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The Manager
Psychoactive Substances Regulatory Authority
Ministry of Health
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Wellington 6145

Email: psychoactives@moh.govt.nz

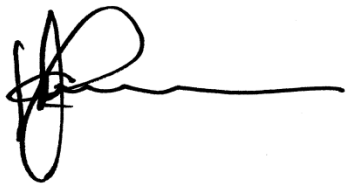
Psychoactive Substances Regulations: a consultation document

The New Zealand Law Society (Law Society) appreciates the opportunity to comment on the *Discussion Document on proposals for regulations under the Psychoactive Substances Act 2013 (February 2014*).

The Law Society's Health Law Committee considered the proposals for regulations and noted that it is clear many of the concepts and structures appropriately reflect other relevant legislation, such as the Medicines Act, Misuse of Drugs Act and regulations, and the Natural Health and Supplementary Products Bill.

The Law Society's comments are attached. If you wish to discuss the comments, please do not hesitate to contact the Health Law Committee convenor, Alison Douglass, through the committee secretary Jo Holland (04 463 2967, jo.holland@lawsociety.org.nz).

Yours faithfully



Chris Moore
President

Consultation questions

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

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

There does not seem to be any attention given to the information required from corporate applicants. It is likely that applicants will, for the most part, be incorporated companies. There therefore needs to be carefully drafted disclosure obligations on the directors and all shareholders of such 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?

Yes

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

Yes

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

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

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

The focus is on the applicant in order to determine whether the individual applicant or the body corporate is of good repute. Again, to be effective, this requires clear disclosure obligations upon all shareholders and all directors of the body corporate.

In addition, a grant of licences under s51 Medicines Act 1981 requires that every person proposed to be a responsible person for the purposes of a licence applied for has a sufficient knowledge of the obligations of a licensee and of the hazards associated with the products in which it is proposed to deal. This knowledge of obligations and hazards should be included in the assessment of whether a person or body corporate meets the fit and proper person test.

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

Yes. This should also include involvement in any medicine-related licensing processes or any involvement in products covered by the Natural Health Products and Supplementary Products Bill.

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

Consideration needs to be given to the permitted form in which records may be held, and in particular whether an electronic record may be permitted. In this regard it is noted that a sale of medicines register pursuant to the Medicines Regulations 1984 (Regulation 54A) may be recorded and kept electronically whereas, by comparison, a controlled drug register (Misuse of Drugs Regulations 1977 Regulation 39) is required to be kept as a physical record.

Attention will also need to be given to records of disposal of any psychoactive substance or product.

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

Entries in a controlled drugs register are required to be kept for 4 years (Regulation 42 Misuse of Drugs Regulations 1977) but this is overlaid by the general requirement to retain health information for 10 years in accordance with the Health (Retention of Health Information) Regulations 1996. Accordingly 10 years would seem to be a reasonable period for which records should be retained.

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

Other factors to be considered with regard to discretionary conditions may include:

- Security of storage of the psychoactive products on the premises. (e.g. out of reach of young children so as to prohibit ready access or a sale without supervision).
- Requirement for responsible persons to be named on the licence (in the same manner as is required for responsible persons to be name for a pharmacy licence under the Medicines Act).
- Whether there is a minimum height at which products must be stored.
- Whether there would be restrictions or a prohibition on sale by vending machine.

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?

Whether any director or shareholder of the applicant or any person having an interest in the applicant (where that is a body corporate) has failed to comply with these licensing requirements for any other body corporate in which they hold an interest.

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, plus information and data on safety of the substance. The Psychoactive Substances Regulatory Authority is responsible for ensuring products meet adequate safety requirements before they can be distributed, so it would make sense that information about safety should be provided with the application.

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

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

As for question 12.

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

Yes

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

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

Limitation on pack sizes e.g. limiting pack sizes to 1 dose (although this may be sufficiently covered by the imposition of quantity and dose requirements)

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

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

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?

Injectables should not be permitted due to the risk of that mode of delivery.

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

See comments above in response to question 8

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

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

There should be restrictions on the display of approved products such as advertising in shop windows and prominent displays on the counter etc – similar to the restrictions on the display of tobacco products.

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

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

Signage should not be permitted to encourage excessive use such as through special or discounted prices, “buy one get one free” type promotions or “gift with purchase” type promotions.

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

Petrol stations (which have similarities, in many cases, to dairies and convenience stores which are to be a prohibited place of sale) and pharmacies due to creating a false appearance of validity, safety and therapeutic use.

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

It is appropriate for there to be a requirement that any advertisement must be consistent with the Advertising Standard Authority's Advertising Code of Ethics.

However, medicines (as governed by the Medicines Act 1981) and controlled drugs (as governed by the Misuse of Drugs Act 1975) and Natural Health Products as proposed to be regulated under the Natural Health and Supplementary Products Bill, nevertheless contain specific restrictions on advertisements and prescribe requirements that must be met by advertisements.

For example advertisements for approved medicines are required to contain information about active ingredients, approved uses, certain warnings etc. It would seem inappropriate for advertisements for psychoactive substances to be less rigorously controlled. In particular there should be restrictions on any therapeutic claims in advertisements and requirements for appropriate warnings to be included.

There should be restrictions on bulk purchases or special deals (e.g. two for the price of one) or on gifts with purchase. These restrictions are similar to those that have been in place for a considerable period of time with regard to restrictions on the advertising of medicines to prevent inappropriate or excessive use.

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

The restrictions applicable to internet sales should be such that a person purchasing a product via the internet is in receipt of the equivalent level of information and subject to the same restrictions (in terms of age of seller and of age of purchaser for example) as would occur in a face to face sale such that the standards are not reduced in an online sale and purchase.

It should also not be possible to purchase more than one package per transaction.

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

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

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

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

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

This submission was completed by:		New Zealand Law Society, Chris Moore (President)
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Are you submitting this:
(Tick one box only in this section)

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

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.)

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.