Regulatory Impact Statement

Psychoactive Substances Regulations

Agency Disclosure Statement

This Regulatory Impact Statement (RIS) has been prepared by the Ministry of Health.

Regulations are required to end a transition period under the Psychoactive Substances Act 2013 and to put in place the regulatory detail necessary to meet the purpose of the Act. Interim licences and product approvals remain in force until regulations are made.

The content and purpose of the proposed regulations is constrained by the Act, and Cabinet decisions in the development of the Bill. This includes, for example, that product labels and packaging be subject to the same safety and other standards as medicines. Cabinet also agreed that the full costs of administering the Act be recovered from industry (CAB Min (12) 35/14). This will be achieved with one-off application fees and an annual levy on licence holders and product owners.

Total costs for the administration of the Act are assessed at approximately $3.8 million per annum over the next five years – a total of $19.1 million. Application fees reflect actual costs of assessment and processing. Levy costs were assessed over five years and divided by five to determine the annual levy. The proposed levies also seek to recover the net costs of establishing the Authority over the transition period (2013/14). The five-year approach was taken to provide certainty for applicants and to remove variation in fees across years when costs will be variable.

In the 2012 RIS on the Bill it was estimated that the cost of running the Authority would be around $1.2 million per annum.

The difference between the costs estimated in 2012 and in this RIS are predominantly due to experience of resource requirements during the transition period, and in particular:

- The size of the market is possibly 4-6 times bigger (in terms of turnover) than estimated prior to 2012. That affects the level of administration, increases the level of risk and consequently requires more resource;
- The role of the Authority has expanded since the development of the Act with the expectation of much greater community participation in retail licensing. This has resulted in indirect costs of liaising with the local government sector;
- The high level of community interest in the role-out of the psychoactive substances regime has persuaded the Authority to include provision for community liaison / public information.

A key unknown when setting fees and levies is demand - that is, how many applications there will be for new licences and products. Modelling of anticipated demand is based on demand for licences and products during the transition period.

The Act provides that the Minister must review cost recovery at least every three years. The review may make provision for under or over recovery of funding in previous years. The Ministry is mindful of the potential impact of demand on cost recovery and, if necessary, would recommend that the Minister conduct a review as soon as may be necessary.

The Act also provides that the Ministry of Health must review the Act within five years of its commencement. The Authority is gathering data, in liaison with other agencies, on the current state of the recreational drug market in New Zealand, including health and other impacts, to enable an assessment of how effectively the Act has achieved its purpose.

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Executive Summary

The Psychoactive Substances Act 2013 (the Act) commenced on 18 July 2013. The Act was the Government's response to concerns about:

- the availability of potentially harmful psychoactive substances with little or no control over their ingredients, potency, place of sale or purchase age; and
- the onus on Government to identify and determine if the substances are harmful before placing restrictions on them.

The Act established the Psychoactive Substances Regulatory Authority (the Authority) and established a transition period to enable immediate controls to take effect (such as prohibiting sales to minors and sales from dairies. The Act also provided for the interim licensing of industry participants and products to enable legitimate trade to continue. Those licenses and products continue in the market until regulations are made.

This RIS discusses three sets of regulations (although they may be made together):

Set 1 regulations on information requirements for licensing and product approval;

Set 2 regulations on harm minimisation and other controls, including infringement fees and forms; and

Set 3 regulations relating to fees and levies.

Set 1 focuses on the information required of product applicants and license holders. These requirements are highly constrained by the Act and best international practice for product testing. The proposals are anticipated by the psychoactive substances industry.

Set 2 regulations seek to minimise harm from the sale of products through the imposition of controls on aspects of the industry. The regulations draw on the experience from the regulation of medicines (eg, packeting and labelling) and alcohol (eg, internet restrictions). These regulations have a low cost impact on the industry but will significantly reduce risk.

Set 3 regulations deal with fees and levies. Cabinet agreed that the cost of administering the Act should be met by full cost recovery from the psychoactive substances industry. Over five years (2014/15 – 2018/19) the total cost is $19.1 million ($3.8 million per year). The one-off fees (based on actual costs) for different licence/ product approval types are as follows:

Research	Import	Manufacture	Whole -sale	Retail	Sell non approved products[1]	Product Approval	Additional Products
2,000	**2,500**	**19,000**	**7,000**	**12,000**	**2,000**	**$175,000**	**$10,000**

The annual levy for licence and approved product holders is proposed at:

Research	Import	Manufacture	Wholesale	Retail	Sell non approved products	Products
3,000	**7,500**	**42,000**	**6,000**	**7,000**	**2,000**	**87,000**

It is also proposed that regulations enable the Ministry to refund fees and levies, to waive fees and to set an hourly rate for any service not covered by fees and levies.

[1] A licence to sell a non-approved product allows someone with psychoactive substances (legitimately obtained) to on sell it to either a licensed researcher or a manufacturer.

Status Quo and Problem

1. In April 2011, the Law Commission tabled in the House its report Controlling and Regulating Drugs: a review of the Misuse of Drugs Act 1975. In its report, the Law Commission identified two related problems regarding the rapidly growing market in new psychoactive substances. Firstly, potentially harmful psychoactive substances are available with little or no control over their ingredients, potency, place of sale or purchase age. Secondly, the onus is on the Government to identify that these substances are available, and determine if they are harmful before placing restrictions on them. The Law Commission made 44 recommendations around establishing a new regime to address these problems.

2. In response to the Commission's recommendations, on 26 February 2013, the Government introduced the Psychoactive Substances Bill. Prior to the Act, all psychoactive products, that were not tobacco, alcohol, medicines or drugs listed in instruments under the Misuse of Drugs Act 1975, were legal for sale to anyone from anywhere. The importation of psychoactive substances was legal (unless regulated through the above legislation). There were around seventy known and registered psychoactive substances and many tens-of-thousands not registered or scientifically identified.

3. The Psychoactive Substances Bill was introduced amid growing concerns that untested or otherwise unassessed psychoactive products were being sold to minors, among others, from up to 1000 retail outlets, including dairies. Later information showed that there may have been 3,000-4,000 retail outlets selling 200-300 products. It was thought the market was around 25 million units at its height (earlier, BZP pills, and later packets of synthetic cannabis mainly in smoking form, such as Kronic and K2).

4. The Health Committee, when considering the Bill added a range of functions to the Authority including licenses to wholesale and retail, provisions for territorial authorities to develop local approved product policies, and expanded the role and reporting of the expert advisory committee. These increased functions have resulted in increased resource requirements for the Authority. In addition, the costs of establishing and operating a transitional regime are reflected in the costs to be recovered.

5. The Act commenced on 18 July 2013 with the purpose of regulating "the availability of psychoactive substances in New Zealand to protect the health of, and minimise harm to, individuals who use psychoactive substances." On enactment, the Act immediately outlawed the sale of any psychoactive products to minors or to anyone from dairies, supermarkets, service stations and liquor outlets, among other places.

6. The Psychoactive Substances Regulatory Authority (Authority) was established on enactment. In the eight months since enactment, the Authority has:

7. The Ministry has informed territorial authorities of their responsibilities under the Act and has assisted councils where they gave chosen to develop a local approved products policy (LAPP). To date, six territorial authorities have adopted LAPPs (Tasman, Napier, Hastings and Hamilton, Waipa, Matamata-Piako) and many others are in development. The Authority has placed a condition on interim licences to retail that the sale of approved products is subject to any territorial authority LAPP. The Authority has required that some retail licence holders stop trading pending consideration of their compliance with that licence condition.

8. Prior to the Act's commencement, there was little data on what psychoactive products were being sold or from where. The 2012 RIS included estimations that:

- at the height of their popularity, around 20 million pills containing BZP (a psychoactive substance) were sold each year with an estimated turnover of $25-$35 million per year (BZP is now a banned substance);
- synthetic cannabis was a similar sized market ($25-$35 million per year)
- 80 to 120 products were being sold from legitimate retailers; (the number of substances being sold casually (pubs, clubs etc) was unknown);
- there were around 10 major importers and manufacturers and around ten small-scale manufacturers;
- there were in excess of 1000 retail outlets.

9. The commencement of the Act and the transition period has enabled the Ministry to obtain more information about the size of the regulated market.

10. The Authority has granted licences to 155 retailers to sell approved psychoactive products. The Authority granted approval to 41 products as posing no more than a low risk of harm, of which 35 were designed to be smoked. The assessment of harm was based on pharmacovigilance data (including referrals to the Centre for Adverse Reaction Monitoring (CARM)) and sales figures.

11. Since the Act commenced licensed importers are required to declare how much psychoactive substance (the active ingredient) is being imported into New Zealand. (Prior to the Act it was not illegal to import most synthetic psychoactive substances). Over the six months since the Act's commencement, approximately 300-350 kilograms of active substance has been imported into New Zealand regulated under the Act. Between three and 3.5 million packets have been sold in this period at an approximate retail value of $70 million. Import and sales data is consistent. Based on these estimates, the estimated annual retail sales is around $140 million.

12. The Ministry understands that the profit margins for product owners, manufacturers and sellers are extremely lucrative. Synthetic psychoactive substances typically, are imported from China at around $1,500-$2,000 per kilogram. A kilogram of psychoactive substance is sufficient active ingredient to manufacture around 10,000 small-medium sized packets of smokable product. The most popular products sell in packets of 1.5 to 2.5 grams. The Ministry understands that the cost of manufacturing a product (packet and contents) is around $1-2 per packet.

13. Packets retail at around $20. A $2,000 outlay for psychoactive substance by an importer/manufacturer could therefore yield around $200,000 gross turnover at retail.

Problem definition

14. The Act established a transition period in which immediate industry controls were put in place pending the development of a robust regulatory framework and third-party funding.

15. The heart of the problem is described in the RIS for the introduction of the Psychoactive Substances Bill. In it the Ministry of Health advised:

> There is a demand for psychoactive products, some of which is met through the market in party pills and other legal highs, but much of which is met through the black market for controlled drugs. The challenge for the new regime is to strike a balance between ensuring that there are robust controls over legal psychoactive substances and that these controls are not so restrictive that users meet demand entirely through the black market.

16. The Act is predicated on the Authority being able to regulate the availability of psychoactive products. To achieve this, the Act gives the Authority the ability to regulate the psychoactive product market from the importation of psychoactive substances, to the manufacture, wholesale and retail of products, and to monitor effects in the market and to users.

17. In particular, regulations are required to end a transitional regime established under the Act, where:

- 41 products have interim approval but have not been tested to the extent anticipated by the Act;
- no new products will be able to enter the market and therefore there would be no potential for innovative products or methods of use (such as vaporisers which might be a safer way of consuming a psychoactive substance);
- many retailers will be subject to LAPPs and many may have their licences cancelled (around 10 retailers are already affected by a LAPP);
- a range of other licence holders will be locked into the market, both without competition and without being subject to new licensing requirements and conditions;
- anticipated linkages between the code of manufacturing practice (which currently is being implemented) and product approval requirements will not be made, leaving important gaps quality control and the ability to track substances and products;
- record-keeping, storage and audit requirements will not be put in place to ensure the Authority can trace bulk psychoactive substances and wholesale and retail sales records;
- harm minimisation and other regulatory measures, including controls on internet sales may not be put in place; and
- there would be no mechanism to raise funding necessary to meet the direct and indirect cost of administering the Act.

18. Each of the above situations would result in unattended risks and would seriously undermine the Authority's ability to regulate the industry in such a way as to achieve the Act's purpose.

Objectives

19. The primary objective of the Regulations is to give effect to the purpose of the Act which is to "regulate the availability of psychoactive substances in New Zealand to protect the health of, and minimise harm to, individuals who use psychoactive substances." The public and the industry must have confidence in the regulations.

20. To achieve this, the regime needs to include controls that enable the Authority to:

- approve products that pose no more than a low risk of harm to the user;
- monitor the manufacture of products and audit product safety;
- verify the character of persons legitimately within the psychoactive market (the Act provides a fit and proper person test);
- approve places of sale, including internet sites, and monitor compliance
- track and trace psychoactive substances from their importation, through manufacture and sale;
- audit sales records;
- ensure that products are presented appropriately (eg, tamper proof and with appropriate health warnings);
- ensure advertising and other marketing strategies are compliant;
- monitor post-market reports of adverse effects of users.

Criteria

21. The criteria used for assessing regulations are:

Health protection – in line with the purpose of the Act, the regulations will aim to protect the health of, and minimise harm to, individuals who use psychoactive substances.

Proportionality – any burden created by regulations (for example, a cost to a licence applicant) should be in proportion to its corresponding benefit.

Certainty – the regulations must be unambiguous so that anyone needing to comply with them is clear about what is required. Any criteria and processes in the regulations should be clear.

Durability –the regulations must be flexible enough to respond to change.

Options

22. The proposed regulations will be discussed in three sets:

    Set 1 regulations on licensing and product approval requirements,

    Set 2 regulations on harm minimisation and other controls, including infringement fees and forms;

    Set 3 regulations relating to fees and levies.

Set (1) Regulations relating to licensing criteria and product approvals

Licensing

23. Licensing is the means by which the Authority can assess the character and circumstances of licence applicants for importing, researching and manufacturing, and selling (wholesale and retail) psychoactive substances and products. Licence applicants are required to provide any information required by the Authority and prescribed in regulations.

24. The Act requires licence applicants to meet a fit and proper test. This test includes the applicant not having convictions under the Medicines Act, Misuse of Drugs Act, and parts of the Crimes Act. If the applicant is a company, the company must be of good repute. In order to assess whether an applicant meets the fit and proper person or good repute test, appropriate personal information must be included on the application form.

25. The proposed regulations relating to licence applications will specify the types of personal and other information that must be provided to the Authority sufficient to ensure that police checks can be undertaken. This would include information such as, residential address, date of birth and gender.

26. Applicants will be required to verify their identity either through the Government's RealMe service, or by an approved alternative (such as a verified copy of a passport).

Requirements relating to corporate applicants

27. The Authority is required to consider whether or not a licence applicant that is not a natural person is of good repute. Such an applicant might be in the form of a company or trust, whether publicly or privately owned.

28. During the interim period, many of the significant applicants in importation, manufacture and wholesale of psychoactive substances and products, were companies. Given the potential street value of the substances and products being regulated and potential links to criminality, and the potential for products to be harmful in nature, it is appropriate that senior decision-makers in the industry within companies also meet the fit and proper person test required of applicants that are natural persons.

29. The Authority therefore considers it important, for public confidence and to mitigate compliance risks, to be able to check through police and territorial authority processes:

    - senior company officers (to second tier managers) and
    - significant shareholders (30 percent) or
    - trustees in the case of a trust.

30. The application rules include provision for the Authority to require personal information from licence applicants that are not natural persons to enable a due diligence assessment on key personnel, company owners, and trustees.

Impact on Industry

31. The information required of licence applicants will be readily at hand and will have no impact on applicants' ability to make an application. Any compliance costs would be insignificant. Associated persons requirements will have an insignificant impact on applicants.

Impact on local government

32. The local government sector considers the fit and proper test is appropriate and has requested to be consulted in respect of retail applicants. The regulations will have a minor fiscal impact on local government but will enhance territorial authority confidence in the persons selling psychoactive products within their communities.

Impact on communities

33. The proposed regulations will not impose costs on communities, however, the process for assessing the character of licence applicants will provide additional assurance to communities that licence-holders are of appropriate character.

Criteria	Status Quo	Proposed regulations
Health protection	No new applications and therefore no further checks on applicants Aspects of CMP not complied with	Enables new products to be safety tested. Full compliance with CMP New licence applications accepted
Proportionality	Does not contribute to meeting the Act's purpose	Minimal cost to applicants. Significant assistance to government checking the identify and suitability of licence applicants
Certainty	No certainty during transition period	Regulations will make new application requirements clear
Durability	No durability during transition period	Regulations on licence applications will suit the Authority's and Police vetting requirements.

Product approval applications

34. Any New Zealand resident (including bodies corporate) may apply to the Authority for approval of a psychoactive product. Any application must be in the form or manner approved by the Authority and include any information prescribed in regulations.

35. Products must be approved by the Authority as posing no more than a low risk of harm to the user. The Act specifies a ride range of matters that must be considered when assessing product safety, including pharmacological, psychoactive, and toxicological effects; and the risks, if any, to public health and the potential appeal to youth.

36. The Act established an expert advisory committee to assess the risk of harm of proposed products and to advise the Authority accordingly. The expert committee has advised the Authority on the types of information that must be provided with product approval applications (and the tests required to produce that information) to enable it to assess the risk of harm for these products. The expert committee and the Ministry have agreed that a pharmaceutical approach is necessary to produce this information and that testing should be based on the framework provided by the International Conference on Harmonisation Guidelines (as amended from time to time).

37. This approach is similar to that used by Medsafe (the Government's drug safety authority) and will provide a robust, internationally recognised product safety framework.

Proposed regulation

38. The regulation will specify that product approval applicants must provide the following information, documents etc to the Authority:

- the product name, formulation (including ingredients and quantities), recommended dosage and frequency of dose;
- how the product is to be administered;
- proposed packaging and label specimens, including different pack sizes;
- evidence that each proposed manufacturing facility is licensed and meets the requirements for Good Manufacturing Practice (GMP);
- the name and address of each proposed manufacturing and packing facility;
- information derived from the results of all medical, physiological and psychological trials and where the effects of the psychoactive substance and/or psychoactive product have been specifically investigated with regard to, but not limited to, the chemical, pharmacological, psychoactive and toxicological effects, and the abuse potential and related behavioural and social effects;
- a detailed plan of how the risk of harm posed by the psychoactive product will continue to be monitored and managed once the product is approved;
- any other information or particulars considered by the Authority to be relevant, and as outlined in guidelines issued from time to time by the Authority;
- material must be accompanied by a completed application form as published by the Authority; and
- the application must be accompanied by the prescribed fee.

39. The guidelines referred to above relate to the methods that may be used to provide the information prescribed in regulations. They will be based on the International Conference on Harmonisation (ICH) Guidelines which is the internationally recognised framework for medicines assessment. The ICH guidelines are not intended to be included in the regulations because:

- they include some trials not relevant to psychoactive substances and products; and
- they are subject to review and change as science and best practice develops which would constantly require updating the regulations.

40. The Ministry's estimates, based on Medsafe and industry information, that this testing could cost in the range of NZ $1 million to NZ $2 million per product for a full product application. In the Ministry's view, the per product cost of testing is likely to fall significantly over time as:

- the results of testing on substances develops and becomes more robust;
- results of trials on some substances will contribute to knowledge about other products which contain the same substances.

Impact on Industry

41. It is estimated that providing the information for full product applications would be between $1 million to $2 million. This does not include the cost of product discovery, manufacturing or protection of intellectual property.

Impact on local government

42. No financial impact but greater certainty about product safety.

Impact on communities

43. No financial impact but greater certainty about product safety.

Criteria	Status Quo	Proposed regulations
Health protection	No new product applications Interim products not fully tested Limited compliance with code manufacturing practice (CMP)	Enables new products to be safety tested Full compliance with CMP New product approval applications can be made
Proportionality	Objective not met	Testing requirements commensurate with risk Significant costs to product applicant (possibly $1m- $2m) proportional to the rate of return.
Certainty	No certainty during transition period	Regulations will make product and licence application requirements clear Compliance with CMP clear
Durability	No durability during transition period	Regulations on licence application and product requirements will be responsive to the Authority's requirements and changes in product testing.

Set 2 Regulations relating to harm minimisation and other controls

44. Section 101 of the Act provides for regulations to be made covering a range of harm minimisation and other controls. The table below sets out the proposed regulations to be made in respect of that provision.

Place of sale restrictions	Specify the characteristics of the types of premises from which approved products can be sold. This includes residential places where minors might inadvertently enter not knowing psychoactive products were being sold from the premises.
Internet sales	Internet site must be approved by the Authority Only internet sites owned by a licensed retailer may advertise approved products Internet sites cannot appeal to minors and must seek to prevent access to minors Age verification processes on internet sales mandatory.
Labelling restrictions or requirements	Approved by the Authority Prohibition on offensive language Restrictions on labels appealing to minors Requirements for labels to clearly show a bar code, batch number, expiry date, recommended dose.
Packaging restrictions or requirements	Packaging to be approved by the Authority Packets to be tamper proof and not to appeal to minors Prohibiting the use of offensive language or images on packets Specifying what information will be required on inserts to the packet (the small packet size means not all information may be able to be presented on the packet).
Health warnings	Requirements for labels to include health and safety warnings relevant to the substance (eg, not to be taken when pregnant or breastfeeding; not to be consumed with alcohol or other drugs).
Prohibitions on form of approved products	Prohibiting intravenous products, products in liquid form.
Quantity, dosage and serving restrictions or requirements	Specifying of minimum and maximum weight and dose contained within packets.
Storage, display and disposal restrictions	Specifying that products must be stored and displayed in a manner that is not visible from outside the premises.
Prescribing a telephone helpline service	Specifying the telephone number of helpline services.
Record-keeping requirements	Specifying the sales records that must be kept and the form in which they must be kept Specifying audit requirements and duties of licence holders to provide information.

45. The regulations will impose immediate controls on the retail market, and pre-market activities. Controls on internet sales, a purchase limit, mandated warnings,

labelling and product display rules will support public safety and enforcement efforts.

46. Internet sales will be subject to the same rules as on-line alcohol sales. Buyers will have to confirm their age is 18 or over before entering the site, and at the time of purchase. Websites will have to display health warnings and the licence details of the seller. Licence-holders will have to inform the Authority of all websites they intend to sell from.

47. The regulations include a limit of five packets per retail transaction. There was strong support from submitters for a limit on purchase amounts. Retailers advise people have been buying up to 100 packets at a time from towns close to Hamilton (which has no licenced retailers at present). There are risks from this activity, including possible harm to users. The ability to purchase an unlimited amount of approved product, however, risks illicit on-selling to minors and others. A purchase limit will help reduce that risk. The limit is based on sales figures from a retailer with five stores, showing that the average purchase is less than two packets.

48. The Act provides for infringement offences for:

- persons under the age of 18 years buying or possessing an approved psychoactive product;
- supplying an approved product to someone under the age of 18; or
- personal possession of a psychoactive substance that is not an approved product.

49. The Act provides for regulations to be made specifying the infringement fee payable for the commission of an offence and providing for the form of infringement notice. The Ministry and Police (who enforce the infringement system) have agreed to that the infringement fee should be $300. This is consistent with other infringement regimes.

Impact on Industry

50. Minimal or no financial impact on the industry. The above proposals will have a minor impact on industry. Proposed prohibitions (not selling products for intravenous use) and labelling and packaging standards will have an insignificant impact on product price. The Ministry understands that the cost of printing and packaging is around fifty cents per item for a standard packet which retails for around $20. Record-keeping regulations will require licence holders to have good financial systems and the audit requirements will impose minor costs on industry.

51. In considering restrictions on internet sales and the verification of age, the Ministry has considered the approach of the Ministry of Justice in its RIS on the Sale and Supply of Alcohol. The Ministry accepts that sellers cannot differentiate between credit and debit cards and that therefore the purchaser's use of a debit card cannot be used as a proxy for age verification. The proposed approach requires remote sellers to verify the age of purchasers. This could include using the government's RealMe service, or other documentation. The minimum requirement will be that the purchaser declares, on entry to the site and before making a purchase, that he or she is over 18 years of age. This approach is consistent with the sale of alcohol over the internet.

52. Restricting the size of purchases to five packets per transaction does constrain trade. However, this constraint will have little impact on legitimate sales as almost all purchasers buy less than five packets per transaction. It will, however, significantly reduce the risk of people buying in bulk from retailers and selling it on.

Impact on local government

53. No financial impact but proposals support the local government community's view that harm minimisation is important with the sale of psychoactive products.

Impact on communities

54. No financial impact but proposals support the local government community's view that harm minimisation is important with the sale of psychoactive products.

Criteria	Status Quo	Proposed regulations
Health protection	Inadequate controls over packaging, labelling, health and safety information, dose and storage of products and controls over financial records	Improved controls
Proportionality	The controls are not commensurate with the risks posed by psychoactive products	Controls are proportional to risk. Many controls based on Medsafe approach to risk management around pharmaceutical products. Costs to industry are minor, but the public health and safety benefits would be significant.
Certainty	No certainty during transition period. Key regulatory controls missing and some controls unclear.	Currently the lack of regulation has left gaps in the control of the psychoactive substances industry. Regulations will make the regulatory system more certain for the Authority and industry participants.
Durability	No durability during transition period	Authority discretion to approve products, labels, packaging, and internet sites among other things will mean these regulations will continue to be fit for purpose.

Options not considered or rejected

55. A number of options were not considered for inclusion in the regulations or considered and rejected.

56. For example, the Authority did not consider plain packaging given that the law relating to plain packaging is currently unclear. It considered but rejected including on psychoactive product packets and labels the same health warnings as required on cigarette packets under the Smoke-free Environments Act. This was rejected outright as a proposal for all products because in the future many products may not be smokable. Even for the smokable products, the risks associated with these products is unknown and may be less or more than the herbal component.

57. The Ministry did not consider price controls to regulate demand on psychoactive products. Cabinet considered this issue during policy development on the Bill and decided to revisit the issue once more was known about the size of the market, and the impacts of price.

Set 3 Regulations relating to fees and levies

58. Cabinet has agreed that fees and levies made under the Act will be sufficient to meet the direct and indirect costs of administering the Act. The policy objective is to internalise the costs of the psychoactive substances industry, within the industry, and to minimise externalised costs to government and communities.

59. In 2012 Cabinet was advised that the estimated annual costs of administering the Act could be $1.2 million. To recover these costs, a fee of $180,000 plus GST per product was proposed per application. Assuming that the regulator will receive 24 applications in the first four years, full cost recovery would be achieved by 2015/16.

60. Since then, the Ministry has had the benefit of the transition period with interim licensing and product approvals. It has based demand for licences and product approvals on the number of applications, licences and approvals granted during this period (from commencement in July 2013 until regulations are made allowing full applications to be made).

61. This period has also provided the Ministry time to assess the costs of running the Ministry given:

- the broader range of functions introduced during the Parliamentary stages of the Bill;
- the size of the interim market is potentially eight times higher than earlier estimates (and the inherent risks and administrative costs this brings);
- the ongoing (and anticipated) costs of providing policy advice on the Act to Ministers and in developing Ministry policy with other agencies to ensure the agency legislation works together);
- original estimates of costs were based on post-market surveillance, whereas the Authority considers there is a need to track and/or trace psychoactive substances from importation to retail sale;
- high degree of community concern about the sale of psychoactive products in their communities. For the Act's purpose to be met, the public will need a high level of confidence in:
  - the ongoing monitoring of the level of harm of products
  - ongoing monitoring of retail sales
  - the way that Authority interacts with territorial authorities and their communities;
- the high degree of international interest in the New Zealand approach to regulating psychoactive substances and products and New Zealand's regulatory reputation if the Act's purpose is not achieved;
- the importance of good quality information to support current and any further interventions.

62. The Ministry also proposes a fee and levy structure better designed to internalise the costs to licence applicants and product owners. Licensing costs have been separated from ongoing regulatory costs because:

- all licence and product approval applicants pay the relevant fee;
- licence applicants pay a fee for a three-year licence;
- product approval applicants apply for approval in perpetuity (once approved, they continue to be legal unless cancelled because of concerns about the risk of harm they might pose); and
- only successful applicants (those benefiting from being a participant in a regulated industry) pay the annual levy.

Objective in setting fees and levies

63. The fees and levies are proposed at level that will recover the full direct and indirect costs of administering the Act.

64. The Act provides that fees and levies and other charges be set at a level to meet direct and indirect costs of administering the Act, other than where funding is appropriated by Parliament. Cabinet agreed that the new regulator manage assessments, approvals, licensing, and post-market surveillance of low-risk psychoactive products, and that the regulator be funded through full cost recovery. (CAB Min (12) 35/14).

What costs are being recovered?

65. Section 90 provides for the recovery of "the direct and indirect costs of administering the Act, that are not provided for by money appropriated by Parliament, through fees, levies and otherwise". This includes the direct and indirect costs by the incurred by:

- the cost of establishing the Psychoactive Substances Regulatory Authority established under section 10 of the Act;
- the Authority's ongoing costs, including the costs of services incurred within the Ministry (such as legal, financial, policy and general overhead);
- the cost of enforcement officers appointed under section 76 of the Act and their activities;
- the costs associated with the Psychoactive Substances Expert Advisory Committee established under section 11 of the Act to consider product approvals; and
- incidental costs associated with the establishment of an infringement system.

66. The proposed fees and levies will not recover any broader social costs incurred on society as a result of the Act (for example, for police enforcement, the health system and correction services). There is no statutory authority to recover these costs through fees and levies.

What costs are recovered through application fees and what costs are recovered through levies?

67. Licence and product approval fees are based on an assessment of the actual costs of receiving, researching, considering each and making a decision on every application (for licence or product). Costs have been attributed as closely as possible to the beneficiary. The amount of the fees differs considerably because of the level of resource required to consider and determine each type of application.

68. Levies will be met annually by licence holders and approved product owners. Levies were calculated based on:

- the direct costs of compliance were charged against the licence group wherever possible (eg, monitoring retail compliance was charged against retail licensees; monitoring compliance with the code of manufacturing practice was charged against manufacturer licence holders);
- where all of the industry benefited from a service (eg, website development) the costs were split between licence categories so that these costs were shared across the industry.

69. The Authority has assessed the total costs of administering the Act over the next five years at $19.1 million ($3.80 million per year).

Authority Establishment Costs

70. The Authority was established by section 10 of the Act on July 18 2013. The Act provided that the Authority undertake a number of duties immediately on establishment, including developing and implementing an interim licensing system for psychoactive substance industry participants and for approving products. Licence fees were raised for this purpose, but the net cost to the Ministry is around $600,000. These costs are included in the levy and are spread across the industry over the years 2014/15 to 2018/19.

Licence fees

71. The Act provides for the Authority to grant licences to:

- research psychoactive substances;
- import psychoactive substances;
- manufacture psychoactive substances;
- sell approved products by wholesale;
- sell approved products by retail; and
- sell psychoactive substances that are not approved products[2].

72. The proposed licence fees are:

Research	Import	Manufacture	Wholesale	Retail	Sell non approved
2,000	**2,500**	**19,000**	**7,000**	**12,000**	**2,000**

73. All licence applicants are required under the Act to meet a fit and proper test (corporate entities are required to be bodies of good repute). As part of the Authority's due diligence, it will need a full police check of all licence applicants. The Ministry of Health costs of obtaining this information is included in the consideration of the licence fees. Provision has not been made to recover the Police costs incurred in providing information (or not) on licence applicants.

Research licence application fees

74. Researchers generally are associated with a manufacturer and are involved in product development. Researchers associated with educational institutions or government science advisors will not be charged a licence fee because their activities are in the public rather than commercial interest. Research licence applications will not require significant service provision other police and other due diligence checks.

[2] This licence allows a person to sell psychoactive substances to a licensed manufacturer or researcher.

Import licence application fees

75. An import licence permits the licence holder to import psychoactive substances and products. To do so, importers must be associated with a licensed manufacturer or researcher. No significant compliance checks are required other than police and other due diligence checks.

Manufacturers licence application fees

76. Fees for a manufacturer's licences are significantly above the cost of police and other due diligence checks. The addition costs are incurred because of the level of compliance checking with the code of manufacturing practice (CMP). It is a mandatory condition of a manufacturer's licence (under section 18 of the Act) that they comply with the CMP at all times. Applicants for a manufacturer's licence will be required to demonstrate that they can achieve and maintain the code's standards. The fees will include the costs of assessing compliance, including site visits and checking equipment.

Fees for licence to sell psychoactive substances that are not approved products

77. This licence allows a person who has a psychoactive substance to sell that substance only to licensed researchers or manufacturers. The licence application fees reflect that there are nominal checks other than police and other due diligence checks.

Wholesale licence application fees

78. This licence allows for people to buy psychoactive products from manufacturers for supply to retail outlets (including internet sales). There are nominal checks proposed other than police and other due diligence checks. Wholesale licence applicants will hold large amounts of psychoactive substance and product, and will have to transport the product. This poses risks that the Authority will require them to mitigate with systems checks such as having a secure vehicle, in which to transport substances. The wholesale fee will cover the cost of the Authority undertaking the additional compliance checks.

Retail licence application fees

79. Retail licence applications are required to comply with section 52 of the Act which specifies a range of types of premises from which psychoactive products may not be sold. This includes dairies, supermarkets, convenience stores, liquor outlets and service stations. It has taken a considerable Authority resource undertaking this function in the transition period under the Act. The estimated costs incurred by the Authority in undertaking the necessary checks on premises, including the costs of enforcement officer checks, is included in the cost of retail licence application fees.

80. Regulations will require retail licence applicants to obtain confirmation from the relevant territorial authority either that: they do not have a local approved product policy (permitted under section 66 of the Psychoactive Substances Act), or if they do, whether or not the premises is in a location that complies with the LAPP. The Authority will not consider a retail licence application that does not comply with a LAPP. The retail application fees include provision for the Authority and its enforcement officers to check retail premises' compliance with section 52 of the Act and the costs of the Authority liaising with the relevant territorial authority.

Product approval fees

81. The Act's purpose is to regulate the availability of psychoactive substances to protect the health of and minimise harm to users of psychoactive substances. The public health approach that sits behind the Act is that a regulated market of tested products will pose less risks for users than either:

    - illicit street drugs (eg, methamphetamine) or
    - untested synthetic psychoactive products either being sold underground or being sold legitimately because of the ineffectiveness of prohibitions.

82. The key to the effectiveness of the Act will therefore be the lawful availability of products that will produce a psychoactive effect but will pose no more than a low risk of harm in the user. Given the importance of the relative safety of each product, the Act specifies the process that the Authority must follow for considering product approval applications including:

    - requiring advice from a Psychoactive Substances Expert Advisory Committee established under the Act for that purpose; and
    - specifying the matters that PSEAC must and must not consider in providing its advice.

83. The key costs incurred in the assessment and consideration of product approval applications are the cost of engaging the relevant expertise to determine:

    - the pharmacological, psychoactive and toxicological effects of a product
    - risks to public health
    - the potential for a product to cause physical or psychological dependence or death
    - the likelihood of misusing the product
    - potential appeal to vulnerable populations.

Additional product approval

84. The Ministry proposes to develop a new product category "additional product approval" which will apply to products with the same psychoactive ingredients (other than flavours or packet size).

85. Currently all product applications are subject to the same fee. However, the experience during the transition period was that some product owners produced packets of product in different sizes (eg, 2.5, 5 and 7 grams) and in different flavours. In the Authority's view, it would be inequitable to charge the same fee for two products with the same risk profile for the same applicant. It is proposed that the cost of the "additional product approval" will reflect the requirement for the expert committee to consider the additional product and to assess whether the non-active ingredients or different sized packet affect the risk profile of the product.

86. The proposed product fees are:

New Product Approval Fee	Additional Product Approval Fee
$175,000	**$10,000**

Options

87. In establishing licence fees, the Ministry is heavily constrained by principles of cost recovery and other requirements under the Act, and Cabinet's decision that the industry meet the full costs administering the Act. The status quo, of not setting fees levies is not a practicable option.

88. The Authority did consider the not having an additional product approval fee. This would have had the effect of reducing the cost of new product applications to around $65,000. However, applicants would be required to meet the $65,000 for every new product, including those that pose minimal additional risk. Under that option, total product approval fees for one product in two flavours and three pack sizes, would cost $325,000. Under the proposed approach, the total product approval fee would be $210,000.

Levies

89. Industry levies have been calculated as follows:

Step 1 Demand for licences and product approvals was estimated, based on figures experienced during the transition period;

Step 2 Costs of administering the Act, less the costs of licensing and product approvals, were determined over five years sufficient to respond to the anticipated demand, and the perceived levels of risk; and

Step 3 Indirect costs were spread, as closely as possible to the demand from each licence type or as overheads.

90. A five year period was used because the Act is under review after five years, and the Ministry considers it will take this period for the Authority to be fully established with a new regulatory regime, with a stable product and retail environment. A longer term outlook was taken to recover set-up costs over a longer period to spread the burden. Furthermore, the five year outlook provides industry certainty given the long lead time for product testing and development and certainty on their annual costs.

91. Examples of costs charged against the levy are:

- establishing and operation of running the Authority,
- maintaining and deploying enforcement officers for non-licensing activities (such as spot visits to manufacturing facilities or retail premises to check compliance with the Act, regulations or licence conditions);
- Operation of the psychoactive substances hotline 0800 789 652
- Maintenance of dedicated databases and website
- Reporting system for adverse effects
- Public health promotion (and supporting work of PSEAC)
- policy advice on the administration of the Act and administration of regulations; and
- stakeholder engagement, for example, between the Authority police or customs enforcement matters.

92. The estimated gross costs for the first five years of operation of the Authority (2014/15 to 2018/19) are as follows:

Expenditure	Cost $
Salaries and staff operational (training, travel, other)	4,250,000
Direct operating costs	
Code of practice for manufacturers	26,000
Data/IT requirements	16,000
Testing programme (complaints, and monitoring etc)	2,160,000
Legal/enforcement	1,200,000
Retail surveillance	1,738,500
Complaints	470,250
Other pre-market surveillance (manufacturing)	220,400
Total direct operating costs	5,831,150
Corporate Overheads	3,268,000
TOTAL	13,349,150

93. licence type, have been charged against the product levy. This includes the following costs (over five years). This includes

- 70 percent of all information technology system costs were charged against product levies;
- 60 percent of the product testing programme were charged against product levies (the remainder was charged against manufacturers): and
- 50 percent of legal and enforcement costs were charged against the product levy).
- The Code is based on New Zealand's approach to regulating pharmaceuticals and takes into account international best practice in chemical manufacturing.details on what psychoactive substances and products are manufactured in the facility, the dose forms (products only), the number (and dates) of batches produced since commercial production began, the batch sizes, and number of individual units produced (products only);
- information on the source, quantity and quality of the psychoactive substance in any psychoactive product, presented as certificates of analysis[3]
- agreed specifications (quality tests) that any psychoactive substance and product manufactured must meet before it is released to be sold
- specifications on how the manufacturing facility will move to a fully certified environment.

94. The proposed annual levies are:

Research	Import	Manufacture	Wholesale	Retail	Sell non approved	Product
3,000	**7,500**	**42,000**	**6,000**	**7,000**	**2,000**	**87,000**

95. The most sensitive variable in setting the cost of fees and levies is demand. Should there significantly greater demand for licence applications than anticipated,

[3]A certificate of analysis refers to an authenticated document that is generally issued by Quality Assurance that ascertains that a product has met its stated specifications.

the cost for processing applications and running the Authority may reduce per licensee / and product.

96. Furthermore, a key factor in the cost of determining licence applications is the cost of due diligence testing of applicants. If an applicant applies for multiple licences at the same time, there would be need for only one assessment of their compliance as a fit and proper person.

97. In either of these eventualities, the Ministry needs the capacity to refund any unreasonable liability. This is permitted under section 95(2)(d) of the Act.

Hourly rate

98. The regulations also include the ability for the Authority to set an hourly rate for services to the industry that are not covered by licence and product application fees or the levy. The Ministry considers that the high level of public interest in psychoactive substances, the high level of potential harms that can affect users of psychoactive products, the high levels of profitability and potential links to crime that is associated with the industry, necessitates a strong regulatory presence. That starts at the importation of substances, manufacturing, wholesale and retail compliance.

99. The Ministry considered a light-handed regulator option with reduced staff resource and fewer compliance audits for manufacturers and retailers (from four site visits to two per premises per year). That led to total expenditure reducing from $19.1 million over five years to $17.3 million. This would have a minor impact on the levy liability.

100. Possible annual levy charges under this option would be:

Research	Import	Manufacture	Wholesale	Retail	Sell non approved products	Product
2,600	6,500	38,000	6,500	6,000	2,000	85,000

101. The Ministry considers that the reduction in industry compliance monitoring would result in significant additional risks to the public that outweigh the resulting benefit to the industry.

Impact on Industry

102. The costs to industry through fees and levies are significant. The costs of administering the Act, including considering licence applications, are estimated at around $3.8 million per year.

103. The Ministry estimates, based on psychoactive substances importations and sales data from six months (August 2013-January 2014) that:

- annual industry turnover at retail is approximately $140 million;
- based on a 100 percent mark-up, $70 million was retained by the retail sector and the remaining $70 million was predominantly spread across the product owners, manufacturers and wholesalers.

104. There are currently 42 products with interim approval owned by 12 product owners. If 25 percent of the estimated retail turnover remained with the product owners, on average each would make around $2.9 million.

105. There are 10 manufacturers. If they were to retain 25 percent of the estimated retail turnover, each would retain around $3.5 million.

106. There are 155 licensed retailers. The Ministry understands that the retail mark-up on each product is at least 100 percent. Therefore, if $70 million of the $140,000

gross retail turnover was retailed at retail, each retailer would retain over $450,000 per year.

107. Profitability within the industry is likely to be very high. A $20 packet of psychoactive product at retail can be made for $1-2.

108. Some industry participants, particularly the smaller manufacturers and product owners may struggle to meet the costs of fees and levies. However, in the Ministry's view, these operators would likely struggle meeting compliance standards, for example, the requirements of the code of manufacturing practice. The Ministry does not consider that the cost of the levy or application fees will have a significant impact on the psychoactive substances market, or the ability to enter the market.

109. In the Ministry's view, given the potential risks of harm for product users, the level of profitability within the industry and the inherent risks this entails including potential links to criminal activity, a robust regulatory environment is necessary. The application fee and annual levy costs reflect this view.

Impact on local government

110. No financial impact. Greater confidence in the effects of psychoactive products and confidence in regulatory controls.

Impact on communities

111. No financial impact. Greater confidence in the effects of psychoactive products and confidence in regulatory controls.

Criteria	Status Quo	Proposed regulations
Health protection	No funding for the administration of the Act. Very limited ability for Authority to specify and monitor industry compliance	Act can be fully operational with harm minimisation regulations put in place, and compliance monitorerd. This includes ensuring products manufactured to specification, with relevant health warnings and sold at compliant premises. Improved confidence by product users as to the health impacts thereby providing a relatively safe alternative to untested or illicit products.
Proportionality	Controls not commensurate with the risks posed by psychoactive products. No ability to specify or monitor industry compliance.	The cost of licence applications and product approvals reflect actual costs. Those costs are proportional to the risks. Levy costs are attributed as closely as practicable to the beneficiary, and reflect perceived risk.
Certainty	No certainty. Interim licences remain and no funding to assess new licence applications. No funding for compliance monitoring would undermine confidence in products and community confidence in the regulatory regime.	The Act will be operating as intended with controls in place. Industry will know that the Authority is funded to put controls in place and to monitor compliance. This will improve compliance levels resulting in improved public and user confidence.
Durability	No durability during transition period.	Authority will be funded to ensure the Act and other regulatory controls can

		be fully operational and responsive to risks as they arise.

112. It is recommended that the psychoactive substances regulations deal with three matters:
    - information required of product applicants. The regulatory settings are highly constrained by the Act and best international practice for product testing.
    - harm minimisation and other controls, such as labelling and packaging, prohibitions on how the products might be used;
    - fees and levies to internalise the costs of regulating the industry.

113. The recommended fees and levies are as follows:

Licence and product approval fees

Research	Import	Manufacture	Wholesale	Retail	Sell non approved products[4]
2,000	**2,500**	**19,000**	**7,000**	**12,000**	**2,000**

Product Approval	Additional Products
$175,000	**$10,000**

Annual levy

Research	Import	Manufacture	Wholesale	Retail	Sell non approved products	Products
3,000	**7,500**	**42,000**	**6,000**	**7,000**	**2,000**	**87,000**

114. Regulations will enable the Ministry to refund fees and levies, to waive fees and to set an hourly rate for any service not covered by fees and levies.

115. The Act provides that the Minister must review cost recovery at least every three years. The review may make provision for under or over recovery of funding in previous years. The Ministry is mindful of the potential impact of demand on cost recovery and, if necessary, would recommend that the Minister conduct a review as soon as may be necessary.

116. The Act also provides that the Ministry of Health must review the Act within five years of its commencement. The Authority is gathering data, in liaison with other agencies, on the current state of the recreational drug market in New Zealand, including health and other impacts, to enable an assessment of how effectively the Act has achieved its purpose.

117. The Minister responsible for the administration of the Act is required to consult any person or organisation that the Minister considers to be representative of the interests of persons likely to be substantially affected by the proposed regulations (section 99(2)(c), section 101(2).

118. To this end, a consultation document was circulated to:

    - interim licence holders and unsuccessful interim licence applicants,
    - industry representatives,

[4] A licence to sell a non-approved product allows someone with psychoactive substances (legitimately obtained) to on sell it to either a licensed researcher or a manufacturer.

- all territorial authorities,
- relevant health sector organisations,
- NGO groups such as the New Zealand Drug Foundation;
- relevant government agencies; and
- DHBs and enforcement officers.

119. The consultation document was posted online on the Ministry of Health website and has been posted on the NZ Police website. Consultation opened on 19 February and ran until 21 March 2014.