20 March 2014

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

Email: psychoactives@moh.govt.nz

Submission on the Psychoactive Substances Regulations

I am making this submission as a private citizen of Napier, a mother and an experienced voluntary community worker who is currently ‘on the front line’ and dealing with the very real damage that the newly-legalised chemical psychoactive substances are causing for individuals, the people around them and also in the wider community. I fully endorse the submission the Authority has received from our Council.

Further to the comments contained in the Council’s submission however, I offer the following commentary on the various elements that the Authority is considering in terms of the regulatory framework that it is tasked to produce. Notwithstanding the following commentary regarding the rules and enforcement regime, I strongly believe these chemical psychoactive substances should be banned, outright, which would negate the need for these new regulations.

As per the NCC submission’s suggestions regarding hours of operation, ie, set standard hours as we do through the Sale of Liquor Act. To illustrate the need for this regulation; the Napier outlet’s opening hours fluctuate which causes customers to pool in Dickens Street while waiting. The business was solely selling sexual aids and products before it introduced chemical ‘legal highs’ to its stock – it’s history as a sex shop for many years had also caused concern in the community but has paled by comparison with the community’s utter outrage at the immorality of the outlet operators, seen to be blatant profiteers of the misery of others’ consequences. There is a high quality hotel co-located as well as many long-established retailers in Dickens Street, and the local hospice’s store too - their businesses are all suffering as a direct result of this pooling of one shop’s customers on a daily basis, some of whom are perceived to be intimidating, including patched gang members – now further exacerbated by the temporary suspension of the licenses of the 2 Hastings outlets so the Napier outlet is being inundated by Hastings customers now too.

This intolerable situation came to a very visible head one morning last week when the outlet owner couldn’t find his keys and the shop didn’t open until 10am, by which time between 100-150 customers were congregated not only outside this particular shop but every other business premise, service lane and in 2 Council carparks. The Napier Police Station is located literally behind the buildings that this outlet is operated from with a service lane running from next to the Station through to the shop – I believe this gives the perception that the Police will always “be there” if there’s any trouble at this shop, however the reality is that oftentimes there are actually very few officers at the Station as they’re out and about in the community or responding to calls.
The following day I sat in the carpark directly opposite the shop from 8.30am to 10am. The shop opened at 8.15am that day and there was no great queue while I was there, steady trade was occurring though. There was a heavy Police presence that morning too, in response to the previous day’s experience, with 5 vehicles and multiple officers undertaking vehicle checks on traffic moving through Dickens Street for approximately half an hour. While I appreciate that the Police believe these types of vehicle check operations may indeed deter a few people from driving to this shop to make their purchase, in fact all it does is produce more fines from infringements for lapsed WOFs and vehicle licensing that are unlikely to be paid and which will then create more work in the courts when community sentences are ultimately substituted for outstanding fines. These “offenders” are then criminalized for non-payment of fines and the imposition of substitute community sentences. It’s not ‘rocket science’ that because their money is being spent on chemical psychoactives, not fines or the basic necessities of life for themselves or their families, this new legalized market is having a serious social impact, played out on a daily basis and in broad daylight. These Police vehicle and driver check operations do nothing to stop the incidence of people driving away from the shop and consuming their chemical psychoactives elsewhere, be that at home, in their car around the corner from the outlet, in a pleasant public space like Clive and Memorial Squares, or anywhere else they choose – it’s legal.

Very near to the Napier outlet is a community mental health support organization that is led by it’s consumers need to have ‘safe’ places to support and develop their living independence in the community. Many of these vulnerable people are on a cocktail of prescription psychoactive drugs as part of their every day living and I wish the Authority to know about one 24-year old female community mental health consumer’s case in particular – it illustrates the folly of the government not banning these chemical-based products and how inadequate any new regulations are likely to be in any practical sense.

I have been this young woman’s mainstay advocate for the past 5 years after she suffered a major and traumatic emotional breakdown at the age of 19, when her son was around 18-months old. She lost custody of her son while an in-patient at the Hawke’s Bay Mental Health Unit situated in Hastings and currently only has sporadic contact with him due to her roller-coaster state of mental stability. Her original breakdown was not drug-related in any way however her ‘treatment’ through the public health system has meant several stints in the Psychiatric In-Patient Unit, sometimes held legally under the Mental Health Act, other times as a voluntary patient when she’s recognized she’s needed to, and she has had several potent drugs prescribed by Psychiatrists throughout that time. At various times she has resisted taking the prescribed drugs, many of which rely on it being taken at the ‘right’ time and consistently, and like many others, this can have huge impacts on the person’s daily life – including a pattern of sustained sleep deprivation, which ‘my’ young lady regularly falls into.

In October last year, the very day my Council was having to formally resolve to create a policy to contain where psychoactive substances can be sold from in our city – which none of us wanted to do - I returned this young woman to the In-Patient Unit as she had been smoking “legal highs” and was completely disassociated and “off the planet”. I’d only called in on the off-chance to see how she was doing and was horrified to see how far she had regressed since I’d last seen her a few weeks previously. She hadn’t slept for 3 weeks and despite approaching the public health providers for help, she was turned away, twice, because the reception staff thought she was just a junkie looking for drugs” as she was presenting with extreme agitation and babbling that she needed something to help her sleep. So after 3 weeks of sleep deprivation, and at the suggestion of her own mother and 20-yr old brother, she smoked some chemical psychoactives because she’d been told they put people to sleep really easily and quickly. It didn’t work – she didn’t go to sleep, instead her mind drifted completely off into “la la land” and as I informed the mental health professionals on the day, much of the ‘babble’ was in fact real memories from her childhood, not irrational
thoughts breaking through. This was different to her past mental health issues when she would often get stuck on one particular ‘track’, ie, the songs on the radio ‘meant’ something in relation to people she knows, memorising the vehicle license plate numbers of people she knows.

As at the time of writing this submission, this young woman is now living in the community again, we’re back at ‘square one’ in terms of ensuring she has adequate supports around her so she can maintain living on a daily basis and that she takes her medications consistently. Unfortunately this takes a huge amount of resourcing and so she is often left to her own devices and vulnerable to the suggestions from the family members who are still around her. And so, while still trying to get her back onto an even keel, last week I again had contact with this young lady and I was angered to find her ‘stoned’ on chemical psychoactive again, with the resulting disassociative behaviour and random babbling. This cycle will keep going unless these newly-legalised chemical psychoactive drugs are banned and made illegal. This young lady, her mother, other family members and the wider community are making the choice to smoke these toxic chemicals simply because they are legal. They do not read the warnings, many have been regular cannabis smokers so have made the switch to ‘legals’ to thus avoid any risk of criminal charges, and they’re also actively sanctioning the legal high habit with their children and young people.

Many, many people have commented to me that this ‘legal high’ situation has caused them to re-think their stand on the decriminalization of cannabis. Cannabis is a natural, grown plant that does not have the same risks that chemical psychoactive substances do. People are saying if these ‘high-chasers’ aren’t going to be dissuaded from smoking anything at all, then they should be choosing to smoke the natural, not chemical product, and further, they should be able to grow it themselves because it would completely undermine the ‘underground market’ and reduce the police/courts/prisons respective workloads too. These people do not want a regulated psychoactive substance market – they want it banned altogether and if it will not be banned, then they believe cannabis should be decriminalized so people can grow their own as well as putting strong regulations on the chemical psychoactives industry.

The Police made strong submissions to the Psychoactive Substances Act that it is better to have this activity under regulation in the community rather than in the “car boots” anywhere in the city. I absolutely refute this as being the case as regardless of whether it’s legal or not, there is already an ‘underground market’ for these products, as with every other product that people seek to use. Making chemical psychoactive substances legal does not mean there is no illegal trading of the product. The regulations must be put in place to avoid the current situation where purchasers have no limits on the quantities they can purchase at any one time and the volume of each product sold. The Napier outlet is currently selling them in $5 denominations ($5, $10, $15, $20, $25) which makes it far easier for under-18s to purchase, albeit through an over-18 making the legal purchase. I have also been told that purchasers are buying in bulk, breaking it down to smaller packets and selling it ‘underground’ anyway – enabled because the original purchase is legal.

The morning I sat in the carpark I witnessed a young group of men come out of the outlet, one with their purchase in his hand, cross the road and hand it to an under-18 year old young man. This was literally within a minute of all the Police leaving the area after their vehicle check operation. This group were pedestrians, not drivers, and due to the local publicity about the Police’s heavy presence in Dickens Street, many of the outlet’s customers are simply parking elsewhere in the city (spreading their presence) and walking to the shop. The Council’s CCTV camera is also well-publicised and although the customers don’t like being on camera, it has no deterrent effect at all.
In summary, the Authority must enable regulations that aren’t dissimilar to those that liquor licensees must operate under. The staff must be adequately trained, including how to recognize anyone who has existing mental health conditions that would be adversely affected by the chemical psychoactive drug they wish to purchase. The hours of operation need to be prescribed and need to take into account the community’s demands that outlets won’t be open when children and young people are most likely to be in the vicinity, i.e., before and after school. The checks on licensees must include others involved in the business, i.e., business and personal partners. Prior to the Psychoactive Substances Act becoming operative, Napier had another outlet selling these products. They stopped selling it after their shop was burgled, the offender subsequently convicted and sentenced and he said he was targeting the ‘legal highs’.

The labeling and packaging must be regulated to be as boring as it can be – no graphics, nothing but warnings in large font, in child-proof containers. The regulations must ensure that individuals cannot buy up large quantities and that minimum pricing is also regulated for. At the moment the ‘humble tinnie’, while illegal, is more expensive than the equivalent chemical ‘legal high’ which can also be purchased legally for as little as $5.

While operators will pay GST on their legitimate stock-lines, chemical psychoactive products must have a further sales tax added which should then be spent on funding addiction and mental health services in the community. These services were already woefully lacking, especially in consideration of the welfare reforms that specifically target people with addictions and mental health issues – the tragic social effects of ‘legal highs’ is causing significant resourcing issues already, and the need for these community services (read: ambulances at the bottom of the cliff) will only exponentially rise.

Thank you for the opportunity to submit on this important set of regulations and I would like to speak to the Hearing of the Authority. I sincerely hope the regulations will not be required if the government listen to the community and instead, ban chemical psychoactive products altogether.

Yours sincerely
Making a submission

Submissions close on Friday 21 March 2014 at 5 pm.
Please note: any submissions received after this time will not be included in the analysis of submissions.

Please detach and return this part of the document.

Consultation questions

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

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

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

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

   On this issue, it is suggested that a "point in time" approach is taken, i.e. the LAPP is considered in relation to the date of licence application. If a premise would later become non-compliant due to a sensitive site moving close by, this should not be considered further until the application next comes up for renewal (if at all – there is a strong argument for existing use rights as occurs with liquor licences and brothels).

   Otherwise there will be no certainty for retailers and no incentive to apply for a licence. This also would guard to some degree against organisations cynically moving close to an approved retailer's site for the purpose of ensuring they must move – something we have anecdotal evidence of having occurred.

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

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

   1. A mechanism for LAPPs to be reviewed by the Authority as to reasonableness and legality;

   2. Withdrawal of the discretionary condition on retail licences making approved products sales subject to the terms of the relevant LAPP;

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

3 Should retail licence applications be accompanied by evidence of compliance with a generic local approved products policy if no policy is in effect in the applicant's area?
4. Are the factors the Authority should take into account when determining whether a licence applicant is a fit and proper person or whether a body corporate is of good repute in section 16(2) enough? The section 16(2) factors are:

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

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

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

Yes.

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

Sales data, adverse effects reports.

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

For at least the period of the licence.

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

Opening hours ought to be consistent with liquor licensing opening hours.

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

No.

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

No. This information has to be provided by the manufacturer in compliance with the Code of Manufacturing Practice. This would simply escalate compliance costs and duplicate the information provided to the Authority. The name of the manufacturer is all that should be supplied.

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

No.

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

There needs to be a differentiation between approved products with interim approvals and new products. Otherwise manufacturing and retail of products with interim approvals, for which full applications for approval are made, would need to cease as the clinical trials are certain to take longer than the date of these regulations coming into force.

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?

Again, there needs to be a differentiation between approved products with interim approvals and new products otherwise manufacturing and retail of products with interim approvals, for which full applications for approval are made, would need to cease as the clinical trials are certain to take longer than the date of these regulations coming into force.

It is not agreed that a product containing the same mix of active ingredient in a different size package or with different flavouring ought to require approval as an additional product. A different size package is not a different product. It does not justify an additional $10,000 fee. Parameters should be set as to how big or small a packet may be at the time of the product approval.

Likewise with flavouring, it is unlikely that the addition of simple flavouring changes the nature of the product to such a degree that $10,000 more of the Authority's time needs to be spent assessing the product.

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

For synthetic cannabis, a dose is very dependent on the user. It would be very hard to determine what a dose is, and potentially dangerous to indicate to consumers that a whole packet was "a dose".

Plain packaging is not desirable. It removes intellectual property rights that owners of product approvals have built up over time. It makes counterfeiting product easier.

15 Are the proposed requirements relating to health warnings sufficient? If not, please make specific suggestions for further requirements (for example, advice on what to do in the case of an overdose).
A suggestion that users keep hydrated could usefully be added.

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

Rather than packaging inserts, required information could be printed inside the packet.

It is difficult to comment on the proposal to prohibit words with "inappropriate connotations" without examples. However, it must be remembered that for these products there is language used which may be considered inappropriate to non-users of psychoactive products, but which are entirely in keeping with the sub-culture. Making a moral judgment will accordingly be difficult.

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

For synthetic cannabis, a dose is very dependent on the user. It would be very hard to determine what a dose is, and potentially lead to overdose for some users if it was indicated to consumers that a whole packet was "a dose".

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

Refer comment at 17 above.

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

Products should not be developed to be injected.

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

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

They should be required to be stored in a secure area, with tamper tape on boxes/packages to prevent tampering.

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

No, the Act is sufficiently restrictive.

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

24. Do you think there should be signage requirements in the regulations? If so, please give specific suggestions.
Retailers should be required to display an R18 sign with the MOH official logo on it, and a sign providing that a retailer has a right not to serve customers.

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

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

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

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

No, the Act is already sufficiently restrictive.

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

There should be a process in place to ensure that people under 18 cannot access the products.

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

No, the Act is already sufficiently restrictive.

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

The product approval fee is out of alignment with fees in the pharmaceutical industry, yet the process for approval is being modelled it seems on that industry (except that efficacy does not need to be determined). Many products contain the same active ingredient — is a new $180,000 fee required for each product whose ingredient has already gained approval in another product? A scale along the lines of that used in the pharmaceutical industry would be much more appropriate.

Also retailer licence fees are out of alignment with licences in other relevant areas such as liquor licensing.

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

Presumably some applications will be more time-consuming to process than others. The difficulty with an hourly rate approach however is that it will make it impossible for applicants to prepare for the costs. The applicant would need to be able to withdraw from the process if the fees were going to be too costly. It seems like it would be difficult to manage and administer. An hourly rate is therefore not supported.

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

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

32 Do you agree with the proposed list of items and process for setting levies? If not, please provide specific suggestions.
The annual fee for a retailer is again out of proportion to the equivalent regime of liquor licensing where the highest annual fee is $1,250.

An annual fee for a product approval of $70,000 seems inordinately high in relation to what administration there could be expected in relation to each product approval on an annual basis.

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  
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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.

✓ Requests that details of its submission not be made public or released under the Official Information Act 1982. It has responded to the call for submissions in a frank manner and utilising a degree of confidential business information. It is not appropriate that this is released to the public.
Making a submission

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Consultation questions

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

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

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

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

   1. A mechanism for LAPPs to be reviewed by the Authority as to reasonableness and legality;

   2. Withdrawal of the discretionary condition on retail licences making approved products sales subject to the terms of the relevant LAPP;

   A process whereby a holder of an interim retail licence can move premises (assuming that the LAPP allows space for a site, which there will be if #1 and #2 above are implemented), or an acceptance that they have existing use rights.
Should retail licence applications be accompanied by evidence of compliance with a generic local approved products policy if no policy is in effect in the applicant's area?

Definitely not. We note:

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

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

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

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.

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

Yes.

What records should the regulations require licence holders to keep?

Sales data, adverse effects reports.

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

For at least the period of the licence.

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

If there are restrictions placed on opening hours then these should be applied consistently to all retailers of the same type.

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

No.
10 Do you agree a product approval application should include information on proposed manufacturing methods and how they will comply with the Psychoactive Substances Code of Manufacturing Practice?

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

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

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

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

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

   A suggestion that users keep hydrated could usefully be added.

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

They should be stored safely in a locked area.

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

No, the Act is sufficiently restrictive.

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

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

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

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

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

No. Retailers are already struggling from the effects of scarcity of retailers in terms of anti-social behaviour, the black market for products, gang interest and so on.

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

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

There should be a process of ensuring that people under 18 cannot access the products.

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

No, the Act is already sufficiently restrictive.

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

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

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


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

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

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

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

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

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

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

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

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

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

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

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

   If you think these factors are not enough, please give examples of additional factors the Authority should consider.
The proposal to include the New Zealand Customs Service (regarding importation compliance) and the Police in the fit and proper person check.

For all licences, we recommend

- The Psychoactive Substances Act lists relevant offences in section 16(2) that are grounds for considering the applicant is likely to fail to comply with the Act. We recommend specifying in the list:
  - Violation of licence conditions and Regulations under the Sale of Liquor Act, Sale & Supply of Alcohol Act or the Medicines Act.
- An applicant with any past conviction or licence suspension/cancellation for the unlawful sale of an age-restricted product to a minor should be rejected.
- The regulations should include a requirement for retail licence holders 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.

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 affective at identifying acute risks from NPS products, establishing long term effects is considerable more challenging.

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

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

In addition we recommend:

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

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

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

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

In addition we recommend labels include details of:

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

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

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

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

Ref:

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

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

See question 14 regarding support for plain packaging.

The other requirements proposed appear sufficient.

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

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


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

Yes, please see above.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Yes

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

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

Yes – levies should be collected to enable:

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

Fees or should be collected from retailers to enable:

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

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

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

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

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

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

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

Alternatively, electronically complete the submission form available at the back of this document, add your comments and email to:  
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Please put 'Regulations Consultation' in the subject line.

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

Additional comments:

a) No provision is made for establishing minimum pricing. Price has been clearly demonstrated to have an influence on use level of legal and illegal products and has been used successfully to reduce tobacco use in New Zealand. The failure to utilise pricing as a public health measure with respect to alcohol consumption has exposed the New Zealand population to avoidable alcohol related harm. We do not wish to see the same mistake made with new psychoactive substances. Product applications must stipulate minimum pricing for a given product and no discounting should be allowed, including sale prices (e.g. “30% off this weekend”) and multi-buys (e.g. “buy two, get one free”). Minimum pricing through taxation also provides the opportunity for a levy to be used to support harm reduction work in public health and treatment settings.

b) “The Act deliberately leaves open the question of how to determine a low risk of harm to the individual, because this is a subjective question, and it is a threshold that may shift over time.” (p19) Allowing for flexibility in this area is sensible but also carries risks, and relies for its success on a rigorous consideration process with appropriately qualified and resourced individuals. It would be appropriate for the regulations to provide a framework for their selection, including oversight and review. Equally, without being prescriptive, it would be sensible to have explicit guidelines to be used for a test of “low risk”. Can these be articulated as part of the framework or would this be an initial task for the expert advisory group? If so it would be good to say this.

In the past we have promoted a more graduated understanding of the levels of risk identified under the Misuse of Drugs Act (moderate, high and very high risk). In doing so we proposed adding low and very low risk. The current legislation may benefit from not only distinguishing low risk from moderate risk, the threshold for allowing substances to be regulated rather than prohibited, but also distinguishing low risk from very low risk, the threshold that justifies robust regulation. We note that caffeine, a stimulant psychoactive drug, is an example of a drug with minimal regulation due to its very risk.

c) Age of purchase has been set at 18. We believe this is unnecessarily liberal for the sale of novel compounds. Youth have been clearly identified as a vulnerable population and we therefore believe 20 would be a more appropriate age restriction.

1 Is the list of proposed information requirements for licence applications comprehensive enough?
2 Should retail licence applications be accompanied by evidence of compliance with a local approved products policy if one is in effect in the applicant's area?

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

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

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

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

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

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

8. Do you think there are factors or issues that the Authority should consider when setting discretionary conditions? If so, please provide details.
9 Should the regulations prescribe other matters the Authority must take into account when deciding on an application? If yes, what should these matters be?

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

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

12 Do you agree with the proposal that the regulations require applications to contain information and data on the toxicity, pharmacology and related clinical effects of the psychoactive substance they are seeking approval for?
Require provision of all data on drug effects etc obtained. Currently the act requires the application to contain information and data in a variety of areas. All available data on a new substance should be provided, to avoid selective use of positive findings. We appreciate that it is not always possible to know what information is withheld, but it is important to make clear that this is the expectation, and this would also provide clear grounds for revoking a license should an individual or company be found to have withheld important data on risk in favour of more reassuring data.

We are concerned as to the adequacy of clinical data on proposed new substances which will be unable to determine long term consequences of use. Does the legislation have adequate mechanisms for the revocation of licence for approved substances should new negative data come to light?

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

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

See point 12 above

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

We strongly endorse the suggestion that in addition to providing the National Poisons Centre number the Alcohol Drug Helpline number, or similar also be required. The former is appropriate for acute risk, the later for ongoing problems, such as addiction, and as an access point for harm reduction information.

Information provided should also clearly state the time a consumer can expect to elapse before maximum drug effect is felt. This will help reduce the risk of users consuming an additional dose in the mistaken belief that the initial dose had been insufficient.

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 proposed health warnings are appropriate but in many cases will not be sufficient. Provision should be made to require the inclusion of any additional health warnings that may apply for specific substances or classes of substances. For example warning particular risk populations, such as those suffering from mental illness, or with compromised physical health, such as liver disease, that use of the substance should be avoided.

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 we agree with this proposal. The clearest way to communicate what is an appropriate recreational dose will be for this to be reflected in the unit of purchase.

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

We strongly support this as an essential component of a harm reduction strategy.

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?
We strongly support prohibiting sale of products in an injectable form, as has been indicated in the policy document. Any tablet or capsule form can be converted to injectable use, but we believe does not carry the implied encouragement to do so that would be the case for product sold in powder form, such as the small bags of white powder containing BZO that were sold in the past. In addition to encouraging injecting use, such forms we believe could be considered to glamorise substance use, drawing parallels with the illicit drug market.

The place of smokeable products is a vexed issue. These products are for the most part intended to be a substitute for cannabis, a product that will remain prohibited and about which we know considerably more. Furthermore cannabis is likely to be lower risk than many of the smokeable products currently available, and quite possibly lower risk than new psychoactive substances that will gain approval under the act.

Smokeable products expose the user to risk of lung damage. Counterbalancing this is that smokeable products are better able to facilitate careful titration of dose than is the case for oral ingestion of a pill form, where a user could take a very large dose almost instantaneously.

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

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

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

We believe that, as per the prohibition on advertising, the Act best promotes harm reduction when any attempts to actively promote the products are minimised. We have learned from the tobacco experience in New Zealand that retailers can use product display as a means of promotion. We would like the regulations to stipulate that product display is restricted to the minimum amount required for a consumer to see what products are available. The most restricted form would be to provide the consumer, on request, with a menu in plain text without graphics describing which products are available and other necessary product information such as dose, effect and price.
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.

   Retailers should be required to display prominent signage intended to warn of the risks associated with substance use and sources of help, such as the Alcohol Drug Helpline.

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

   We believe the restrictions as proposed are appropriate.

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

   We believe there should be a complete prohibition of any advertising of psychoactive products. This prohibition should be broad enough to cover event sponsorship, free giveaways, or any other means of product promotion. This would result in treatment equivalent to what occurs for tobacco products in New Zealand.
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 allowing online sales exposes New Zealand to considerable risk of international sales of new psychoactive substances. This could be mitigated by clear regulations prohibiting sending products offshore, but we believe this would only be partially effective. Sales to other countries poses a significant risk of damaging New Zealand’s international reputation and could bring unwanted attention.

Furthermore the internet offers the potential for 24 hour sales with very rapid delivery as occurred with BZP (this was primarily via mobile phone sales but we see no reason why the same marketing strategy couldn’t be used 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.

Yes we do. See our response to question 22 above.

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?
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) Assoc Prof Simon Adamson
Address: (street/box number) 4 Oxford Terrace (town/city) Christchurch
Email: Simon.adamson@otago.ac.nz
Organisation (if applicable): National Addiction Centre, University of Otago Christchurch
Position (if applicable): Assoc Prof

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

X Yes □ No

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

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

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

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

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Please put ‘Regulations Consultation’ in the subject line.

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

□ I do not give permission for my name to be listed in the published summary of submissions.
Making a submission

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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?

License applicants should be asked why they want to sell substances that are highly addictive and damaging to the health of people. I personally think that the sale of psychotic substances should be banned except for painkillers on a medical doctor’s prescription.

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

Yes

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

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

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

The authority should consider that anyone who willingly wants to sell harmful products to young people must be of dubious character. A list of all such people who gain licenses should be made freely available to the public.

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

Yes

What records should the regulations require licence holders to keep?

Name, age, and what they bought with each purchase made.

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.

Any user or buyer of their psychoactive product who commits a crime while under the influence of that product should result in a charge of 'incapacitating a person who then commits a crime as they lose the reason to discern between right and wrong', to the seller/license holder.

There should be restrictions on opening hours.
There should be rules that they be not situated on main street shopping centres, near a school, bus stop or public spaces like parks. Banning the license to sell psychoactive drugs at all should be made.

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?

Every one who buys a legal high should have their details forwarded to WINZ and their benefit cut. From my observation most buyers of these highs are unemployable addicts and if buying the drugs forfeits their right to government assistance that ideally is a hand up not a hand out they might think twice before they fritter tax payer dollars up in smoke. The Police also should be notified and a register kept of these people.

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.

As with cigarettes all packaging should be plain with health warnings emphasised.
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).

Currently there are no health warnings on legal synthetic highs. I agree that the four standard health warnings should be mentioned as well as a clear warning that using psychoactive drugs on a regular basis will greatly increase your chances of becoming mentally ill and eminently unemployed.

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

Inserts are often never read even inserts in kosher medicine packets. The packaging needs to be of larger size so that all the pertinent information can clearly be seen on the outside of the packet.

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

Yes as these drugs are harmful.

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

Yes so use of these drugs is minimised.
19. Do you think there should be restrictions on the form products can take? If so, what forms do you think should and shouldn’t be allowed?

Yes I think it should be in tablet form as smoking forms mean second-hand smoke affects other people. Also tablets are not as attractive to use so hopefully it will discourage their use altogether.

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

Yes I agree there should be a maximum size for amount of display and also a maximum amount able to be stored on the premises.

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

All storage should be out of sight to the public and secured behind dead-locked doors.

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

The display of these products should not be visible from the street as suggested. They should not be a lighted display to render them attractive and also the health warnings should be boldly proclaimed around the display.
23 Do you think restrictions or requirements should be set regarding the disposal of approved products? If so, what should they be?

I personally think they shouldn't be sold, therefore displayed at all.

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

Signs should be plain black lettering on a plain white background. In Henderson the shop is colourfully advertised to the street unashamedly pushing their poison on the weak willed and ill-educated.

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

They should not be sold on main streets, near schools (in Henderson the legal high shop is only 200m from a school and directly opposite a bus stop where school students catch the bus), near bus stops. Auckland should follow Hamilton's lead and ban them inside the metropolitan area.

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

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

Internet sales of psychoactive substances should be made illegal as you have no control of what and how much people buy.

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

The regulations should clearly state that all advertising of these products is illegal.

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

I do agree with the set fee for the licenses.

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

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

A flat excise tax of $100.00 on any psychoactive substance sold should be implemented – i.e. So their extreme expense of buying such substances discourages use.

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

The annual levies should be higher so that it discourages amoral businessmen from going down this track.

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) Darryl Eastabrook
Address: (street/box number) 342 Great North Rd
(town/city) Henderson, AUCKLAND 0612
Email: wight@visique.co.nz
Organisation (if applicable): Visique Wight Optometrists
Position (if applicable): Owner
Are you submitting this:
(Tick one box only in this section)

other (please specify): an affected retailer and concerned citizen ........................................

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

☐ Yes

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

Please return only one copy of your submission no later than 5 pm on Friday 21 March to:
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☐ I do not give permission for my name to be listed in the published summary of submissions.
Making a submission 087

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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?
   
   I am unsure if what I have written here is covered under question 4 below. I think it is, but I've elaborated upon it further here for completeness:
   As part of the “fit and proper person” test it would be appropriate to include some evidence that speaks to the applicant’s personal qualities around issues pertaining to alcohol or behaviours and practices that are contrary to the social norm and those of a responsible member of society. This consultation document mentions information about previous involvement in other regimes such as alcohol licensing processes. However, I am unclear as to whether compliance with “alcohol licensing processes” considers the individual’s personal record in relation to for example alcohol-related offences. Presumably a “fit and proper person” would be without any such personal background history that could influence the way in which psychoactive substances are brought into use promoted or sold.

2  Should retail licence applications be accompanied by evidence of compliance with a local approved products policy if one is in effect in the applicant’s area?
   
   Yes.
   It would seem entirely reasonable that the introduction of new potential risks to local communities through any aspect of the chain from manufacture to supply of psychoactive substances are in keeping with local laws, practices and/or norms prevailing at local level. Media reports have increasing reported on social outrage at the availability of such substances in neighbourhoods and the effects these products have in individuals in such communities. Some Local Authorities have already taken action and mechanisms to facilitate this seem appropriate.

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?
   
   If a specific local policy is not in operation then an adherence to some generic minimum standards/expectations would seem to be in a positive direction. This will contribute to avoid vast variations in practices in local communities across New Zealand.
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.

See response to question 1

I am unsure if what I have written here is covered under the first and last bullet points highlighted above. I think it is, but I've elaborated upon my concerns further here for completeness:

As part of the "fit and proper person" test it would be appropriate to include some evidence that speaks to the applicant's personal qualities around issues pertaining to alcohol or behaviours and practices that are contrary to the social norm and those of a responsible member of society. This consultation document mentions information about previous involvement in other regimes such as alcohol licensing processes. However, I am unclear as to whether compliance with "alcohol licensing processes" considers the individual's personal record in relation to for example alcohol-related offences. Presumably a "fit and proper person" would be without any such personal background history that could influence the way in which psychoactive substances are brought into use promoted or sold.

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?

The proposed additional sales recordkeeping under the regulations is confusing and may be counterproductive to achieving its ends of product leakage and diversion. The consultation document sets out that there should be a record of product movement between licence holders (manufacturer, distributor, retailer), but that retail sales are excluded. It's not clear how excluding retail sales will prevent diversion to the illegal market. What's to prevent a retailer operating in both sectors (legitimate retail and illegal markets with the latter having potentially profit higher margins and be outside any of the retail sale requirements)?

Whilst requiring some form of recorded identity of each purchaser would seem extreme, perhaps there are some other mechanisms that could be brought into operation to confirm the retail sale of products-copies of retail till slips, or the ability to randomly audit such sales against stock?

7. How long should licence holders be required to keep records for?
Presumably there is some norm generally used – I see no reason why this scenario should be different from such a norm (75 years)

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

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

Retailers should be prohibited from providing advice in regard to alternative modes of use or cocktails of psychoactive substances either alone or in combination with other products. A review of some social media/blog sites frequently share users experience and recommendations regarding modes of use and combination cocktails and it would seem totally 'unprofessional' for any retailer to encourage the use of the psychoactive products in any way other than the licence application intended them to be used.

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?

In determining the risk of harm or, the potential thereof, consideration should also be directed to the potential use of the psychoactive substance when used in a mode other than the application indicated that it should be used. Whilst may not be intended that these products are smoked or inhaled it is quite likely that the nature of the user or user community at large may intentionally, or through accepted user-community practice, use these products in alternative modes of administration.

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).

In addition to considering contacts details listing the National Poisons Centre or the number of Alcohol and Drug helpline, the contact details for the Centre for Adverse Reactions Monitoring (CARM) should also be included.

Whilst the National Poisons Centre and Alcohol and Drug helpline will be important in the management of acute episodes, ensuring that the there is a mechanism to report all forms of adverse events in the context of the use of Psychoactive Substances by user, carers or health sector interface will be essential for the ongoing monitoring of the safety profile for the substances.

Reports to CARM are likely to provide evidence of the complete spectrum of adverse events from relatively minor to severe and seriously incapacitating episodes which may not all be fielded by either the National Poisons Centre and/or the Alcohol and Drug helpline. In addition reports to CARM have the potential to be more comprehensive and be processed through clinical review by a team already established in monitoring adverse event reports to licensed therapeutic medicines and vaccines with proven mechanisms to feed high quality reviewed data into regulatory processes.

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

They seem reasonable.

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

Yes.

Hopefully this will go some way to preventing over dosage on the assumption that ‘one dose’ is deemed to be sufficient for the intended effect. If a user consciously intends to exceed the single-dose then opening multiple packages may go some way to reducing this behaviour which may increase the risk of adverse events.

Single-dose packages will also reduce the chance of accidental overdose by non-intended uses (e.g. animals and children).

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?

Only oral forms

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

As per good manufacturing and storage practice applied to medicines and other foodstuffs, or as might be required due to the nature of the composition and its stability parameters

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

As per good manufacturing and storage practice applied to medicines and other foodstuffs, or as might be required due to the nature of the composition and its stability parameters

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

Like tobacco products advertising should contain some reference to the potential hazards with the use of psychoactive substances.
23 Do you think restrictions or requirements should be set regarding the disposal of approved products? If so, what should they be?

Yes.
Products intended for disposal should follow some form of environmentally safe practice perhaps as set out in other legislation in regard to the disposal of the potentially hazardous material (e.g. medications).

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

Signage should refer to potential health risks.

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

No beach vending or vending at gatherings and events such especially concerts.

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

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

No internet sales as there is no means of guaranteeing that psychoactive substances are not sold 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.

Advertising restricted to the name, banner, logo and active ingredient. No claims made about the products 'beneficial' attributes

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?

And hourly charge beyond a fixed minimum.
Whilst currently the active ingredient may be limited to a few in vogue active components, the potential exists that other new or novel active components may be brought into use which may require more extensive review and research. Economies of knowledge from frequently used active components will help to establish the fixed minimum fee.
31 Should fees be set for other specific functions? If yes, please state what they should be set for.

In the event that a significant safety issue is identified that may require further follow-up review, action or the management the consequences arising from large numbers of either the cases themselves or dealing with the consequences of such an issue in dealing with adverse effects (e.g. substance fuelled destructive behaviour, excessive burden to the health sector managing remedial interventions etc.), then the applicant should be responsible for the costs of supporting these activities. This proposed in the light of the notion that apparently these substances are deemed to be of no or low risk of harm. That being the case there should not be a need to invoke such cost recovery.

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

Yes

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) Dr Michael Tatley
Address: (street/box number) Box 913 (town/city) Dunedin
Email: michael.tatley@otago.ac.nz
Organisation (if applicable): New Zealand Pharmacovigilance Centre/CARM, University of Otago
Position (if applicable): Director
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 ADVERSE DRUG EVENTS MONITORING AGENCY...

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.)

michael.tatley@otago.ac.nz

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Making a submission 088

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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?

   Ban it

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?

   Ban it

C

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?

   Ban it

C
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.

Ban it

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

Ban it

What records should the regulations require licence holders to keep?

Ban it

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

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

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

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

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

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

Ban it

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

Ban it

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

Ban it

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

Ban it
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?

Ban it

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?

Ban it

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

Ban it

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

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

Ban it

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

Ban it

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

Ban it

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

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

Ban it

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

Ban it

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

Ban it

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

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

Ban it

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

Ban it

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.)

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Making a submission

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Please detach and return this part of the document.

Consultation questions

1  Is the list of proposed information requirements for licence applications comprehensive enough?
   If not, what else should be required, and why?
   No.
   Should also involve internet check of applicant to support fit and proper person and if any other licences have or currently held.
   Background check through referees

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.

That the applicant or body corporate meet and consult with community and/or church leaders prior to establishment of outlet or outlets.

How an applicant can contribute to the health and well being of the community directly affected.

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

yes

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

All relevant information regarding purchase from and distribution to, of products under this regulation.

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

Psychoactive Substances Regulations: Submission form
For a minimum period of 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.

No

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

Locality and community consultation.
Impact statement
Health and wellbeing of community

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.

Plain packaging
Health warnings
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).

Advis recommended daily dosage and advice in case of overdose.

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

yes

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

Yes as this would prevent tampering and support recommended safe dosages

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?

No injectable products

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

Limit product storage on site

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

Restrict product requisition on a daily basis to control storage restriction and sale.

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

Align with current tobacco restrictions.
No display of product only licence label.
23. Do you think restrictions or requirements should be set regarding the disposal of approved products? If so, what should they be?

Use by or expiry date of product and return to safe place for disposal.

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

Signage to state age restriction and penalties if breached.

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 in premises that sell other products or merchandise to children.
Should not be sold in premises not restricted to 18yrs.

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

restrict where any advertising of approved products can be seen by minors.
That the advertising be only in written form.
27 Do you think the regulations should prescribe restrictions or requirements on internet sales of approved products? If so, please provide specific suggestions.

Proof of age and restriction of amount sold and a physical address

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

Advertising should not be appealing to youth but be specific to approved customer.

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

yes

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

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

for breach of conditions
disputes
any changes in licence restriction
changes in location
using more than one premise to store or sell

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

Yes if the health and well being of the community directly affected is considered

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

This submission was completed by: Damien haami
(name)

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

Email:

Organisation (if applicable): Te runanga o tanaupoko

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

The Manager
Psychoactive Substances Regulatory Authority
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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.
20 March 2014

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

psychoactives@moh.govt.nz

Dear Sir/Madam,

Psychoactive Substances Regulations

Please find the Gisborne District Council’s submissions of the above regulations.

The Council makes four submissions. The first asks that on Approved Products Policy be allowed to include a decision to ban the sale of substances in the District, if that is what the Council decides. The Mayor and Councillors are very concerned about the effect psychoactive substances have had, and continue to have on our community. There are very strong community views seeking to ban the sale of substances in the District as a key tool to reduce the effect their consumption is having.

The submission also contains some alternative submissions should the first be rejected.

The Mayor has expressed a strong desire to speak on the submission.

Yours sincerely

[Signature]

Judy Campbell
Chief Executive
Submission of Gisborne District Council

Psychoactive Substances Regulations

The Council has four submissions on the regulations.

1. Concern about effects of legalisation

The Mayor and Councillors of the Gisborne District Council are very concerned about the substantial negative effect of psychoactive substances on the community in the Gisborne District and the potential ineffectual nature of the Psychoactive Substances Act 201.

There is a lot of community concern over the increased use of psychoactive substances and the effect that is having on users’ lives, their families, and the community as a whole. The Gisborne community is already dealing with some of the highest rates of domestic violence, crime, unemployment, poverty and health issues including mental health issues. The use of psychoactive substances is exacerbating these issues in our community.

There are also some highly visible issues around the single outlet in the city and how the use of psychoactive substances in public places is affecting the amenity value of the public space and retail areas of the city.

Due to the short time of the making of submissions the Council has had limited time to gather evidence, however media reports and anecdotal evidence the Council has received is:

- Use of psychoactive substances is coming up in family and street violence as well as harm caused by cannabis, methamphetamine and alcohol.
- Children are affected – grandparents are looking after their grandchildren and great grandchildren.
- Some areas in Gisborne have a real problem with substance abuse. People working in that area are looking at three fronts to help: media, legalities, action. The community feels it is under attack and needs to be proactive.
- Users are loitering around the central city area where the substances are being sold and begging for money. It is intimidating pedestrians who feel they cannot walk past the areas frequented by substance abusers.
- One church located in the CBD has seen a significant increase in homelessness and use of its Tuesday night meal. They estimate in the last year the homeless sleeping in their carpark has increased from 1 to 10. The attendees at their meal are now often affected by use of psychoactive substances and behavior at those meals has become more aggressive.
- There is an increase in antisocial behavior related to use of psychoactive substances in the city.

The community is looking to the Council to have a measurable impact on these problems. The Council has very limited tools to do this. Council wishes to express its disagreement with the policy of the Act and frustration that the Council is unable to give effect to the strong community sentiment against the legal sale of these substances.

Council submits that Councils should be empowered, if they wish, to pass policy to ban the sales of psychoactive substances in their district.
If central government insist on continuing to allow sale of psychoactive substances and submission 1 is rejected, Council has some views on assisting Council to manage permitted sales of psychoactive substances.

2. The Ministry of Health make education and support services available for those affected by addiction issues

The legislation has been enacted without any apparent regard to education (particularly of young people) and the support services needed by those who use the products.

Council strongly urges the Ministry to increase resources for education and addiction support programmes to prevent and mitigate some of the harm caused to our community by psychoactive substances.

3. Retail sale restrictions

Council submits there should be consistent recording of buyers details (name, address and identification verifications) for sales in the same way required with dispensing of prescription medicines and sale of "pharmacist only" products.

The long term effects of psychoactive substances are not yet known. Some may have the potential for more adverse effects than our more closely monitored pharmacy products.

The benefit of doing so is that records are kept of consumption levels of a customer not only for their own health needs, but to also assist Police with monitoring on-supply to under 18 year olds.

It would also build up information to allow study on the long term effects of approved products to be monitored.

4. Regulations include infringement fines for consumption of psychoactive substances in public where prohibited by a bylaw

As well as being concerned about the wider social effects that these products are having on individuals and their families the Gisborne community is concerned about the effect on the amenity of our public spaces and streets by the public consumption of the products. The streets and public spaces around the outlet in the city are occupied by heavy users who consume the products in public and then remain in those areas. Retailers complain that they are also responsible for begging and intimidating shoppers.

A mechanism for Councils to deal with this might be through amendment to public places bylaws.

The most effective mechanism for enforcement of a bylaw is the ability to issue infringement fines on the spot. For this to occur, the infringement fine must be prescribed in regulations. Accordingly, the Council submits that the regulations contain infringement fines for public consumption of psychoactive substances where this has been prohibited by a bylaw under the Local Government Act.

The Mayor wishes to speak to this submission.
Making a submission

Submissions close on Friday 21 March 2014 at 5 pm.

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

Please detach and return this part of the document.

Consultation questions

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

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

   This could work as long as the LAPP is working within the sprit of the act and does not create a prohibitions zones.

3. Should retail licence applications be accompanied by evidence of compliance with a generic local approved products policy if no policy is in effect in the applicant's area?
4 Are the factors the Authority should take into account when determining whether a licence applicant is a fit and proper person or whether a body corporate is of good repute in section 16(2) enough? The section 16(2) factors are:

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

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

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

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

For retail, proof of purchases e.g. invoices

7 How long should licence holders be required to keep records for?
Should be the same as what is required by ir 7 years

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

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

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

   yes

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

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

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

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

yes

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

yes

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

What is one dose, the present sizes are adequate

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?

No

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

No storage restrictions and requirements should be a matter between retail store and there insurance company.

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?

Ref to sale of liquor act this should be the same
23. Do you think restrictions or requirements should be set regarding the disposal of approved products? If so, what should they be?

As above

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

As above

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

Near schools

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

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

Yes no internet sales
How can you tell who you are selling the product to.
How do you know the person selling is a licensed distributor?

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 liquor

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

It should be the same as the fees applied to a liquor on licence for retail

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

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

no

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

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

This submission was completed by:  (name) 
Address:  (street/box number)  (town/city)

Email: 
Organisation (if applicable): 
Position (if applicable): 

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

+ 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

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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.
Responses to submission questions

Licence applications

1 We do not believe the information requirements for licence applications are comprehensive enough.

The current information requirements may be adequate with respect to the research, manufacturing, wholesale and import licences. However, for retail licences, we propose that the licence model should more closely reflect the licence framework set out for the sale and supply of alcohol. The information requirements will change accordingly.

Under this proposed model, retailers would require a licence to sell psychoactive products and the terms of that licence would be:

- A retail licence is tied to the premise and business, together.
- A retail licence is non-transferrable. A change of location or business operator would require a new licence.
- Information supplied in the application must include:
  - the name of the business (or individual)
  - the names of directors and shareholders
  - the address of the retail location
  - a floor plan of the retail premises, clearly showing any adjoining doorways to other property.
  - if adjoining doorways are present in the retail premise, the operator name, address and phone numbers of those businesses shall be supplied.
- 'fit-and-proper' person checks shall be conducted for all directors and shareholders (as per liquor licences)
- psychoactive substance wholesalers may only sell to holders of an active psychoactive substance retail licence.
We propose the creation of a Psychoactive Substances Manager's Certificate. A retailer would be required to have at least one certified psychoactive substances manager on duty and present at all times during trading hours. Both the retailer and the certified psychoactive substances manager on duty would be responsible for any infringements under the Act or regulations.

The psychoactive substances manager certificate:

- is issued by the regulatory authority
- is held by an individual
- subjects the bearer to the 'fit-and-proper' person criteria
- requires the bearer to undertake an approved training course, covering a range of workshops including, but not limited to:
  - mental health awareness
  - substance-use and addiction awareness
  - de-escalation techniques
  - first aid
  - knowledge of available support services for problematic and addictive use
  - host responsibility training - so that sellers are trained to recognise intoxication to avoid selling products to people already intoxicated
- requires the bearer to be trained and versant in the Act and regulations
- requires annual renewal
- requires triennial testing of regulations knowledge
- does not entitle the bearer to privately sell psychoactive substances

We recommend that research licences only be issued to applicants that do not hold any other psychoactive substances licence type. Additionally, they must be not be affiliated with any other licence-type holder. The separation of those that would profit from the sales of psychoactive substances and those that determine the safety and effects of psychoactive substances is essential to the integrity of the industry. Research of psychoactive substances must be free from a conflict of interest.
We do not support the requirement of evidence of compliance being included with the application.

As the licence issuer, we propose that the Authority is responsible for determining whether an application complies with the respective local approved products policy.

In making their determination, the Authority may seek additional information from the relevant local authority to support their decision. Any information supplied by a local authority shall be done on a cost-recoverable basis.

We support the creation of a generic approved products policy for areas where no local approved products policy exists. In our research of councils nationwide, we have found:

- A perception from council staff that legal highs are not a problem for their district. This is particularly true when there are no operating interim licences in the area. However, many fail to take into consideration the temporary impact of the interim regime and the potential for issues to arise once regulations have come into effect.
- A belief that existing district plans and retail policies provide adequate protection.
- Smaller authorities have limited resources available to dedicate to the development of a local policy. Diverting these resources away to a perceived non-issue is difficult to justify.
- For authorities with a local policy, or engaged in the development of a policy, there is:
  - significant diversity in the buffer distances defined for sensitive sites and retailer proximity. In one case, no distances were specified; in another, 750m separation between retailers was proposed.
  - diversity in the types of sensitive sites defined.

For these reasons, we agree with the development of a generic local policy as a fall-back option for applications from areas where no local policy exists. Additionally, this could be used by authorities as the starting point in the development of their own local policy.
In particular, the generic policy needs to:

- clearly define the types of sensitive sites.
- set a minimum buffer zone around sensitive sites.
- set a minimum buffer zone between psychoactive substance retailers.
- create a standard definition for how those distances are measured (we recommend edge of property measurements, rather than centre of property).

It is our view that no local approved products policy shall be able to:

- nominate a lesser distance than those set out in the generic policy
- declassify a sensitive site type as identified in the generic policy

We do not support the requirement of evidence of compliance being included with the application. We propose that ownership of the generic policy shall sit with the Authority. As the licence issuer, we propose that the Authority is responsible for determining whether an application complies with the respective local approved products policy.

In making their determination, the Authority may seek additional information from the relevant local authority to support their decision. Any information supplied by a local authority shall be done on a cost-recoverable basis.

We believe that additional factors should be taken into consideration when determining whether a licence applicant is a fit and proper person, or whether a body corporate is of good repute. The definition of relevant offence needs to be broadened to include:

- Convictions for violence
- Offending against other people
- Driving offences for impairment
Also, our observation of and discussions with local psychoactive substance retailers suggest there is significant trade volumes for these substances. As such, we submit that all parties involved in the trade or research of psychoactive substances must have clean financial backgrounds and demonstrate an ability to establish and manage a reputable business.

This may include information on convictions for dishonesty or a history of bankruptcy or being involved with business that has gone into receivership.

We recommend that the applicant also provide at least two written references from within their community that support the fit-and-proper person test.

We agree with the requirement for applicants to provide details of their involvement in other regulatory regimes. Additionally, we expect that an applicant’s history with those regimes will be checked for any infringements, to inform the fit-and-proper person test.

We agree with the proposed additional sales record keeping requirements in the draft regulations. We believe that traceability and transparency are essential for the successful regulation of psychoactive substances.

At a minimum, all licence holders must be required to keep:

- all records required under statutes applicable to businesses
- all sales records
- all records related to supply including, but not limited to:
  - purchase records
  - purchase requisitions
  - returns records
  - stocktake records
- all documentation and written communications with respect to licensing
- all written communications with territorial authorities
- all written complaints and related correspondence
- records of the on-duty certified psychoactive substances manager, including dates and times
To ensure compliance, we strongly recommend that all licence holders be subject to annual audit by the regulatory authority, with all costs paid for by the licensee. The findings of the audit may be used to initiate proceedings if non-compliance with the regulations is discovered. The audit shall assess:

- processes to ensure compliance with regulations and the Act
- records for compliance to the regulations and the Act

**We recommend that licence holders be required to maintain records for a period of not less than 10 years.** This is consistent with the requirements applied to Pharmacies under the Misuse of Drugs Act and regulations.

Records must be made available to the regulatory authority upon written request. Like any reputable business, licence holders must take reasonable steps to ensure the safe and secure keeping of records. Failure to produce accurate and up-to-date records within 28 days shall result in:

1. a fine, to be determined by the authority, proportional to the scale of infringement.
2. a review of the licence holder to ascertain whether they continue to meet the conditions of holding a licence.

**We agree with the requirement to display a licence on the premises; however we believe that this should a mandatory condition of all licences.**

For retail licences:

1. the licence must be clearly on display at the point-of-sale.
2. the name of the on-duty psychoactive substances manager must also be on display at the point-of-sale.

For all other licence types, the licence must be clearly on display at the entrance to the business.
We agree with the ability to set restrictions on retailer opening hours. We propose:

- At a national level, we propose the Authority sets hours during which trade is prohibited. For example, between the hours of 10pm and 7am.
- At a local level, authorities must be given the opportunity to impose further trading hours restrictions as part of the licence requirements. This may include an assessment of the impact on amenity and good order in the locality in which the retail premises are located.

We agree with prohibiting the sale of food, confectionery, soft drinks and other household goods. This is consistent with the requirements of the Act, prohibiting dairies, convenience stores, service stations etc. from selling psychoactive substances. We also expect that any business accessible through adjoining doorways that matches these conditions would be taken into consideration when issuing a licence.

We recommend a requirement that all licence holders take steps to reduce the chances of theft or misappropriation. These might include the use of security screens, CCTV cameras or security guards. The restricted, controlled nature of psychoactive substances and products make them potentially harmful in the wrong hands. Additionally, their size and value make them highly desirable items from a theft point-of-view.

We recommend that a psychoactive substances risk framework be developed, in much the same way as has been done for alcohol licensing. Retail premises would be classified as high, medium or low risk, each subjected to different conditions. The use of such a framework allows the authority to apply harm mitigation specific to the licensee and their location, based on objective rationale.

When considering a retail licence, applicants must provide evidence of employment of a certified psychoactive substances manager as part of their application. This would demonstrate that the applicant has access to an individual or individuals with suitable knowledge of the regulations and the Act.
Product approval applications

10 We agree with product approval applications requiring information on proposed manufacturing methods. For quality control purposes, it is essential that manufacturers are familiar and comply with the Psychoactive Substances Code of Manufacturing Practice. Prior to seeking product approvals, evidence must be obtained that the manufacturer can comply with these standards.

11 We recommend that testing regimes and procedures also be included a product approval application.

12 We have serious concerns about the current toxicity and effects of psychoactive products currently on the market. There are increasing anecdotal reports from mental health crisis teams and acute units that these products can cause psychotic reactions and heightened paranoia, in some cases resulting in schizophrenia.

We agree that all product applications must contain information on the toxicity, pharmacology and clinical effects of the psychoactive substance. Information shall also be included to indicate how that chemical has been identified as being psychoactive.

13 We agree with the proposed information and data requirements. Additionally, we also recommend the following be supplied with product approval applications:

1. range and severity of effects
2. known interactions
3. contraindications - particularly relevant when considering populations that are likely to be vulnerable to the effects of psychoactive substances use
4. differential responses for genders, ethnicity and age
Labelling and packaging

We agree with the proposed labelling requirements. In addition we recommend:

1. Restricted 18+ warning clearly displayed on front of pack.
2. Ingredients list with active ingredients listed first and in bold typeface. The word "natural" must not be used to describe any ingredient.
3. Tamper warnings - if the sealed package appears to have been tampered with, do not use the product.
4. Safe storage instructions - temperature, light, etc.

We also strongly support the idea of plain packaging for psychoactive substances. As a predominantly smokeable product, we consider this an appropriate requirement.

Our observations and experience with populations that are vulnerable suggests that current health labels are not well understood by some users. Additionally, their impression of the safety of the product is largely determined by a belief that because these products are legal they are also entirely safe to consume, in whatever quantity they desire.

It is for this reason we agree with the proposed health warning requirements. These must be prominently displayed on the product packaging.

Additionally, we expect that the product will include the following health warnings and advice, most likely as an insert to be included in the packaging:

1. The types of possible adverse reactions and what to do
2. What to do in the case of overdose or suicidal ideation
3. Medication and known contraindications information
4. Contact details of support agencies for users concerned about the impact the substances are having on them, or they have queries about their usage.
With respect to the proposed health warnings, we note there is an item that refers to driving or operating machinery whilst under the influence. In the event these warnings are ignored, we question if there are appropriate roadside testing kits to identify whether a person has been using psychoactive substances. We recommend the Authority works with appropriate agencies to develop or procure a test to identify whether a person has recently used a psychoactive substance and their relative functional impairment.

16 We agree with the proposed packaging requirements and restrictions.

17 We have witnessed significant problems with people consuming large amounts of psychoactive substances in single sittings, ignoring written warnings on packets. This is exacerbated by the availability of bulk packs or large doses.

We agree with restricting packets to one dose. We recommend this should be combined with imposing a limit on the number of packets that can be purchased at one time. These are important components of harm reduction.

18 We note that most of the current products are designed to be smoked. Notwithstanding our concerns about the health implications of smoking these products, smoking gives the user much greater control over the level of dose consumed. However, for orally consumed products, the level of dose is more difficult to control and thus splitting the dose is more appropriate.

Therefore, we agree with requiring a dose to be split. We recommend half doses.

1. For smokeable products - two sealed tamper-proof half-dose sections.
2. For pressed tablets - two separate half-dose tablets, or a single scored tablet.
3. For capsules - two separate half-dose capsules.
We recommend that there should be restrictions on product form.

1. We note that New Zealand has set a goal of being smoke free by 2025. We expect the regulations would align with this goal, and ensure that smokeable products are not permitted after this point.
2. Injectable forms should be prohibited
3. Liquid forms should be prohibited, i.e. not sold as a form of psychoactive drink, except for use in electronic cigarette dispensers.
4. Edible forms should be prohibited, i.e. not sold as a form of energy bar
5. Aerosol/inhaler form should be prohibited
6. Topical forms should be prohibited

Products should be stored in such a way as to maintain their integrity and standard. We recommend that these conditions be determined by the manufacturer of the products and clearly displayed on the labels.

We disagree with the exclusion of disposal requirements in the regulations. For clarity, we recommend the regulations include a reference to provisions in relevant legislation.

We recommend that product storage for approved products be aligned with the recent Smoke-free environments (Controls and Enforcement) Amendment Bill.

We recommend that display of approved products be aligned with the recent Smoke-free environments (Controls and Enforcement) Amendment Bill.

1. Psychoactive products must not be visible from public places outside the retail premises
2. At each point of sale, the psychoactive substance display is limited to a maximum number of units
3. Psychoactive products may not be displayed on a countertop or similar surface
4. If smokeable psychoactive products are displayed within two metres of a point of sale, a sign stating "SMOKING KILLS" must be displayed in clear view of the customer at the point of sale.

We recommend that disposal of products be undertaken by the manufacturer. By devolving this responsibility to a single licence-type holder, the disposal process can be managed effectively.

1. Retailers and suppliers to return unused or expired products to the manufacturer for disposal
2. Manufacturer manages disposal process
3. Disposal undertaken using an approved, specific process
4. Disposal request and proof of disposal kept by the manufacturer

We view signage as a pre-purchase opportunity to warn the consumer about psychoactive products and the rules and regulations about them. We recommend that all psychoactive substance retailers be required to display a sign (or signs) with the following warnings and information:

1. Psychoactive products are strictly R18.
2. Purchase only from an authorised psychoactive substances retailer.
3. Smoking kills.
4. Psychoactive products will not be sold to intoxicated persons.
5. It is unlawful for minors to possess or be supplied with psychoactive products.
6. It is unlawful to sell psychoactive products unless you are an authorised licence holder.
7. Fines and penalties apply to infringements.
8. Adverse side effects should be reported to the National Poisons Centre.
9. Contact the Psychoactive Substances hotline for any further information.
10. The name of the on-duty certified psychoactive substances manager

The sign (or signs) must be clearly visible at the point of sale, and large enough to be easily read when making a purchase. To ensure consistency, we recommend these signs be created and controlled by the Authority, and made available to licence holders for purchase.
Place of sale and advertising

25. Although unlikely to occur, we recommend prohibiting the sale of psychoactive products in cafes and restaurants.

26. We are opposed to any form of off-site or external retail store public advertising for psychoactive substances. We accept there will be promotional materials created within the industry (i.e. supplier to retailer), but from a retail perspective there should be no advertising in any form to the general public.

We agree with the proposed restrictions, and recommend extending these to include:

1. Mail outs or flyers - distributed to letter boxes, hand outs, emails, etc.
2. Billboards - static or moving (buses, etc.).
3. Posters.

27. We have serious reservations about allowing retailers to sell psychoactive substances online. We believe that the current mechanisms for verifying the purchaser is 18+ are too easy to circumvent. The potential for underage sales is too great. Therefore, we propose:

1. A retailer’s sales website must have integration with the RealMe Identity verification system. This mechanism must be used to verify the age of the purchaser prior to sale.
2. Debit cards should not be accepted, or any payment mechanism available to people under the age of 18.

In order to minimise the potential for leakage, and minimise the potential for abuse or harm, we recommend imposing daily, weekly and monthly online sales limits per person. These controls should be applied at a national level so that purchases across all internet retailers are taken into account.
We are opposed to any form of on-site advertising that promotes psychoactive products. We support the restriction of on-site advertising to objective information only.
Fees and levies

29 We support the proposed fees for different licenses.

30 We support the fixed-fee structure, and recommend that this include a set number of deliverables or work hours. Any work beyond the agreed included deliverables would be charged at an hourly rate, to recover costs.

31 We recommend setting a range of additional fees for functions outlined in this submission.

   1. Annual audit fee - to ensure compliance with the regulations and the Act
   2. Psychoactive Substances Manager Certification
      a. Initial certification fee - includes first year certification
      b. Annual re-certification fee
      c. Triennial re-testing fee
   3. Manufacturing compliance audit fee - to ensure manufacturing processes meet quality requirements.

32 We agree with the proposed levies and process for setting levies. However, we have concerns that these levies do not address any of the costs incurred by local authorities and other agencies that work with licence holders. Scope must be given for local authorities to implement a local levy structure to recover costs including, but not limited to:

   1. Security and safety programmes
   2. CCTV monitoring
Members of the Wise Group

Pathways
The founding member of the Wise Group and its largest organisation. Pathways provides a range of services from specialist through to community-based, to support people with experience of mental illness and/or addiction to live well and flourish in the communities of their choice. These include peer-led services, alternatives to hospital admission, home-based support, housing facilitation, employment and a broad range of wellbeing services. www.pathways.co.nz

Te Pou
Supporting and developing the mental health, addiction and disability workforces in New Zealand. The Ministry of Health and Health Workforce New Zealand fund Te Pou to provide the mental health sector with information and research evidence to build a strong and enduring workforce, and develop a culture of continuous quality improvement. Te Pou incorporates Disability Workforce Development and Matua Raki (addictions workforce development).
www.tepou.co.nz

Workwise
An employment agency providing evidence-based supported employment services using an Individual Placement and Support (IPS) model, to help people with experience of mental illness find and keep paid employment.
www.workwise.org.nz

Keys Social Housing
Provides safe, healthy, comfortable and affordable homes and practical support to people who need homes in Auckland, Hamilton, Whanganui, New Plymouth and Wellington.
www.keyshousing.co.nz

Real
Supporting young people, and their family and whanau, by providing a suite of wellness and wellbeing services and information designed to contribute to young New Zealanders feeling great about their futures.
www.real.org.nz

Linkage
Linkage has developed Webhealth in response to people struggling to get access to good information about health and social services. It is a unique online resource that provides information on health and wellbeing, and includes regional directories for health and social services. The public can access this information online at home, or through free web health kiosks in places like shopping malls and public libraries. Linkage, using Webhealth, provides an expert navigation service that assists people to find their way through the government, health and social service systems and find solutions that best meet their needs.
www linkage.co.nz

Blueprint
A private training enterprise delivering a diverse range of training at all levels, to a wide range of health, mental health and social sector agencies.
www.blueprint.co.nz
Wise Management Services
Delivering business infrastructure and development services for the entire Group including an extensive communication and design service and information services.
www.wisegroup.co.nz

Social Angels
An online giving community supporting many small charities and causes to create fresh possibilities and improve life for people and communities in New Zealand. Every cent donated goes directly to the chosen cause.
www.socialangels.org.nz

The Monastery
A Waikato-based wellness retreat currently offering free five-night retreats to people directly affected by the devastating Canterbury earthquakes. www.themonastery.co.nz

Mental Health Solutions
A centralised contract-holding company providing a single point of entry for any Crown agency to contract and fund a member of the Wise Group. Mental Health Solutions also plays a critical role for the Group in sponsoring and supporting the establishment of innovative, transformational services. Within the Wise Group it is referred to as the development unit.

Wild Bamboo
Developing and delivering smart information systems for the community and non-government sector. www.wildbamboo.com
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 council’s 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.
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.

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

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

In addition, we recommend for retail licences:

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

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

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

Yes

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

No comment

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

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

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

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

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

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

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

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

In addition we recommend:

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

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

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

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

In addition we recommend labels include details of:

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

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

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

In addition, suggest adding two further warnings:
- 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 recommend 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): Waikato Business & Development Association

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): someone against legal highs

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---

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

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

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

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

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

Yes and that should be taken into consideration as per question 4
6. What records should the regulations require licence holders to keep?

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

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

As per alcohol licensing

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

There should be absolutely no discretionary conditions to allow licensing of psychoactive substances.

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

Yes as below:

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

Regardless of the LAP the public must be able to request modifications to opening and closing times of interim or full retail licenses.
10. Do you agree a product approval application should include information on proposed manufacturing methods and how they will comply with the Psychoactive Substances Code of Manufacturing Practice?

Yes-definitely.

11. Do you think any further particulars, information, documents or other material should be prescribed in the regulations? If yes, what should these be?
There should be prescribed Psychoactive Substances licensing officers provided by the Ministry to City Councils and paid for by the industry to enforce compliance of stores/importers/manufacturers.

It is concerning that the Ministry of Health has still not defined what a low risk Psychoactive Substance is. In this regard public must have input into the definition of "low risk".

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

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

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

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

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

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

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

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

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

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

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

The Ministry of Health must be held accountable for any resulting health and social issues from approved Psychoactive Substances and be prepared to immediately ban and fund the solutions.
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 as per question 11.

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

Labelling should follow the same as cigarette labelling.

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

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

Labelling should follow the same as cigarette labelling.

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

Yes to minimise overdoes and to ensure appropriate pricing controls.

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

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

Should not be allowed to inject (break skin) or inhale via cigarettes (as we are trying to ban smoking).

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

Yes as per Cigarette restrictions.

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

Yes as per Cigarette restrictions.

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

Yes as per illegal drug disposal.

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

Yes as per Cigarette restrictions.

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

They should only be sold in specialty stores and far away from residential, schools, community places.
26. Do you think the regulations should prescribe restrictions or requirements for advertisements of approved products? If so, please provide specific suggestions.

Yes as per Cigarette restrictions.

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

Internet sales should not be allowed as this will be impossible to regulate and monitor.

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

Yes along the lines of the Cigarette restrictions.

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?

Fees must be paid for by the industry, no public taxpayer should money used.

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

Fees must be paid for by the industry, no public taxpayer should money used.

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

Fees must be paid for by the industry, no public taxpayer money should be used.
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) Barney Manaia

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

Email:  

Organisation (if applicable):  
AT Tamaki

Position (if applicable):  
Chairperson

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

☐ as an interim licence holder

☐ a person or body corporate intending to apply for a licence

X other (please specify): As a concerned New Zealander and Chairperson who opposes legalisation of psychoactive substances

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

X Yes  ☐ No

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

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

The Manager  
Psychoactive Substances Regulatory Authority  
Ministry of Health  
PO Box 5013  
WELLINGTON  
Email: psychoactives@moh.govt.nz
Alternatively, electronically complete the submission form available at the back of this document, add your comments and email to:

psychoactives@moh.govt.nz

Please put 'Regulations Consultation' in the subject line.

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

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

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

X I am fine with all details of my submission being made public
Submission from
Canterbury District Health Board

Psychoactive Substances Regulations
Consultation Document

21st March 2014
Introduction

The Canterbury District Health Board (CDHB) welcomes the opportunity to comment on the Psychoactive Substances Regulations Consultation discussion document.

The reasons for making this submission are to promote the health of people and communities and to improve, promote and protect their health pursuant to the New Zealand Public Health and Disability Act 2000 and the Health Act 1956. The CDHB’s vision is to promote, enhance and facilitate the health and wellbeing of the people within the Canterbury District.

These comments have been prepared in consultation with clinical and public health specialists and have the formal support of Senior Management at CDHB.

Consultation questions

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

   The CDHB recommend that the following information is required:
   - ‘Name’ should be specified as ‘full legal name’
   - Applicants phone contact details should include cell phone number
   - Name of Owner and Manager
   - List of Company websites used for internet sales

   The CDHB supports the requirement for a statutory declaration under the regulations. The potential issue for people becoming licence holders as a front for those who are unable to meet ‘the fit and proper person test’ should be addressed. A similar issue exists for liquor licensing application.

   When the application is assessed consideration should be given to the background of other key personnel involved in the operation/premises.

   License applicants should also be required to provide a Risk Management Policy including how it will enforce the legal age restrictions on sales of psychoactive substances, deal with intoxicated customers, manage difficult customer and include a process for reporting adverse harm complaints.

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.

   All retail licence applications should be accompanied by evidence of compliance with the LAPP to ensure a licence is not issued for non compliant premises.
3 Should retail licence applications be accompanied by evidence of compliance with a generic local approved products policy if no policy is in effect in the applicant's area?

Yes agree.

A generic locally approved products policy would provide vulnerable people/communities with some protection.

If a generic local approved products policy is developed the proximity to children's institutions, such as schools and preschools, health facilities (such as mental health facilities), and density should be considered.

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.

Often applicants would have held, or currently hold licences for other regulatory regimes for example food premises, liquor licences or sale of tobacco products. Their compliance record in these areas is relevant to establishing whether they are a fit and proper person or a body corporate of good repute.

A police check or enquires to Customs will not identify poor compliance in these regulatory regimes.

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

Yes agree, as specified above.

It is important for Enforcement Officers to be informed of the connections with other regulatory regimes.
6 What records should the regulations require licence holders to keep?

The CDHB agree with the requirement to keep records on the quantity of products received and distributed and that the licence number of both the seller and the purchaser is noted for every sales transaction (except retail sales).

The name of the product and batch identification should also be required to be recorded in order to track product in the event of a recall.

The establishment and maintenance of a complaints register is also recommended.

A specified timeframe for the notification of importation is required to allow sufficient time for Enforcement Officers to take regulatory action or carry out checks as necessary.

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

Seven years, as required by most other legislation relating to records.

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

CDHB supports the proposed discretionary conditions for retail licences and those listed under other issues being considered. The CDHB recommends that discretionary conditions should be used as a tool to prevent or minimise harm.

The condition relating to the sale of food should be widened to include the sale, manufacture and storage of food. By doing this the Enforcement Officer would not be required to prove that food was available for sale.

CDHB suggests that consideration should be given to the following matters:

- The amount of an approved product that might be purchased in a single sale
- A limit on the range of non-related products, such as clothing, which is able to be sold in retail premises licensed to sell approved products.
- A limit on the hours a retail premise selling approved products may operate.
9. Should the regulations prescribe other matters the Authority must take into account when deciding on an application? If yes, what should these matters be?

Yes, as noted above in the answer to question 4.

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

Yes agree.

It is a good opportunity to reinforce the use of 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?

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, agree.

Detailed guidance as stated in the consultation document will be required to ensure that the information provided by the applicant is robust, scientific data that is useful to PSEAC. The data required should be no less comprehensive than required for medicines.
13 Do you agree with the proposal that the regulations require product approval applications to contain information and data on:

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

Yes agree.

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

The name of the product, the active ingredient and any other ingredient (such as filler, vegetable matter) should also be required to be listed on the label.

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.

There should be a warning not to consume if you are being treated for a mental illness.

There should also be advice about what to do in case of overdose, in addition to the contact details required for the National Poisons Centre.

Any guidance material in packaging or on the internet should include where to seek help and support to manage drug problems including the National Drug Helpline number.
16 Are the proposed packaging requirements and restrictions sufficient? If not, please make specific suggestions for further requirements.

The proposed packaging requirements and restrictions are insufficient. The CDHB recommend that plain packaging is required or that there are at least similar restrictions to those which now exist for tobacco packing.

If however the proposed packaging are accepted the CDHB recommend that as well as prohibiting the use of swear words and other words with inappropriate connotations on the packaging, that inappropriate pictorial content is also prohibited.

The Regulations should specify how different products should be packaged.

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

Yes agree with the proposal to restrict a packet to one dose to reduce the likelihood of accidental overdose occurring.

Controls are required in order to correctly establish what is considered to be a single dose.

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

Yes agree with the proposed requirement that one dose is split into several units to minimise harm to children who accidentally consume products.
19 Do you think there should be restrictions on the form products can take? If so, what forms do you think should and shouldn’t be allowed?

Yes agree.

Products should not be in a form that can be injected as drugs in powder form can be reconstituted for injection.

CDHB recommend that the regulations specified that any product in powder form is not readily soluble.

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 restrictions should relate to the storage requirements as specified by the manufacturer.

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

To reduce the level of product entering the black-market through theft, it is suggested that limits should be set on the quantity of products allowed to be stored at the retail premises.

Product that is not displayed for sale should be required to be kept in a secure location, out of customer view.

Product should be stored in a clean area free from contamination.
22 Do you think restrictions or requirements should be set regarding the display of approved products? If so, what should they be?

The display of approved products for sale inside a retail premises should not be visible from any place outside the retailer's place of business as this would act as a form of advertising.

Product should be required to be kept under or behind the counter so that customers can only view them at the counter in close proximity to the vendor.

The CDHB recommends restrictions or requirements regarding the display of approved product in line with the requirements under the Smoke-free Environments Act 1990.

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

The disposal of approved products should be specified and this should be in line with methods outlined for the disposal of medicines.

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

The CDHB recommend that signage requirements should mirror those required under the Smoke-free Environments Act 1990 for tobacco products.

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

The CDHB recommend that the regulations specify that approved products may not be sold at pharmacies.
26. Do you think the regulations should prescribe restrictions or requirements for advertisements of approved products? If so, please provide specific suggestions.

Yes.

Restrictions on advertisements should be in line with the types of restrictions imposed on tobacco products, at the very least, something similar to the Voluntary Code of Practice is required. The CDHB strongly encourage compulsory restrictions.

It is very important that Psychoactive Products are not glamorised by advertising.

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

Yes.

Sales should not be allowed to occur over the internet due to the difficulty in controlling the restriction on under 18 sales. If internet sales are permitted a limit on the volume of product allowed to be sold is required to reduce the likelihood of illegal on-selling.

If approved products are sold online then credit card details should be used to verify the age of the purchaser.

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

Yes agree with restriction on advertising.

The CDHB recommend that additional restrictions are required on the discounting of product, for example 2 for 1 sale or promotions encouraging people to use/buy more.

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

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

No comment.

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

No comment.

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

Yes agree.
A levy should take into account the costs associated with the administration of the Act and the maintenance and deploying of Enforcement Officers for non-licensing activities. It must be clear how the levies are collected and how they will be passed onto the enforcement bodies. There should also be an appropriate enforcement provision in the regulations for the non-payment of levies.
Person Making Submission
Public Health Specialist
Canterbury District Health Board

Postal Address
Community and Public Health
Healthy Physical Environments
PO Box 1475 Christchurch 8140

Phone:  Fax:

Contact Person for this application:

Email:

Submitting this as:
Other (please specify): Enforcement Authority

I do give permission for the organisations name to be listed in the published summary of submissions.
Proposed Psychoactive Substances Regulations

Marlborough District Council Submission to the Ministry of Health

SUBMISSION DATE 21 March 2014

INTRODUCTION

Marlborough District Council (Council) is a unitary authority with the functions of both a regional and district council.

Council is currently consulting on a proposed Local Approved Products Policy. A copy of the draft policy has been sent to the Psychoactive Substances regulatory Authority. Submissions close on 28 March 2014.

Council has read the submission on the proposed regulations made by the Local Government New Zealand. Council supports all of the matters raised in that submission. In particular, Council agrees with LGNZ that the Ministry of Health should develop a communications strategy to inform New Zealanders about the nature of the new regime and the relative roles of the different agencies involved in implementation. Council also agrees with the LGNZ submission that local government representatives should work alongside Ministry of Health official in developing the retail regulations.

COUNCIL'S POSITION ON THE PSYCHOACTIVE SUBSTANCES REGIME

Council is opposed to the import, manufacture, sale and supply of psychoactive substances in its region. The harm caused by psychoactive substances is such that they should be banned. Creating a licensing regime for them gives the public a false view about the safety of these substances. Council will continue to lobby government to ban them.

In the meantime, Council is taking a pragmatic approach and, without accepting that this regime is the right or best way to manage psychoactive substances, wishes to ensure that the regulations and other processes are robustly developed.

It is in this spirit that Council makes this submission.

COMMENTS ON THE SPECIFIC PROPOSALS IN THE CONSULTATION DOCUMENT

Licence application requirements

Licences may only be applied for and held by New Zealand residents. None of the information required shows whether the applicant is in fact a New Zealand resident. Information such as a birth certificate or evidence of residency should be required.

Licence applications should be accompanied by evidence that they comply with the relevant LAPP. The evidence should be independent of the applicant.

Generic LAPP

Council supports the imposition of a generic LAPP in principle. The consultation documents do not give any detail of what a generic policy would contain. Council would prefer to see such detail before committing to the imposition of a specific "generic" policy.

Fit & Proper Person Test

Local authorities may hold information relevant to the fit and proper person test. If the applicant has applied for a licence under the alcohol licensing regime, Council will hold details of any complaints or breaches of the alcohol legislation.

The Authority should consult with local authorities in determining whether the applicant is a fit and proper person to hold a licence.
Other relevant offences should include and drink- or drug- driving offences.
Complaints, formal warning and infringements, not just convictions, should also be considered
to be relevant when determining whether a person is a fit and proper person.

Discretionary conditions

Discretionary conditions should include hours of opening of retail and other premises. The
Blenheim Youth Workers Collective sought that Council's Local Approved Products Policy limit
opening hours to 9am to 3pm (school hours).

In Council's view, the opening hours should be limited to the regular opening and closing hours
of other retail premises in the vicinity (i.e. 8 or 9am to 5 or 5.30pm).

Labelling

Labels should contain a statement that they are not to be sold to or taken by people under age
18.

Health warnings

Health warnings should include:
- what to do in case of an overdose or an adverse reaction; and
- what effects a person should expect from taking the product and what the effects of long
term use may be.

Packaging

Council considers that the packaging should be plain and look like prescription medicines.

There should be "use- by" dates on the packaging. Approved products should not be able to be
sold beyond the "use by" date and they should be safely disposed of.

Appearance of products

Council considers there should be restrictions on the form products can take. Pills should be
white and round with no decoration (no shapes or colours that may appeal to minors). They
should not look like sweets.

Advertising and display

Advertising and display of approved products should be restricted in the same way tobacco is. It
should not be able to be seen from the street. Advertising and display should contain all the
health warnings that are required to be on the packaging. Any advertising should not glamorize
or romanticise the product.

Places of sale

The regulations should further limit the places from which approved products may be sold.
Premises selling clothing, books etc. should not be able to sell approved products. Approved
products should not be able to be sold from dwellings or in any residential zone.

Internet sales

Internet sites should have clear health warnings on the home page and at the point of sale. The
internet page should not glamorise or romanticise the products. The same limitations that are
placed on advertising and display should apply to the internet.

Fees and Levies

Levies should include an amount to be paid to local authorities to cover the costs of
development of local approved products policies and the interaction local authorities will have
with the Regulatory Authority when it is determining licence applications. If local authorities are
to provide some form of confirmation that an applicant complies with the local approved
products policy or have any other interaction with the licensing, monitoring or enforcement of
the licensing regime, the costs of the local authority should be met by the applicant. This could
be by way of direct fee or (as below) a levy.
This submission was completed by: Kaye McLveney

Address: P O Box 443
         Blenheim 7240

Email: Email: kaye.mclveney@marlborough.govt.nz

Organisation: Marlborough District Council

Position: Solicitor

Council wishes to receive updates about the development of the psychoactive substances regulations.
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

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?
   
   They should not be allowed to sell this substance at all.

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

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

No Sales

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

No Sales

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

Get rid of it

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

There has been a huge number of young people who have been admitted to A&E because of the consumption of synthetic highs being sold in shops. Therefore there should be zero sales.

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

The regulations should make synthetic high illegal.

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?

There should be no manufacturing of psychoactive substances.

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

No Sales!!!
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 like - Suicidal Tendency
- Psychosis
- Vegetated brain function

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

See above...

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

Should not be sold

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

No

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

Should not be sold

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

No sale

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

No dose No product.
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?

   No Sale

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

   No Sales

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

   No Sales
23. Do you think restrictions or requirements should be set regarding the disposal of approved products? If so, what should they be?

Get rid of them

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

Yes-

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

Yes- No Sale

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

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

No Sale

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
No sales at all

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

No license to sell this stuff that is killing our kids.

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

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

- No Sales of psychoactive substances
- No Suicides
- No Depression
- No Deaths

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

See above.

When I walk the streets of West Auckland there are huge amounts of young people smoking this stuff openly on the streets. It is wrong for our government to allow the sale of these killer drugs, that allows our babies and children be exposed to this behaviour. It is also wrong for the government to allow the sale of these drugs that are killing our kids and leaving them as addicts or braindead, causing crime and abuse, suicide and death.

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

This submission was completed by: Winnie Retimana

Address: 

(street/box number) 

(town/city)

Email: winnie.retimana@hoani.waititi.co.nz

Organisation (if applicable): Hoani Waititi Marae

Position (if applicable): Kaitoko Whanaia

Tikanga Facilitator.
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 provide an email address.)

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

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

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

Please put ‘Regulations Consultation’ in the subject line.

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

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

Submissions close on Friday 21 March 2014 at 5 pm.

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

Please detach and return this part of the document.

Consultation questions

1. Is the list of proposed information requirements for licence applications comprehensive enough?
   If not, what else should be required, and why?
   
   The need to be clear: needs to outline the main purpose.

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?
   
   Totally agree, all applications need to stipulate the pros & cons of the product in order for it's sale to proceed.

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?
   
   Agree, but definitely not to be sold if it is to affect the ability of ones mind body soul and move around them.
As a matter of fact, 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.

There needs to be harsher penalties when discussing communities, organisations, and the wider areas as well as the individual itself.

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

This is not an optional question.

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

All records for at least 7-8 years at any time.

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

As above.

2 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.

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

No. This effects us as a nation!
Get rid of it.

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?

Totally, But get rid of this rubbish!
Waste of money.

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

No

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

Agree to this but not for the manufacturing of psychoactive substances!

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

No

There needs to be more advertising around the effects that this product has on different individuals and their families.
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).

Advertising needs to be very "CLEAR!"

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

No
Like the smoking packets, they (packaging) needs to be supported as well (show what effects this product can & will do).

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

None
That's the restriction of sales for any local outlet.

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

No!
One dose half dose they are all the same!
Get rid of it
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 products at all.

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?

This product is a waste of taxpayers' money & a waste to talk about. Just get rid of product!

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

No.

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

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


25. 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.

I am totally opposed to any psychoactive substances (drugs) because of my work with families who have unfortunately been involved. The effect on total family well-being has been horrific. 

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/address) 
(town/city)

Email:

Organisation (if applicable):

Position (if applicable):

Dame June Hinchaburkura Marie

Hoani Waititi Marae
Oranga Whanau: Total Family Well-being.
D.N.Z.M. J.P.

Psychoactive Substances Regulations: Submission form
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. There should be information about the damage caused accompanying licensing or no licenses granted.

2. Should retail licence applications be accompanied by evidence of compliance with a local approved products policy if one is in effect in the applicant's area?
   
   No. No licences should be granted.

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

Applications need to be made aware of damaged caused.

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?

Full records of sales

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

Seven years

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.

Authorities need to consider the damage caused to consumers and not profits made by retailers.

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?

This issue needs a more holistic view instead of focusing on a small portion of the picture.

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

No. There should be no product approval.

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

No. There needs to be no applications granted. Prosecutions should be implemented.

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?

Even if regulations have the above it will not help our rangitoki.

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

There should be no products sold.
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. If there is a complete ban the would be no need for advice on what to do for an overdose.

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

No

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

There should be no doses.

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

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

Products should not be sold

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 they are not sold they won't need to store anything

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

No

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

They should not be displayed
23 Do you think restrictions or requirements should be set regarding the disposal of approved products? If so, what should they be?

There should be no approval of products.

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

No signage.

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

No products should be sold.

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

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

No products should be sold.

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

No products should be advertised.

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

No licences should be granted. Granting licences legitimises substances that should not be on the market.

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

Don't make any more money out of these products. Don't grant licences.
31 Should fees be set for other specific functions? If yes, please state what they should be set for.

No

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

Don't set levies, they only further legitimise substances that should be banned.

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/or number]  [town/city]
Email:  [email]
Organisation (if applicable):  [organisation]
Position (if applicable):  [position]
Are you submitting this:
(Tick one box only in this section)
☐ as an interim licence holder
☐ a person or body corporate intending to apply for a licence
☒ other (please specify): As a futur of rangi-tahi

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?
   - A 10-year verified business history, including referees.
   - Details of previous involvement in the hospitality industry.
   - Details of any experience in selling any product that may be harmful and what precautions they would take to prevent/minimise risk of harm.

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

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

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

   We believe that licences should only be issued to individuals, not to bodies corporate in the same way that alcohol licences are issued. The factors stated are sufficient.
5  Should the regulations require applicants to provide details of their involvement in other regulatory regimes, such as alcohol licensing processes?

Yes – we feel strongly that this should be the case.

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

We would like licence holders to keep a detailed register of each purchaser, including their full contact details. These should be submitted quarterly to the Psychoactive Substances Regulatory Authority.

The rationale behind this is for use in the future to assist with the assessment of the long-term effects of these substances.

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

These records should be kept indefinitely by the Psychoactive Substances Regulatory Authority.

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

We agree with the proposed discretionary conditions and would like to add that each sale is accompanied by a fact sheet outlining the risks to health and precautionary advice on emergency procedures.

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

Yes and we would like an opportunity to review these once proposed.

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

Yes – we feel strongly that this should be the case.

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

Yes – detailed records of the origins of all ingredients.

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

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

Yes to all of the above.

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

We would like the emergency number 111 included on the label.

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 like to also add the following: "Potential users should take into consideration that you may have a genetic predisposition to this product that may trigger permanent psychosis."

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

We propose that all of these products are sold in plain packaging (zero branding), with the same regulations as those which cover tobacco products.

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

Yes, in order to reduce the likelihood of users taking the product to excess. We believe that the ability of people to make good decisions will be compromised after taking one dose of the product, as they lose self-awareness and the perception of reality.

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

Yes.

Do you think there should be restrictions on the forms products can take? If so, what forms do you think should and shouldn’t be allowed?
Yes. We believe that the only form that should be allowed is split dosage tablets. No smokeable products should be permitted.

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?

Psychoactive substances should be kept in a locked safe. This requirement will help to reduce the likelihood of crime, such as burglary.

For this reason we believe that the amount of psychoactive substances that can be stored by a retailer at any given time should not exceed two weeks of average sales.

The quantity allowed would be reassessed every quarter by the Psychoactive Substances Regulatory Authority, based on their latest sales report.

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

Approved products should also be kept in a locked safe. This requirement will help to reduce the likelihood of crime, such as burglary.

For this reason we believe that the amount of approved products that can be stored by a retailer at any given time should not exceed two weeks of average sales.

The quantity allowed would be reassessed every quarter by the Psychoactive Substances Regulatory Authority, based on their latest sales report.

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

They should not be on display to the public, in a similar way to tobacco products.

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

They should be disposed of in a safe manner by an approved agency.

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

Yes. Signage should include maximum dosage advice, a health warning and educational messages about the use of these substances. This information should occupy at least 30% of the total area of the sign.

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 at major public events and gatherings such as music festivals, or within the proximity of specified sensitive sites such as schools, kindergartens and places of worship.

Their location should be restricted to designated areas deemed appropriate by the territorial authority.

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

Yes, advertisements should be restricted in the same manner as they are in the tobacco industry.

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

They should only be available on R18 websites. Only registered users should be able to access websites selling these products.

All sales should be registered and returns sent quarterly to the Psychoactive Substances Regulatory Authority.

All internet sites must be registered with the Ministry of Health and listed on their website.

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

They should contain objective information only and zero branding, in line with the plain packaging requirement.

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

No opinion.

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

No opinion.

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

No opinion.

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

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

This submission was completed by: Jill Greathead
Address: PO Box 224
          Carterton
Email: jill.greathead@cdc.govt.nz
Organisation (if applicable): Wairarapa Psychoactive Substances Working Group
Position (if applicable): Chair

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

☐ as an interim licence holder
☐ a person or body corporate intending to apply for a licence
X other (please specify): Working group consisting of political and officer representatives from Carterton, Masterton and South Wairarapa District Councils.

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

X Yes

(jill.greathead@cdc.govt.nz)

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

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

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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