. The ambulance at the bottom of the cliff seems a bit pointless.

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

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

That does seem a bit pointless. Are we saying any more than 1 dose can cause harm to the person using it and if so why are we selling it. Do we sell cigarettes one at a time?

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

I don't agree, why we are splitting the dose. Are we saying harm can come from overuse and if so why would we allow something to come into our country that has the potential for harm. The products very nature is to be addictive to change the chemical structure of the brain. This does and will have grave consequences for our young people.
19. Do you think there should be restrictions on the form products can take? If so, what forms do you think should and shouldn’t be allowed?

The question is around harm to the individual, family and community. Will this product impact on the user in a negative way in the short term and the long term.

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?

Are these psychoactive substances dangerous, can they cause harm, do they need to be kept in a safe place. The answer is yes in another country.

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

They need to be stored in another country to prevent harm to our young people.

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

If the product is safe to use with no harmful effects and this has been documented then no restrictions should be required.
23 Do you think restrictions or requirements should be set regarding the disposal of approved products? If so, what should they be?

If the product is safe to use with no harmful effect to the user or the environment no restrictions are required.

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

If the product is proved to be harmless to the individual and the environment then no signage need be required. If we are to sell a product that has the potential for harm then this needs to be spelt out clearly with the ambulance at the bottom of the cliff waiting.

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.

If the product is safe to use with no harm to the individual or the environment then no restrictions need apply.
27 Do you think the regulations should prescribe restrictions or requirements on internet sales of approved products? If so, please provide specific suggestions.

If the product is safe to use with no harm to the individual or the environment then no restrictions need apply.

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

If the product is safe to use with no harm to the individual or the environment then no restrictions need apply.

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

The licences should reflect the harm to the individual, family and the community. The greater the harm the greater the cost for the licence.

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

Fixed fee linked to the products harm potential.
31 Should fees be set for other specific functions? If yes, please state what they should be set for.

The cost for all testing, documentation and enforcement would be at the manufactures cost.

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)  Stephen Deakin
Address:  (street/box number)  PO Box 21947 Henderson
          (town/city)  Auckland
Email:  steve@changeworks.org.nz
Organisation (if applicable):  ChangeWorks Trust
Position (if applicable):  CEO
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): Organisation working with young people

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.
Dear Ministry of Health,

Below are the suggestions we wish to summit for the next stage of legal high selling:

We are a true adult shop and have been trading as such for the last thirty years. Our hours have always been longer than most shops for the convenience of our customers, and due to the fact that a lot of our customers do not wish to shop when other businesses are open – they like digression. We have always closed at between 9 p.m. and 10.00 p.m. at night, but since selling legal highs we are now opening earlier, between 7.30 a.m. and 8.00 a.m. to prevent annoying retailers around us with customers hanging around waiting for us to open. One retailer in fact requested us to open earlier for this very reason. We believe this should be able to continue as it seems to be working for us and probably would work for other retailers as well.

I believe licenses should be held by more than one person per store – to prevent issues e.g. with death of a partner etc. My husband and I would both like to hold our license. This should be transferable to our children in the event of our deaths or if we wish to retire, so long as they have reputable standing as per the laws.
I also believe that licenses should be transferrable in location in the event of a disaster, e.g. fire or flood or earthquake (e.g. Christchurch).

We also believe to help control the selling of legal highs; you not only need a retailers license, I would like to see everybody selling this product hold a seller’s license so they can hold some liability to ensure they uphold the law. I know that employers have been caught selling to underage customers and incurring a fine of $200 but no loss of license, that is why a lot of licensee will not serve in their shops so there is no risk of them losing their license.

I would like it to be made law that all people wishing to purchase legal highs need to produce ID every time like if you were purchasing alcohol.

I believe all stores should have cameras both inside and outside the premises, to help law enforcement. It also helps identify adults purchasing legal highs for the underage. All products should be kept in secure safes, e.g. we brought a bank safe, to prevent easy access if anybody tries to break in.

We also hold an online store and have been selling legal highs online. We ensure that all people purchasing legal highs must submit photo ID for proof of age. We only accept driver’s license, passport, 18 plus card or a firearm license. We also send out all deliveries via signature required bags so they need to sign for the purchase.

Local Bodies have the right to enforce laws but need to work with the government in this matter not against it. Restricting how many stores in a town makes sense to me, otherwise you get to competitive, Where they wish stores to locate makes sense to a certain extent for pop-up
stores but not for established stores that have been running over 10 years, at the same location.

I do agree with not being able to advertise this product, as from personal experience it does not need to be advertised. They find us anyway. I also believe shops that do this should be closed, I think advertising legal highs in mags e.g. the new Kiwigirl should be not allowed, also having websites with legal high in their address is another form of advertising and should not be allowed either. All stores wishing to sell legal highs online need to use their store name.

I believe more education needs to be made available to the public on how to use legal highs. Especially the young users who have no idea that you should be drinking water when smoking legal highs and you should only smoke the stuff until high, it is not like alcohol – the more you drink the drunker you get.

Yours faithfully
21 March 2014

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

Dear Sir/Madam

SELWYN DISTRICT COUNCIL SUBMISSION ON PSYCHOACTIVE SUBSTANCES REGULATIONS CONSULTATION DOCUMENT

The Selwyn District Council thanks the Ministry of Health for the opportunity to comment on the consultation document for the proposed regulations under the Psychoactive Substances Act 2013. The Council has provided feedback on areas related to the sale of approved products and retail licences.

Introduction
At present there are no retail stores selling psychoactive substances in the Selwyn district. The Council has considered the possible issues around the sale of these substances and has yet to decide if it will prepare a Local Approved Products Policy for the district. Although the Council would prefer to have regulations covering retail licences implemented at the same time as the regulations for other licence types, the Council supports the extra time provided to TAs to prepare a local approved products policy (LAPP).

Retail licences
The Council considers LAPPs to be an important tool which can provide communities with the ability to have some measure of control over the sale of approved products. The Council therefore supports the proposal to have retail licence applications comply with a LAPP and the Council recommends that a licence not be granted unless it complies with the LAPP.

Generic LAPP
The Council is unclear how a generic LAPP would work as by definition, it would no longer be a “local” policy specific to the needs of that area. However, if a generic policy was to be prepared as part of regulations, the Council suggests that this generic policy includes a provision prohibiting approved products being sold in residential areas/residential zones.
Fit and proper person test
The Council supports that regulations require applicants to provide details of their involvement in other regulatory regimes as applicants’ history with other regulatory regimes should provide indication of their future behaviour under this regime.

Discretionary conditions
The Council supports the proposed discretionary conditions:
• a requirement to display the licence on the premises
• a declaration if internet sales are proposed.

The Council also supports having conditions on ensuring the required degree of physical separation is met, opening hours and prohibiting the sale of food and household goods at licensed premises.

Labeling and packaging
The Council supports the proposed labelling requirements and the four compulsory health warnings on page 15-16 of the consultation document. The Council also supports the packaging requirements on page 17.

Quantity and dose requirements
The Council is unsure if limiting dose amounts per pack would truly protect consumers as there is a greater chance people would buy more than one pack if they considered the dose size too small per pack. The Council suggests that if a pack contains several doses, each dose is packaged individually within the pack to ensure consumers can tell what a single dose would be.

The Council does support the splitting of doses wherever possible (e.g. splitting a tablet into four) and agrees that this measure could reduce the risk of over dosing.

Restrictions on form of product
The Council agrees that regulations on smokeable products should be consistent with New Zealand’s policies on smoking tobacco.

Signage
The Council supports regulations that require signage to state that approved products cannot be sold to people under 18 years of age.

Advertising
The Council supports requirements to have advertisements be consistent with the Advertising Standard Authority’s Advertising Code Ethics.

Internet sale restrictions
The Council supports the proposed requirements for internet sales listed on page 23 of the consultation document.
Conclusion
The Council supports the proposal to ensure retail licence applications comply with a LAPP and recommends that licences not be granted unless it complies with the LAPP. In general the Council is supportive of the proposed regulations as identified above.

The Council appreciates the opportunity to provide feedback on the proposed regulations. Please direct any questions to Mel Renganathan, Research and Policy Advisor, telephone: 03 3472712 or email: melissa.reenganathan@selwyn.govt.nz.

Thank you.

Yours sincerely

Kelvin Coe
Mayor
Selwyn District Council
19 March 2014

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

Dear Mr Hannah,

Psychoactive Substances Regulations – Submission

1. Thames-Coromandel District Council (the Council or Council) thanks the Ministry of Health for the opportunity to provide input into the development of the psychoactive substances regulations.

INTRODUCTION

2. Since enactment of the Psychoactive Substances Act 2013 (the Act) the Council has maintained awareness of progress and has participated in a working group with other councils in the Waikato Region. Through this group a Local Approved Products Policy (LAPP) template has been developed and the Ministry of Health has received a collective letter from a number of councils in the group regarding concerns with the Act and the implications for local councils.

3. This submission has been prepared in discussion amongst the working group and with awareness of the submission being made by Local Government New Zealand (LGNZ) on behalf of all territorial authorities.

4. Council approved the development of a LAPP at its meeting on 26 February 2014, and the work will be undertaken later this year.

5. There are currently two interim licences in the Thames-Coromandel District (the District) – both located in Thames.

6. Although the Council has not yet undertaken formal consultation on this matter, concerns have been raised in the community regarding negative social impacts in the District and wider, as a result of the retail premises’ operations.
7. The consultation document on the regulations has a broad scope and deals with a number of matters that extend beyond the normal focus of councils, such as manufacturing, labelling and importation. The Council has a view on a number of these issues.

8. The Council notes its general agreement with the LGNZ submission, and for ease of reference purposes our submission points are set out in consistent reference to those made by LGNZ, where relevant. Several additional points have been raised.

9. We have focused our submission points on areas where Council has a strong view and to provide Council context, and/or to raise a further or different point to those made by LGNZ.

SUBMISSION

General comment

10. Council would like to express our concern over the short period of time provided to make a submission, as this makes it difficult for elected members to have meaningful input to the submission document.

11. Making policies without knowing the full extent of council's powers or the range of national regulations that the Authority itself might apply (such as hours of operating) has made the local policy making process more difficult than perhaps it needed to be. Especially for those councils that have already engaged in policy development.

12. The result is that councils are in something of a 'catch-22' because the regulations that are meant to guide the development of LAPPs are yet to be finalised and notified (expected in early 2015). Circumstances now dictate that policies need to be in place before the regulations are notified otherwise councils may not be able to influence the location of shops once licenses cease to be interim licenses.

13. Consequently, councils have been obliged to take a pragmatic response and face the risk that once regulations are notified the LAPPs might need to be amended to conform to the new regulations.

Compliance with local approved products policies

14. The Council agrees with the general points made by LGNZ regarding generic policies, changing premises and providing evidence of compliance with a LAPP, however makes several further comments as follows.

15. Regarding generic policies the Council would note that it is somewhat unclear what is meant by a "generic policy".

16. Saying this, the Council considers that a generic policy could be a sound approach to avoid a retailer setting up on the boundary between a council with a policy and one without, potentially contradicting a community's views about the appropriate location of retail premises selling approved products.
17. In regards to **changing premises** and the issue raised in the consultation document about how retail premises operating in areas that are outside the provisions of an adopted LAPP should be dealt with (assuming reference to premises operating under an interim licence prior to the notification of retail regulations), the Council would make the following points.

18. The Ministry of Health has outlined in a letter to all council Chief Executives the course of action that the Regulatory Authority will take in the event that a retailer holding an interim licence is non-compliant with the applicable adopted LAPP.

19. This has been demonstrated recently in Hamilton City where interim licences found to be inconsistent with Hamilton City Council's adopted LAPP have been suspended, initially for 21 days but with the potential to be cancelled. It is noted that interim licence holders who cannot continue to operate will be able to apply for a full licence in a designated area once regulations are notified.

20. Although the Council supports this approach and is very pleased to see evidence of consideration to and implementation of LAPPs, we recommend that consideration be given to flow-on effects of suspending or cancelling interim licences, such as those created by users then travelling to a retail premises in a nearby district. Anecdotal evidence suggests that Thames-Coromandel District is now facing consequences associated with the suspension of the interim licences in Hamilton City.

**Fit and proper person test**

21. The Council agrees with points made by LGNZ.

**Discretionary conditions**

22. The Council generally agrees with points made by LGNZ, however would add the following.

23. The Council would strongly support regulation that specifies a maximum amount of an approved substance that might be purchased in a single sale. This would restrict the on-selling of the product and therefore associated implications.

24. The Council considers that such controls should be set by national regulation, not as a discretionary condition that may be applied by councils through LAPPs. This reflects a view that the Ministry of Health is best placed to set appropriate controls considering the intent of the Act.

**Place of sale**

25. The Council agrees with points made by LGNZ.

**Local government policies for approved products**

26. The Council agrees with points made by LGNZ and would add the following.

27. We note that under the Act as it is written, there is no clear connection between an LAPP and the Regulatory Authority as decision maker. Therefore regulations will
provide the only mechanism by which an LAPP can be considered. This uncertainty between the Act becoming law and regulations being approved is far from ideal for councils.

Advertising

28. The Council agrees with points made by LGNZ.

Fees and levies

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

30. Council acknowledges that the development of a LAPP in its District allows it to have an on-going input into the social and health matters for the District and this constitutes a public good. However, where any process arising from a LAPP that involves input from the Council then provision must be made for the full recovery of these costs from the applicant/licence holder.

Communications

31. Council agrees with the LGNZ recommendations that the Ministry of Health develop a public communications strategy to inform New Zealanders about the nature of the new Psychoactive Substances legislation and the relative roles of the different agencies in its implementation.

32. This is to address the current situation where many perceive councils as having a greater ability to regulate the location of retail outlets than is the case.

Conclusion

33. The Thames-Coromandel District Council would like to thank you for the opportunity to provide feedback and we hope our comments are useful in your deliberations.

If you have any further queries please do not hesitate to contact Christine Tye, Strategic Planner & Policy Analyst on (07) 868 0200.

Yours sincerely,

Murray McLean
Chairperson, Judicial Committee
On behalf of
Thames-Coromandel District Council
Good afternoon,

Further to our submission sent earlier today to the Psychoactive Substances Regulations, we would like to please add the following covering note:

Subsequent to internal Committee approval of our submission to the Psychoactive Substances Regulations and making that submission to the Ministry of Health, we have become aware of several changes to the submission yet to be made by LGNZ, which we reference in our submission. Such changes are in regards to placement of comments to 'Generic policies' and 'Fit and proper persons test'. We note these discrepancies regarding references and placement of comments and ask that in consideration to our submission, this be taken into account.

Kind regards

Thames-Coromandel District Council
Private Bag, 515 Mackay Street, Thames.
Psychoactive Substances Regulations Submission

This submission on the Psychoactive Substances Regulations consultation document was prepared by the Nelson Marlborough District Health Board (NMDHB) Public Health Unit’s two designated Psychoactive Substances Enforcement Officers.

We are strongly supportive of the development of Regulations and see them as an opportunity to help protect the health of, and minimize harm to individuals who use psychoactive substances.

We understand the need to have a regulated approach to manage psychoactive substances in order not to create a black market.

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 list of proposed information on the licence application is comprehensive. When the licence is granted we feel it would be reasonable for the Enforcement Officers to have a copy of the Licence or placed on the Ministry of Health’s Web site and made accessible to enforcement officers. This would facilitate verifying licence details at the time of the annual compliance 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, we agree that applications should provide evidence about the 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 are in agreement. Retail licence applications should provide evidence of compliance with a generic LAPP if a local policy is not in place.

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

The authority should consider creating a fit and proper person approach similar to the approach used in the Sale and Supply of Alcohol Act 2013. Reference Section 222

What records should the regulations require licence holders to keep?

We suggest that there would be benefits if licence holders were required to keep the following
- Documented training for staff on intoxication and sales to minors.
- Records on any client reporting adverse reactions.

Record keeping should be the same as that required by the Hazardous Substances and New Organisms Act 1996 and regulations. (licence of certificate)

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

The standard for keeping records is 3 years.

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

We agree there is a need for discretionary conditions and support the proposed conditions in the consultation document. In addition we suggest the following
- Designating the premises as R18, therefore only allowing people over 18 to be on the premises.
- Conditions that state no sampling or tastings, promotional give a ways etc.
- Trading should be restricted to retail trading hours only. This point has been motivated from our experience with a retailer using a mobile number to facilitate after hours trading.

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

No comment

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?

We support the need to include information on proposed manufacturing methods and how the product complied with the 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?

Nationally consistent templates for a number of tasks would assist the Authority to gather meaningful information. For example documentation of training, staff records, recording adverse reactions, detailing a recall system.
Standardized templates would enable consistent decisions and provide faster actions on issues.

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 with the above statement.

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

As above

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

We believe the information requested on the label in the Regulations is comprehensive however wish the Authority to consider
- A statement "R U18" and that "It is illegal to be in the possession of this if you are under 18 years of age".
- Disposal of the product in an appropriate mean. Look to Material Safety Data Sheets for possible wording.

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 would be keen to have the label give a warning stating that if the person has an adverse reaction arising from the use of the approved product then they should notify the retailer.

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

We agree that the proposed packaging requirements and restrictions are sufficient.
<table>
<thead>
<tr>
<th>Question</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do you agree with the proposal to restrict a packet to one dose? Please give reasons for your answer.</td>
<td>Yes we agree the packet size should be restricted to one dose. A packet size of 1 dose is an easily identifiable measure.</td>
</tr>
<tr>
<td>Do you agree with the proposal that a dose, in whatever form the product takes, is split wherever possible?</td>
<td>Yes we agree that a dose is split wherever possible as this initiative is for the safety of the user and unintentional user.</td>
</tr>
<tr>
<td>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?</td>
<td>We think there should be restrictions on the form the products can take and that the form should be restricted to the current pills, and something that can be smoked. It is difficult to predict the future of these products and a proactive approach until other forms have been assessed would be appropriate.</td>
</tr>
<tr>
<td>Do you think there should be restrictions or requirements on the storage of psychoactive substances? If so, what should the restrictions or requirements be?</td>
<td>Psychoactive substances should comply with the same requirement of the Hazardous Substance &amp; New Organisms Act 1996 requirements. Hazardous Substances and New Organisms Act 1996 and Regulations. (licence of certificate)</td>
</tr>
<tr>
<td>Do you think restrictions or requirements should be set for the storage of approved products? If so, what should they be?</td>
<td>Storage of approved products should be provided by the manufacturer as the quality of the product should be important to all in the production, wholesale and retail of the product.</td>
</tr>
<tr>
<td>Do you think restrictions or requirements should be set regarding the display of approved products? If so, what should they be?</td>
<td>The display of approved products should be treated the same as other similar products for instance adopting the Tobacco Control methods. Reference Section 23A of Smoke-free Environments Act 1990. Display requirements should be considered to avoid normalization of the products.</td>
</tr>
<tr>
<td>Do you think restrictions or requirements should be set regarding the disposal of approved products? If so, what should they be?</td>
<td></td>
</tr>
</tbody>
</table>
The disposal of approved products should occur in an environmental appropriate manner away from under 18 years of age access. Disposal methodology should be stated on the packaging.

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

We suggest that the signage requirements should follow the principles of the Smoke free Environments Act Reference Part 2 Section 22 – 29AAB.

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

We have no comment on this question.

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

We consider that the Advertising Standard Authority's Advertising Code of Ethics is sufficient.

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

We believe that there should not be any internet sales. Regulation relating to internet sales is difficult to enforce especially with respect to sales to minors.

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

Yes we think the regulations should prescribe restrictions on advertising of approved products and that the onsite advertising should be restricted to objective information only.

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

We agree that there should be different fees for different licences and that it should all be open and transparent.
30 Do you support a fixed fee or an hourly charge for processing applications for product approvals?

We have no comment on this question.

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

We think that there should be a fees charged for the following
- Annual compliance visit.
- Complaints or enquiries from the Ministry of Health, especially if the complaint or enquiry is justified.

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

Yes we agree with the proposed list of items set for annual levies.

This submission was completed by:  (name) Psychoactive Substances Enforcement Officers, Colleen Kem and Jan Anderson

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            (town/city) 36 Franklyn Street Nelson 7010

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Organisation (if applicable): Nelson Marlborough District Health Board – Public Health Service

Position (if applicable): Psychoactive Substances Enforcement Officers

Are you submitting this:
  x other (please specify): As above

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

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

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

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

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

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

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