

Regulatory Impact Statement

New regulatory regime for psychoactive substances

Agency Disclosure Statement

Cabinet has agreed to the consideration of new legislation to address the unregulated sale of party pills and other legal highs. This new legislation would introduce a pre-market approval scheme for these substances and make the importation and sale of all unapproved substances illegal.

The consideration of the potential impacts of policy options for the new regime has been hindered by the lack of information about the likely scale of a regulated market. The Ministry has been unable to ascertain from industry representatives the size of the current market and has made some assumptions based on what is known of the legal market in BZP prior to its scheduling in the Misuse of Drugs Act in 2008. We do not know how many of the products that have previously been sold in New Zealand would be submitted to the regulator for assessment under the new regime. Of these, it is unknown how many products would subsequently be approved.

Without knowing the potential number of applications for assessment, the Ministry is unable to accurately estimate the likely costs to operate the regulator. The Ministry thinks that the number of applications would be very small, probably fewer than ten in the first year.

The Ministry has collated data available on the use of “legal highs” in order to build a picture of the user, estimate the potential scale of use, and the potential impact on the health system associated with their use. The most complete information available relates to BZP which was legally available until April 2008 and had been used at that time by 5.6% of New Zealanders aged 16-64 years in a preceding 12 month period. BZP users were significantly more likely to be male than female and were predominantly aged 18-34. Users were more likely to be Māori. Prevalence of use of products approved under the new regime will be monitored through national surveys, which will contain questions around legal high use.

The new legislation may have an impact on the consumption of other legally available products or illegal drugs. The Ministry will monitor displacement effects, including changes in the use of illegal drugs or alcohol, which may be replaced by approved products.

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Introduction – the Law Commission Review and Government Response

1. In July 2007, the Government invited the Law Commission to review the Misuse of Drugs Act 1975 (the Act) in response to concerns that sponsors of new psychoactive substances were not required to establish the safety of such products before they could be legally sold.
2. The Law Commission carried out a first principles review with a mandate to make proposals for a new legislative regime consistent with New Zealand's international obligations under the United Nations drug conventions and taking account of a range of issues and concerns about the Act. In February 2010, the Law Commission published an Issues Paper providing a detailed discussion of the problems with the current legislation and proposing options to address these problems. The Law Commission conducted targeted and public consultation and received 3,800 submissions on the Issues Paper. On 3 May 2011, the final report of the Law Commission was tabled in the House.
3. In relation to the issue of the sale of new psychoactive substances, the Law Commission identified two inter-related problems with the status quo. Firstly, potentially harmful psychoactive substances are available with little or no control over their ingredients, dose, place of sale, and purchase age. Secondly, the onus is on the Government to identify that these substances are available, and then to determine whether they are harmful before placing restrictions upon them.
4. In its final report, the Law Commission recommended a regime that would require sponsors of psychoactive products to demonstrate that products do not pose an undue risk of harm before they are marketed. This recommendation and alternative options for addressing the problems identified by the Law Commission were analysed in the RIS which accompanied the Government Response to the Law Commission recommendations.¹
5. On 8 September 2011, the Government Response to the Law Commission recommendations was tabled in the House. In the response, the Government agreed to consider the development of legislation for psychoactive substances posing a low risk of harm, which may require the supplier or manufacturer to apply to a regulator for approval or otherwise demonstrate that it meets required standards before substances can be manufactured, imported or distributed, subject to regulatory impact analysis (CAB Min CBC (11)59/CBC(11) 8/19).

Status quo

Prevalence of psychoactive substance use and population profile of users

6. 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.

¹<http://www.health.govt.nz/about-ministry/legislation-and-regulation/regulatory-impact-statements/government-response-misuse-drugs-act>

7. The Ministry has collated data available on the use of “legal highs” in order to build a picture of the user, estimate the potential scale of use, and the potential impact on the health system associated with their use. There is no current prevalence data for party pills and other legal highs. The most complete information available relates to BZP which was legally-available until October 2008. BZP is a stimulant and information about its use may not be comparable with other products, such as legally-available synthetic cannabinomimetic products.
8. National survey data is available from the New Zealand Drug Use Survey 2007/08, which reports on the prevalence of use of illegal and other drugs for 16-64 year olds. Lifetime use of BZP, which was still legally available at the time of the survey, was reported at 13.5%, and past year use at 5.6%. This compares to illegal stimulant use: 7.2% lifetime use of amphetamines and 2.1% past year use, and 3.6% lifetime use of cocaine and 0.6% past year use. BZP users were significantly more likely to be male than female and were predominantly aged between 18-34. Users were more likely to be Māori.
9. The Ministry has also reviewed publicly funded hospital discharge data from the National Minimum Dataset (NMDS) from 1 July 2006 until 30 June 2011 (prior to the first TCDN). This includes information on BZP while it was legal, and synthetic cannabinomimetic substances. Although there are no specific diagnosis codes for legal highs or BZP, it is possible to extract free text diagnosis descriptions from discharge data. Using the encrypted form of National Health Index (NHI) identifier, the Ministry linked this discharge data with demographic data (age, gender, ethnicity, NZDep 2006 quintile), emergency department attendance data, and information on secondary mental health and addiction service use. This resulting linked dataset allows the Ministry to build a profile of the people most at risk of harm from drug use – in effect using hospitalisation as a proxy for a certain level of severity.
10. The introduction of a district health board performance measure in the 2008/09 year encouraged greater use of free text for discharge diagnosis and procedure descriptions in the NMDS. This means that the data for the period July 2009-June 2011 is more detailed for the purposes of comparison. During this period, there were 37 people with hospital discharges involving legal highs, compared to 3161 for cannabis, and 808 for stimulants. Compared to people with hospital discharges involving cannabis use, legal high users were younger (median age 23, compared to 30 for cannabis users), were less likely to be Māori (41% compared to 51% of cannabis users) and less likely to be living in an area of high deprivation (NZDep 2006 quintile 5) (27% compared to 40% for cannabis users).
11. Health service use data from the linked dataset gives some indication of the general health status of legal high users. Caution is required with the interpretation of these data as there may be no direct relationship between health service use and a person’s drug use. It would appear that legal high users have similar numbers of visits to emergency departments (the reason for the visit is not recorded) to cannabis users, and a similar percentage of people have had contact with secondary alcohol and drug teams. A greater percentage of users of stimulants and opioids have had contact with secondary alcohol and drug teams and these users had a higher number of visits to emergency departments than users of legal highs.

12. Out of the 37 people with hospital discharges involving legal highs in the two-year period examined, eight had no indication of any other drug use in the hospital discharge data for this period (22 percent). The remaining 29 people did have indications of cannabis or other drug use in the same period.

Nature of the market

13. There is no comprehensive information on the size of the market in New Zealand. With the introduction of the TCDN in August 2011, the legal market changed as a number of products were removed from it. The Ministry has made some estimations based on the BZP market prior to its scheduling in the MoDA in 2008 and on the height of the market prior to the TCDN.
14. It is estimated that 20 million pills containing BZP were sold in New Zealand in the period between 2001 and 2006. This resulted in turnover of around NZ\$25-\$35 million per year at the height of their popularity. Comparable data on the size of the market for legal cannabis-like products in New Zealand is not available. However, the Ministry considers that the market for these two types of product in New Zealand is broadly comparable.
15. The Ministry estimates that at the height of each of these substance's availability there would have been between 80 and 120 products available. The types of products that have been sold include capsules/pills, bags of pure chemical powders, bags of powders containing chemicals mixed with excipients, and both natural and synthetic smoking products.
16. There are approximately 10 major importers and/or manufacturers of these products in New Zealand and potentially a further 10 smaller businesses supplying their local markets. Domestic manufacturing capability exists in New Zealand and a large proportion of the tablets, capsules, and smoking products on the market in New Zealand would have been locally manufactured using imported active ingredients.
17. We estimate that at least 1000 retailers traded in legal cannabis-like products at the height of their availability in 2011. This is greater than the number of retailers that traded in BZP products at the height of their legal availability in 2008. This may be as a result of the different type of product, or it may demonstrate a shift towards more aggressive marketing practices by industry.
18. The types of retailers that have traded in these products include specialist stores, adult stores, on-line suppliers, clothing stores, and smaller community-based businesses such as dairies. The Ministry understands that the greatest volume of these products was sold through specialty stores but that this type of store made up only a small proportion of retailers in New Zealand. The Ministry estimates that the market consisted of roughly 20 specialty shops, 30 adult stores, 5 major internet based retailers, and as many as 1000 dairies.

Current Regulatory environment

19. The current mechanisms for dealing with psychoactive substances are:
 - a) New Zealand has ratified three United Nations (UN) drug conventions that require New Zealand to make the cultivation, distribution, and possession of drugs listed in the conventions' schedules a criminal offence. New Zealand meets its international obligations by scheduling drugs in the Act.

The Act prohibits the importation, manufacture, cultivation, possession and supply of substances listed in the Act's schedules. Exemptions are in place to allow the medical use of certain controlled drugs. The Act classifies controlled drugs in three schedules according to the risk of harm from each substance: Class A substances are considered to pose a very high risk of harm, Class B a high risk of harm and Class C a moderate risk of harm. The schedules determine the maximum penalties for offences against the Act and determine certain enforcement powers and provisions such as prescribing rights.

The Expert Advisory Committee on Drugs (EACD) is a statutory body charged with providing the Minister of Health with advice on drug classification matters. The EACD assesses drugs against criteria of harm including public health harms, and the potential for a substance to cause dependency and death. If a substance is considered to pose a moderate or higher risk of harm, the EACD will advise the Minister to schedule it in the corresponding class in the Act.

- b) The analogue provisions of the Act state that substances with molecules structurally similar to those of controlled drugs are analogues of these drugs and automatically considered Class C controlled drugs.
 - c) The EACD can advise the Minister to classify substances assessed as posing less than a moderate risk of harm, under the restricted substances schedule of the Misuse of Drugs Amendment Act 2005 (MODAA 2005). The MODAA 2005 makes provision for the regulated sale of psychoactive substances. There are currently no restricted substances listed in the MODAA 2005.
 - d) The Smoke-free Environments Act 1990 prohibits the sale of herbal smoking products, such as synthetic cannabinomimetic substances, to people under the age of 18.
 - e) The Temporary Class Drug Notices (TCDN) introduced by the Misuse of Drugs Amendment Act 2011 provide an emergency mechanism to prohibit for a twelve month period the importation, manufacture, sale and supply of substances listed by a notice in the *Gazette*. These may be extended once for an additional twelve months.
20. In August 2012, the Government agreed to the development of proposals for new legislation which would require that low-risk psychoactive products be approved by a regulator before they can be sold.

Problem definition

- 21. There is no mechanism to prevent psychoactive substances not already scheduled in the Act as controlled drugs or structurally similar analogues from being sold. The current system relies upon Government identifying that a substance is being sold and then reacting accordingly.
- 22. The EACD is tasked with providing evidence-based assessments and recommendations to the Minister. However, for many of the emerging substances such as legally-available party pills, there are delays while evidence is collated or research is commissioned before the appropriate level

of harm can be determined and recommendations made to the Minister. This means that substances which could eventually be found to cause moderate or even high levels of harm could remain uncontrolled until such time as adequate evidence is available.

23. GHB (fantasy) was identified as a popular party drug in 2000. Between 2000, when it was assessed by the EACD and its eventual scheduling in the Act in 2002, Auckland Hospital reported over thirty admissions and one death associated with GHB misuse.
24. This system differs from the system in place for food, alcohol, medicines, and hazardous substances. In the case of medicines, there are significant requirements on the pharmaceutical industry to demonstrate the safety of their products before they are approved for use. In the case of alcohol, no alcoholic products can be sold without a licence and there are a number of restrictions around purchase age, advertising, pricing controls, and manufacturing standards.
25. There is no requirement for manufacturers or distributors of psychoactive products to provide any consumer information about contents, dose, or potency. There are no manufacturing standards or safety requirements for products. Unlike medicines, there are no requirements around labelling, ingredients, dose, potential side-effects and/or drug interactions. Unlike tobacco, there are no requirements for health warnings.
26. The legal status of psychoactive substances is ambiguous and can change rapidly. This affects users, retailers, manufacturers, and importers and gives industry no market certainty and little incentive to invest in safety testing and labelling. There is ambiguity at the New Zealand border with some shipments being held by Customs for testing and importers not using existing provisions of the Hazardous Substances and New Organisms Act 1996.
27. To address these problems, the Government has agreed to the development of proposals for a regime that requires low-risk psychoactive products must be approved by a regulator before they can be sold. Currently, there is no accepted definition of low-risk that can be used to set the bar for approvals. The criteria for classifications in the Misuse of Drugs Act are intended to determine moderate, high, and very high risk of harm to individuals and society. The criteria are very broad and rely on the EACD's technical judgement which cannot always be informed by scientific data given the novel nature of the substances being considered. The Ministry therefore does not consider the criteria in the Misuse of Drugs Act to be suitable for this approval process.
28. There is also no accepted definition of a psychoactive substance. Psychoactive is a broad term which applies to a substance that "affects the mind" and could therefore include many common products, including a number of foods and plants. Certain psychoactive substances are already regulated under existing legislation, such as some caffeine products, alcohol, and tobacco. The interface between the new regime and existing regulatory regimes will require the development of a clear definition of psychoactive substance.

Objectives

29. The primary objective of the proposed legislation is to develop a regime capable of dealing with the rapidly evolving market in psychoactive substances, balancing the risk of harm to individuals and society with the demand for access to such substances.
30. The regime should:
 - provide a mechanism for effectively regulating psychoactive substances before they reach the market,
 - provide public confidence about the risk profile of the psychoactive products legally available for sale,
 - place controls on the availability of psychoactive products, including purchase age and place of sale,
 - provide information for consumers on product contents, dose and potency,
 - provide certainty on the status of psychoactive substances, reducing the risk that people will seek them through the black market, and giving the industry long-term financial confidence,
 - provide an equitable process that does not disadvantage one segment of the market over another by imposing onerous requirements on either import or domestic manufacture
 - establish an enduring regime to replace interim measures, analogue and restricted substances provisions.

Regulatory Impact Analysis

31. The Regulatory Impact Statement prepared for the Cabinet Paper to agree the Government Response considered four options for addressing the two problems identified by the Law Commission. The option agreed to by the Government was to introduce a regime that would require sponsors of psychoactive substances (importers or manufacturers) to demonstrate that products they wish to market do not pose an undue risk of harm and apply for a pre-market approval from a regulator.
32. As recommended by the Law Commission, the definition of psychoactive substance should be those substances taken for the primary purpose of inducing a psychoactive effect. The Ministry does not think this should be limited to synthetic products as this could create a loophole and distort the market leading to the sale of potentially harmful psychoactive plants. Psychoactive substances already controlled by existing legislation, such as alcohol and tobacco, should be excluded from this regime. Other substances that have a psychoactive effect, but are not used primarily to induce this effect, such as industrial chemicals, garden plants, and some foods should be excluded through the definition. There may still be some interface issues at the boundary between legislative provisions, and we consider there should be a declaring power for the regulator to declare something to be a psychoactive substance for the purposes of the new regime. This is consistent with the Natural Health Products Bill and the Medicines Amendment Bill which contain a regulatory power to declare. This would address an attempt to market a product with psychoactive properties in such a way as to avoid control. For example, products have previously been marketed as incense or plant food.

33. This Regulatory Impact Analysis considers the proposed model and other options for how the regime might work. It covers the following issues:
- What the criteria for approval should be and what evidence would be required to meet approval standards (Part A)
 - What the appropriate regulatory vehicle should be (Part B)
 - What the process should be for the importation of psychoactive substances (Part C)
34. This paper also describes issues which the Ministry is still working on, namely:
- Offences and penalties (Part D)
 - What the retail restrictions should be for approved products (Part E)
 - Trade issues (Part F)

Part A - Approval criteria

Problem/status quo: A means of assessing which products can be approved and what constitutes low-risk is required. A balance is needed between a robust process which ensures that risk is minimised, and a process which is not so restrictive that no products are approved and consumers satisfy demand via the black market.

The Law Commission recommendations

35. In its final report on the Misuse of Drugs Act, the Law Commission recommended criteria against which psychoactive substances could be assessed. These are:
 1. the nature of the harms and benefits of the product,
 2. whether the harms can be effectively managed through regulation,
 3. likely consequences of regulation compared to prohibition,
 4. potential displacement issues.
36. The first criterion is intended to encompass an assessment of the composition, pharmacology, and toxicology of the product. The other criteria relate to the potential impacts of regulation. The Law Commission did not make any recommendations on the types of evidence and data required to adequately assess products submitted to the regulator.
37. There are options for the stage at which an approval would take place. Firstly, the regulator could approve each active ingredient. Secondly, the regulator could approve the finished manufactured product which may contain more than one active ingredient.
38. The Law Commission recommended that it should be the final manufactured products that are given approval. The Ministry agrees with this approach as it will ensure that each combination of active ingredients is assessed for drug interactions, that a final approved dose per product can be set, and that the manner in which the product is meant to be administered can be considered. This approach will also provide industry with some protection over intellectual property as each product would have trade mark protection, whereas approval based on the active ingredient would result in that substance being available for sale by any manufacturer or retailer.
39. We think there is a strong enough argument to proceed on the basis that applications should be made for finished products and not substances. We have structured our analysis below accordingly.

Objectives:

The primary objective is to render ineligible for legal sale the products that cause common adverse reactions, impact on a user's health, and may cause societal problems such as aggression. This will be measured in our analysis below as "valid criteria".

In addition to the primary objective, the approval criteria need to:

- provide industry and the public with confidence that decisions and the assessment processes are transparent, evidence-based, and objective,
- minimise unintended consequences such as driving people to the black market,
- ensure the process is efficient and straightforward to administer.

Options

40. There are two options for the level of pre-market approval required for psychoactive products. The first is a process similar to the self-certification model for the Natural Health Products Bill. The second is a requirement for a consistent package of toxicological and behavioural data to be submitted to the new regulator to inform each application.

| CRITERIA | OPTIONS | |
|----------------------------------|--------------------|---|
| | Self-certification | Assessment by the regulator of toxicological and behavioural data |
| Valid | x | ✓ |
| Transparent/objective | partial | ✓ |
| Minimise unintended consequences | ✓ | partial |
| Minimise harms | x | ✓ |
| Efficient | ✓ | partial |

Self-certification

41. A self-certification system would operate in a similar way to the proposed system for registering natural health products, such as vitamins and health supplements. This requires sponsors to self-certify on an on-line database before marketing a product. The database has a list of permitted ingredients and a list of prohibited ingredients.
42. If a sponsor wishes to use a new ingredient, not on the permitted list, they would notify the regulator who would have the option to assess the ingredient for its safety.

Impact on industry

43. A system similar to this approach would have low compliance costs for industry as sponsors would complete an on line form and be expected to provide evidence regarding the products if required. Requirements could include that all active ingredients are listed, in addition to the likely effects and side-effects. This would be quick, straightforward, and cheap. The cost estimates for notifications of natural health products are around \$100 per product.
44. However, unlike natural health products, most of which have a long history of use with little evidence of adverse health effects, the new regime will apply to new substances with little or no history of use. This option would be efficient but would not give the public confidence that approved products had been robustly assessed for toxicity. Accordingly, we do not believe that self-

certification can meet the primary objective of effectiveness and the Ministry does not support this option.

Assessment by the regulator of toxicological and behavioural data

45. This option would require consistent toxicological and human clinical trial data for each product submitted for approval. The regulator would then examine the dataset for each product and make a determination as to whether it meets the criteria of low risk. This is broadly similar to the approval process for new medicines but without the requirement for a product's sponsor to establish the product's efficacy.
46. A separate application would be required for each product (that is any variation in name, dose, or identifier such as flavour would require a new application), although an application would be able to specify that a product is "based on a parent product".
47. At the minimum we think that data should be required on acute toxicity, repeat dose toxicity, genotoxicity, and observations from human clinical trials. We are also considering whether requirements for carcinogenicity and developmental toxicity testing will deliver enough additional benefit to be justified. These extra tests would provide greater clarity about the risks of a substance, but would significantly increase the costs to industry and the time required to bring a product to market.
48. Industry and scientific experts have been consulted on the testing requirements that we propose. Both of these groups support the validity of this approach as a way of measuring the harm of a psychoactive product.

Impact on industry

49. The option of self-certification would have a significantly smaller impact on the industry than requiring toxicological and behavioural data. However, we do not believe that self-certification will be able to protect the public from harmful products.
50. For this reason, we propose a requirement that the industry obtain toxicological and behavioural data for each product seeking approval. The cost of this is difficult to quantify until the nature of the testing requirements has been confirmed. However, based on our initial proposals we estimate that this testing could cost in the range of NZ \$1 million to NZ \$2 million per product. This does not include the cost of product discovery, manufacturing or protection of intellectual property. We have consulted with the industry on this and almost all manufacturers that responded to our discussion document support this approach and are willing to fund this testing.
51. The Ministry also understands that one company is considering initiating testing now with the knowledge that the regime is still only at the stage of policy development.

Impact on the public

52. We think that a requirement for toxicological and behavioural data will protect the public from most adverse drug reactions. Requiring this data will provide an indication of what the common short term and longer terms harms of a product may be and will disqualify from legal sale any product which is clearly adverse to humans.

Part B – the regulator

Problem/status quo: The Government, in its response to the Law Commission’s Misuse of Drugs Act (MoDA) review, agreed that manufacturers and suppliers of low-risk psychoactive substances would be required to apply to a regulator for approval before substances could be marketed. Currently there is no body responsible for this process and either a new stand-alone regulator will need to be established or an existing agency or regulator will need to take on this function.

Objectives:

The primary objective is to provide an appropriate mechanism for effectively regulating psychoactive substances before they reach the market. The other objectives are:

- Independence - the Law Commission emphasised the importance of having an impartial regulator to determine which products to approve, and that there was distance between decisions and political processes,
- efficient and proportionate - the process for approving products needs to be efficient in terms of financial costs and other resources and proportional to the projected size of the market,
- suitability - there needs to be an appropriate “fit” between the new regulator and the agency where it sits,
- meet the Government’s priority to minimise new regulators and regulations.

| CRITERIA | OPTIONS | | | | | |
|----------------------------|-----------------------|------------------|------------------|---------|------------------|--------------------|
| | Stand-alone regulator | MPI ² | EPA ³ | Medsafe | MOH ⁴ | Minister of Health |
| Independence | ✓ | ✓ | ✓ | ✓ | ✓ | x |
| Efficiency/proportionality | x | ✓ | ✓ | ✓ | ✓ | ✓ |
| Government priorities | x | ✓ | ✓ | ✓ | ✓ | |
| Suitability | ✓ | x | x | x | ✓ | x |

Option one - a new stand-alone agency

53. A new stand-alone agency could be established to act as the regulator with administrative functions and scientific expertise for the assessment of products submitted to the regulator.
54. A stand-alone regulator would provide a clear point of contact for queries from the industry and the public. In addition, this option would also be considered the most independent by public and industry. As it would be purpose-built, it would meet the suitability objective.

² The Ministry for Primary Industries

³ The Environmental Protection Authority

⁴ The Ministry of Health

55. The Ministry does not consider a new stand-alone agency would be justified in light of the estimated annual number of applications for approval. The Ministry estimates that in the first two years at least, the regulator would be considering fewer than 10 products. It would also not be consistent with the government commitment to provide value for money and minimise unnecessary administration.

Option two - Ministry for Primary Industries

56. Establishing a regulator for psychoactive substances within the Ministry for Primary Industries (MPI), which administers food legislation and standards, was not an option that was considered by the Law Commission. However, MPI regulates some products which have psychoactive effects, most notably food containing caffeine, and so the Ministry has considered it as an option for the regulator.
57. There are already provisions in place in the Australia New Zealand Food Standards Code for the assessment of novel foods which could have psychoactive properties. Food Standards Australia New Zealand (FSANZ) is the trans-Tasman agency responsible for the development of food labelling and composition standards, including the assessment of 'novel foods' (foods without a history safe use in Australia or New Zealand). MPI participates in the FSANZ assessment and provides advice on New Zealand's position in relation to food safety issues. Decision-making on approvals for novel foods is carried out by Ministers from New Zealand and the Australian States and Territories.
58. The Ministry considers there are more appropriate options than the MPI for the new regulator. The approval process for psychoactive products is likely to be closer to medicines than novel foods. Moreover, FSANZ which carries out the novel food pre-market assessments is an Australia public service agency (though jointly funded by Australia and New Zealand) and may not be a suitable to regulate New Zealand's regime for psychoactive substances.

Option three - Environmental Protection Authority

59. The Law Commission considered whether the regulator for the new regime should be the Environmental Protection Authority (EPA) which implements the Hazardous Substances and New Organisms Act 1996 (HSNO), and other environmental legislation.
60. The EPA operates a pre-approval regime under the HSNO to manage the safe importation, manufacture, transportation, and use of hazardous substances. These are substances that meet defined minimum degrees of hazard criteria, including toxicity and corrosivity. All hazardous substances require an approval under the HSNO unless otherwise exempt such as finished dose medicines.
61. The raw materials meeting minimum degrees of hazard used in the manufacture of psychoactive products, including the active ingredients and the incipients, will require HSNO approval. The excipients which are the binders and bulking agents used to flavour, colour or for consistency, are likely to be used in the manufacture of other substances and may already have HSNO approval. Consequently, and irrespective of the option agreed to, the EPA will have a role in the regulatory process for psychoactive substances.

62. The EPA's role could be extended to administer the whole process for approving and managing psychoactive substances, including active ingredients and the finished product. Enforcement would probably need to be carried out by other agencies, including the Ministry of Health, Customs, and Department of Labour, as is currently the case for hazardous substances enforcement.
63. The Ministry does not consider the EPA to be the best fit for the new regulator. The mandate of the EPA is environmental protection, and psychoactive substances would have no environmental impact. When assessing the risks to people from hazardous substances, the EPA generally only assesses unintentional or inadvertent exposure, rather than intentional consumption (cosmetic products and tattoo inks are the exception). Drugs, principally medicines, are only regulated by the EPA when they are bulk pharmaceutical active ingredients and not in a manufactured dose form. From the point of manufacture to retail and end-use, regulation is managed by Medsafe.

Option four - the Ministry of Health

64. The Law Commission recommended that the regulator be established within the Ministry of Health. The Ministry of Health's mandate is to improve and protect the health of New Zealanders. It currently administers legislation both for illegal drugs and tobacco and has experience controlling and regulating recreational substances. The Ministry of Health is also the lead agency for the National Drug Policy: a public health focused policy to reduce the harm from alcohol, tobacco, illegal and other drug use. The Ministry of Health also has experience in pre-approval processes, licensing, auditing, and enforcement.
65. The new regulator for psychoactive products could either be part of Medsafe which is a business unit of the Ministry of Health responsible for the regulation of therapeutic products, or within another unit of the Ministry.

Medsafe

66. The benefit of Medsafe being the regulator is that it already operates a pre-approval regime for new medicines and post-market surveillance for approved medicines. There would be potential savings in sharing administrative functions. Staff are familiar with toxicology data packages, licensing, and retail restrictions.
67. The limitation with Medsafe being the new regulator is the lack of fit as the focus of the new regime is to regulate recreational substances with no therapeutic purpose. Furthermore, the development of the trans-Tasman regulator, Australia New Zealand Therapeutic Products Authority (ANZTPA), would have implications for Medsafe's capacity to regulate psychoactive products which would be outside the scope of ANZTPA.

Ministry of Health

68. There are other areas of the Ministry where the new regulator might more comfortably sit. For instance, the Natural Health Products Bill establishes a new regulator, to be administered by the Ministry of Health. The regulator would operate a pre-market notification database for natural health products, administer lists of permitted and prohibited ingredients, and conduct safety assessments as required for new ingredients. There will be auditing and

surveillance, in addition to enforcement activities. There is potential for back-office administrative functions for the psychoactive substances regime to be shared with the proposed regulator for natural health products.

69. The Ministry funds and manages Public Health Units in each District Health Board area. These units have enforcement responsibilities through the Health Protection Officers which carry out controlled purchase operations around the retail of alcohol and tobacco. There are also monitoring and compliance investigators employed within the Ministry. The Ministry of Health is also an enforcement agency for the HSNO.
70. The advantage of the regulator being in the Ministry of Health would be to provide a link between the approval of products and monitoring and enforcement. The Ministry administers the MoDA which schedules drugs considered to pose a moderate to very high risk of harm, and is secretariat for the expert committee which assesses them. This would provide an easy conduit to refer unapproved substances which are found to pose more than a low risk of harm to the Expert Advisory Committee on Drugs for assessment.

Option 5 – the Minister of Health

71. In the case of medicines, the final decision regarding the approval of new medicines lies with the Minister of Health. There is a precedent for Ministers to issue approvals on matters relating to public safety. The Minister of Health is also empowered to issue Temporary Class Drug Notices to prohibit psychoactive substances for a period of up to 12 months.
72. The Law Commission considered that decision-making around drugs has the tendency to become highly politicised and that the Minister of Health might not be seen as independent or objective in the approval process. The Minister may also wish to keep a certain distance from the process to avoid any sense that a product has ministerial endorsement.

Impact analysis

Costs of the regulator

73. At this stage, it is not possible to be clear about the cost of establishing and running the regulator, as there is no information on the likely demand for the regulatory activities. The Ministry of Health's preliminary estimate is that it could cost \$1.00 million at a minimum per annum. This is based on an estimated three FTE and overheads, such as a dedicated database. However the Ministry has identified a number of cost saving or funding measures that could be used in the first two years until we know the scale of the market.
74. The regulator will need to be funded for the following outputs:
 - a. regulatory advice,
 - b. standards setting,
 - c. import/export licences,
 - d. compliance, audit, licensing manufacturers, and monitoring,
 - e. enforcement.

Fee setting

75. Marketing psychoactive products is a commercial activity and the Ministry considers it appropriate that fees are charged to fund the activities of the regulator.
76. Fees need to cover the cost of all aspects of regulatory process necessary to assess safety and quality before the product enters the market and safety monitoring after it is on the market.
77. Option 1: Full cost recovery (including set up costs, which may need to be met up front by the Crown and recouped through fees), including regulatory advice and enforcement activities.
78. Option 2: Cost recovery (including set up costs) but not charging industry for enforcement activity. However, it must cover the cost of post-market safety activities including compliance, audit, and monitoring.
79. Each element of the regulatory function can be met by companies via a fee for service. Because we currently do not know exactly what, and how many products are likely to apply for approval to sell, the fee should be based on a conservative estimate of the number of approvals. A funding review would be undertaken after three years to determine whether the fees charged matched the actual costs of providing the regulatory services.

NB: EPA fees are low because of lower cost recovery. In the case of hazardous substances and new organism approvals, the fees are set low because hazardous substances must demonstrate a benefit to society and the economy and therefore there is a large element of public good.

Examples of similar regulatory functions:

| | EPA | Medsafe | New Regulator |
|------------------------------|---|---|--|
| Functions required | Admin, Toxicology, risk assessment and decision making | Admin, Toxicology Secretariat for technical committees | Admin, Toxicology Secretariat for technical committee (initially piggy back off Natural Health Products and or expertise at Medsafe) |
| IT requirements | Database/Word/CRM/EDRMS | Database | Clone Medsafe database |
| Approvals received per annum | 130 – 170. In 2010/11 EPA carried out six full assessments which each took on average 220 hours to complete | 200 of which 40 brand new medicines which require pre-clinical data | Unknown but expected to be fewer than 10 |
| Approval Fees | \$17,250 per substance – hourly rate of \$115 can be charged for new high risk substances that require | \$88 000 (high risk medicine containing new active | Unknown and to be reviewed after three years. Expected to be in |

| | | | |
|--|---|-------------|-------------------------------|
| | extensive assessments, which could make this fee much higher ⁵ | substances) | line with medicines approval. |
|--|---|-------------|-------------------------------|

80. Because we currently do not know exactly how many products are likely to request approval, it is intended that in the first three years of the scheme, the approval fee be based on a new medicines approval of \$88,000. The Crown would initially meet any shortfall, which would subsequently be recovered from industry. We expect that at most there will be 10 approval applications in the first year or two. In reality there may only be one or two approvals in the first year and hence the need to cost recover in out years. If the regulator is placed within the Ministry of Health we believe there are ways we could attempt to keep costs to a minimum by integrating some of the regulator's functions with similar functions already in place.
81. The Ministry will still be required to work within the FTE cap. Staffing the regulator will have implications for servicing other Ministry priorities. There are opportunities for sharing back office functionality with other regulators including the proposed natural health products regulator.

⁵ There is also a reduced risk rate of \$5,750 which applies to substances for which there is a reference substance already in active use in New Zealand.

Part C - Border issues

Problem/status quo: a transparent and efficient system for importing active ingredients for the manufacture of psychoactive substances and manufactured products is required. Currently, the process is not sufficiently clear to industry and this has costs to both industry and Customs. Industry has to wait for products to be tested at the border and must pay for testing. Customs has to investigate imports which may not be labelled and which lacks appropriate certification.

Objectives:

The primary objective is that there is an effective, safe and efficient mechanism to manage the importation of psychoactive substances. The objectives are to:

- provide certainty and avoid ambiguity for importers of active ingredients and finished products,
- ensure adequate coverage and that gaps between legislative provisions are minimised,
- manage any risks and safety issues associated with importation,
- ensure an efficient process at the border.

| CRITERIA | OPTIONS | | |
|-------------------------------|------------|--------------------------------|---------|
| | New regime | New regime + HSNO ⁶ | HSNO |
| Certainty for industry | partial | ✓ | ✓ |
| Adequate coverage | ✓ | ✓ | partial |
| Safety | ✓ | ✓ | ✓ |
| Efficient | x | ✓ | x |

87. Psychoactive substances are hazardous substances as defined by the Hazardous Substances and New Organisms Act 1996 (HSNO) as they are target organ toxicants. The HSNO places controls on the importation of hazardous substances. HSNO controls could be used to regulate the importation of both active ingredients used in the manufacture of psychoactive products, and the importation of finished manufactured products.
88. Alternatively, the Ministry has considered whether it would be possible or practical to use the new regime to control the importation of active ingredients and finished products.
89. A third option would be to use HSNO controls to regulate the importation of just the active ingredients, but the importation of finished manufactured products would be controlled under the new legislation. This split approach is consistent with the legislative mechanisms for controlling the importation of medicines.

⁶ Hazardous Substances and New Organisms Act 1996

Option one - Hazardous Substances and New Organisms Act 1996

90. The purpose of the HSNO is to protect the environment, and the health and safety of communities, by preventing or managing the adverse effects of hazardous substances and new organisms. Under the HSNO, the EPA is empowered to assess and decide on applications to introduce hazardous substances or new organisms into New Zealand.
91. Approvals by the EPA are granted with controls to regulate the whole life-cycle of the hazardous substance, from import and manufacture through to use and disposal. In a few cases, the HSNO only regulates part of the life-cycle of a substance. One such case is human medicines, where the life-cycle ends at the point at which the pharmaceutical active ingredient is manufactured into a finished dose product. There is an exemption under the HSNO regulations, and Medsafe regulates medicines from this point to retail and end use under the Medicines Act 1981.
92. It would be possible for the HSNO to regulate the importation of both the active ingredients used to manufacture psychoactive products and the manufactured products. One potential benefit of this is the signal it would give about products being hazardous. It would be straightforward for industry as a single piece of legislation would regulate the whole life-cycle of the products.
93. The disadvantage is that, if the EPA was assessing the manufactured product for importation, it would mean that the EPA would be required to consider the end-use and retail of the products. This would essentially make the EPA the regulator for the new regime. Part B of this analysis has discussed why, on balance, the Ministry does not consider the EPA to be the best option for the regulator. The Law Commission also considered that dedicated legislation for psychoactive substances was preferable to using the HSNO. This is principally because the HSNO controls a large number of highly varied substances, and the monitoring and evaluation of controls on psychoactive substances may be better targeted with specific legislation.
94. The Ministry also considers that HSNO would not provide the desired amount of control over importers of psychoactive substances. Once an active ingredient or product has a HSNO approval, anyone can import it. The EPA does have discretion to set additional controls and, were this option preferred, it may be appropriate to include controls over importers. The Ministry for the Environment (MFE) administers the HSNO and does not support this option.

Option two - new regime

95. The new regime could include provisions to control the importation of both the active ingredients used in the domestic manufacture of psychoactive products, and finished products.
96. In the case of active ingredients, any risks associated with their importation and transportation would need to be managed, including requirements for packaging and labelling. Active ingredients would be registered with the new regime's regulator before they entered New Zealand, and importers would be required to provide sufficient safety information to demonstrate that any toxicity or other factors such as volatility could be adequately managed. There would need to be an exemption from control under the HSNO.

97. In the case of manufactured products, approval by the regulator would be required prior to importation, and the approved product would come in to New Zealand ready for retail. If products were allowed into New Zealand before approval had been granted by the regulator, products would need to be held by Customs pending approval. This is not practical. However it would be appropriate to provide for a licence to import small amounts for testing and research purposes.
98. The benefit of using the new regime to manage the importation of both active ingredients and manufactured products would be that the whole life-cycle of products, from ingredient to end product and disposal, could be covered by a single piece of dedicated legislation.
99. The disadvantage of this option may be some lack of certainty for industry as some of the active ingredients may be used in other areas of manufacturing. Some ingredients may already have HSNO approval and this may create confusion.
100. This option creates unnecessary regulatory duplication as the importation of chemicals is already regulated by the HSNO. It would require the new regulator to establish systems and expertise for managing the safe importation of chemicals which would entail both set-up and on-going costs. This option is not supported by MFE, Customs, or the EPA.

Option three - HSNO and the New Regime

101. Option three is the model used for human medicines, and is the option preferred by all agencies. This uses both the HSNO to control the importation of active ingredients used in domestic manufacture, and dedicated legislation to manage the importation of finished manufactured products. In the case of medicines, this is the Medicines Act and for psychoactive products it would be the new regime. The importation of the active ingredients used in the manufacture of medicines is regulated by a HSNO group standard approval. The controls under the Medicines Act 1981 take effect at the stage the ingredient becomes a finished dose product. The EPA is not required to consider the end-use of the pharmaceutical ingredients it approves for importation; this is done by Medsafe.
102. This option would minimise duplication by using the existing provisions in the HSNO to import active ingredients for manufacture of psychoactive products. It would use dedicated legislation to manage the approval and importation of the manufactured product, in addition to retail and accompanying offences and enforcement powers.

Impact analysis

Costs to industry

Active ingredients

103. The costs to industry of importing active ingredients under HSNO controls depend upon the approval granted by the EPA. There are two types of assessment and approval: individual and group standard.

Individual approval

104. Each hazardous substance must go through an assessment and meet data requirements regarding toxicity, and other risk factors. Once a substance has a HSNO approval, anyone can import or manufacture it in accordance with the controls imposed on that approval.
105. Requirements for individual approval include: full chemical identification, chemical properties of the substance such as boiling point and solubility, and the life-cycle of the substance including manufacture, use, and disposal. A sponsor must provide information about potential risks and benefits of approving the release of a hazardous substance. Information on the hazardous properties of the substance must be provided including whether it is corrosive, explosive, toxic, flammable, or ecotoxic.
106. The EPA charges fees for an individual approval. For instance the fee is \$17,250 for a new active ingredient requiring a comprehensive information package, or a reduced risk rate of \$5,750 applied to substances for which there is a reference substance already in active use in New Zealand. This does not include the costs to industry of conducting testing required for a HSNO data package.

Group standard approval

107. Group standards under the HSNO apply to groups of hazardous substances of a similar nature, type, or use. Group standards are in place for many different types of hazardous substance including: laboratory chemicals, pharmaceutical active ingredients, as well as for additives, process chemicals and raw materials.
108. Generally group standard approvals expect industry to certify that a substance comes under one of the group standards. Importers would be expected to have relevant data available but a substance would not go through HSNO assessment process for individual approval. Group standards are often developed by the relevant industry.
109. The exact cost of issuing a new group standard is arranged by negotiation between industry and the EPA but is usually around \$15,000 (ex. GST) excluding hearing costs. The process for issuing a group standard generally includes public notification and opportunity for submissions to be made. Once established, importers generally self-certify that substances are covered by a group standard. There is no cost for self-certification to import substances covered by a group standard.

Discussion

110. The Ministry considers that if industry is required to put active ingredients through HSNO individual assessment in order to import ingredients for domestic manufacture, it may have the effect of distorting the market. This is because the new regime proposes carrying out the approval process discussed in Part A for finished products. This would mean that domestic manufacturers would be required to pay HSNO fees of up to \$17,000 per ingredient, and then pay fees of around \$80,000 for the finished product approval.

111. On the other hand, importers of finished manufactured products would only be required to pay fees to the new regulator for assessment of the finished products.
112. The Ministry proposes using the HSNO group standard approval mechanism to import active ingredients and then both products manufactured domestically and those manufactured overseas would go through the same approval process with the new regulator. The EPA agrees with this approach.
113. The onus would be on industry to initiate this process and there would be some initial cost shared across industry in establishing a group standard. Once the group standard is in place, there would be minimal additional costs.
114. There would be a small additional cost to importers of active ingredients in the form of licences granted by the new regulator. The licence would provide some additional controls over who can import active ingredients which are not generally provided for under a HSNO group standard.

Finished products

115. The cost of importing finished products would be the cost of an approval by the new regulator, set out in Parts A and B.
116. There would be some small additional cost to importers in the form of a licence to import a small quantity of unapproved finished product for testing purposes.

Impact on agencies

117. Customs has indicated there may be some savings associated with the new regime if active ingredients and products are accurately labelled and managed appropriately through the HSNO and the new regime. However, Customs considers that this is likely to be marginal.
118. The enforcement of the controls on the importation of active ingredients under the HSNO is part of Customs' core business and is expected to be met within baselines. However, the import and export of approved products under the new regime may have financial implications. As yet, there is insufficient information on which to assess this impact. Customs intends to monitor this situation.

Part D - Offences and penalties

Problem/status quo

The new regime requires appropriate offences and penalties for breaches and non-compliance. The Law Commission has made a number of recommendations in this regard, and agencies are considering these recommendations, and offences and penalties in similar legislation, including the Misuse of Drugs Act (MoDA), the Medicines Act, and the Hazardous Substances and New Organisms Act (HSNO). The new regime would make the analogue provisions in the MoDA redundant. Currently, it is necessary to demonstrate that a substance is structurally similar to a controlled drug and it is then treated as a Class C controlled drug. Under the new regime, this would not be necessary as all unapproved substances would be captured. However, there is concern by Police and Customs that this will affect their ability to deal with potentially harmful drugs if the powers and penalties under the new regime are not the same as those currently available for analogues.

Objectives

Police and Customs will need to have adequate powers to address the illegal import, manufacturing, dealing, supply of, and intention to supply, of unapproved substances. Penalties and offenses will need to:

- Minimise the harms associated with sanctions, such as imprisonment, by ensuring that offences and penalties are proportionate to the harm associated with the behaviour,
- Be consistent with other similar pieces of legislation to ensure that enforcement agencies have appropriate powers, and that offences and penalties are compatible with the MoDA and HSNO,
- Minimise the resource burden to the enforcement agencies and the justice system,
- Be fair to individuals.

119. The Ministry of Justice is considering a suite of appropriate criminal offences and regulatory breaches, and the penalties for them. It is intended that these are compatible with the MoDA and the HSNO as the most comparable legislation.

120. The detailed work on offences and penalties will be carried out separately and reported back to Cabinet Social Policy Committee, along with the potential criminal justice cost implications by 1 October 2012.

Part E – Retail restrictions

Problem/status quo: currently products can be sold without restrictions on their purchase age, place of sale, advertising or packaging and without accurate information for consumers

121. With other psychoactive substances, particularly alcohol and tobacco, the Government restricts the access of young people, and minimises the visibility through controls on advertising and display. There are also restrictions on products such as medicines to provide consumer information on ingredients and dose, and emergency information in case of concern.
122. It is intended that regulation-making provisions are included in the new regime to allow for controls to reduce the demand for approved products, control availability, and to require the industry to provide accurate consumer information.
123. Controls will be based on the Misuse of Drugs (Restricted Substances) Regulations 2008, together with the recommendations of the Law Commission. In May 2012 the Ministry undertook a targeted consultation with industry on a proposed set of retail restrictions. Industry members were generally supportive of the proposed controls. However, some in the industry argued for a more restrictive model of distribution that would allow them additional controls over who may access their products.
124. We have been unable to give due consideration to this proposal in the time available. We intend to report back to Cabinet Social Policy Committee by 1 October 2012 with a detailed rationale and impact analysis for a set of retail restrictions for approved products. The retail restrictions we will propose in this report back will have the primary objective of mitigating harms from the legal availability of psychoactive products and will take into account the views expressed by industry in the targeted consultation we undertook in May 2012.

Part F – Trade issues

125. Consideration will need to be given to trade and the export of approved products. The Ministry is still considering possible implications under the Trans-Tasman Mutual Recognition Act 1997 (TTMRA) and the World Trade Organization (WTO) Technical Barriers to Trade.
126. Whilst some psychoactive products may be approved for sale in New Zealand, their legal status may be more ambiguous in other countries. Other jurisdictions are taking different approaches to addressing the issue of emerging uncontrolled substances, such as emergency measures including temporary bans. This means the legal status of substances can change quickly and exporters may find products in a legal limbo.

Trans-Tasman Mutual Recognition Act 1997

127. The TTMRA establishes the obligation that a product which is legally able to be sold in New Zealand can be legally sold in all Australian states and territories, and vice versa.
128. This is overarching legislation so it overrides any other goods-specific legislation, unless there is a standing exclusion (such as prohibited imports in the Customs and Excise Act 1996) or if there is a permanent exemption as there currently is for therapeutic goods.
129. It is proposed that all unapproved substances would be prohibited imports under the Customs and Excise Act. This means that products legally available in Australia could not be imported into or sold in New Zealand unless approved by the New Zealand regulator. New Zealand approved products, however, could enter Australia under the TTMRA provisions. Australia may, in due course, establish similar regulatory scheme at which point it may be possible to apply trans-Tasman mutual recognition again.
130. The Ministry has initiated discussions with officials in the Australian States and Territories about New Zealand's proposals for new regulation. The Ministry will continue to work through these issues with Australian officials.

Technical Barriers to Trade

131. The World Trade Organization (WTO) Technical Barriers to Trade aims to ensure that regulations, standards, testing and certification procedures do not create unnecessary obstacles, while also providing members with the right to implement measures to achieve legitimate policy objectives, such as the protection of human health and safety.
132. New Zealand will need to balance its WTO obligations, obligations to domestic industry to allow legitimate export trade, and its relationship with other countries that might be concerned about New Zealand exporting psychoactive substances.
133. The Ministry plans to notify the WTO of this proposed new regulatory scheme once Cabinet has agreed to a policy direction.

Consultation

134. The Law Commission published an issues paper in February 2010 which set out options for a new regime for psychoactive substances. The Law Commission carried out targeted and public consultation and received 3,800 submissions on the paper. On the basis of the feedback received the Law Commission made 45 recommendations for a new regime. The Ministry has taken these into account in the development of policy proposals.
135. The Ministry has also collaborated with other government agencies on the proposals, namely: the Ministry of Justice, New Zealand Police, and the New Zealand Customs Service. The Ministry has consulted with the Ministry for Primary Industries, the Ministry for the Environment, the Environmental Protection Authority, the Ministry for Consumer Affairs, the Treasury, and the Ministry for Economic Development.
136. A number of scientific experts, including toxicologists, psychiatrists, and emergency department specialists, have been consulted on proposals for the approval criteria and retail restrictions.
137. The Ministry has met with key industry members and ran a targeted consultation in May 2012 on some proposals such as on the approval criteria and retail restrictions. The Ministry has requested market information from industry to ascertain the current scale and the potential scale of market activity under the new regime but has received little information in this regard.

Implementation

138. If Cabinet agrees to the policy approach proposed, the next stage will be for the Parliamentary Counsel Office to draft a Bill for First Reading in the House. There are a number of details that will be worked through during the drafting stage, including the offences and penalties, and any necessary consequential amendments to other legislation.
139. There would be a number of impacts following enactment. Following enactment, the importation and supply of any unapproved substance would be illegal. There will also be regulations restricting which retail outlets are permitted to supply approved products. The Ministry has considered options for transitional and amnesty arrangements to allow those affected by the change make the necessary changes.
140. There are three options. The first option is that there is no transition or amnesty, which means that industry and retail outlets would need to be compliant with the legal changes immediately following enactment. This would mean that all substances being legally sold at the time of enactment would need to be removed from sale pending approval. This would have a cost to industry from lost revenue while applications are made to the new regulator for assessment. There would also be a loss of revenue to retail outlets. During the period between enactment and the approval of products, there would be no psychoactive products legally available, which would affect the public. The Ministry considers it likely that the continuing demand for psychoactive substances would be met during this period through the black market.
141. The second option would allow for an amnesty during which, industry and retail outlets could adjust to the legislative change without being prosecuted. This

still has many of the negative impacts of the first option and there would still be a vacuum leading to consumers satisfying demand through the black market.

142. The final option is that there is both an amnesty and a transition period. During this period, permitted outlets would be allowed to sell those products which were on the market six months prior to enactment provided the product sponsor was in the process of applying for assessment under the new regime. Products without a pending application would need to be removed before the end of the amnesty period. If, during the transition period, there were any health problems associated with a product being sold, the regulator would have the power to issue a recall notice. This option allows for some market continuity for industry and avoids the vacuum that would be created by removing all products. It is proposed that the retail restrictions are enforced following the amnesty period. This would affect industry as this may require repackaging and over-labelling.

Monitoring, evaluation and review

143. Although consistent with the way New Zealand controls medicines, food, and hazardous substances, a pre-market approval regime is a novel approach for drug control. The Ministry therefore considers it appropriate that there is a review of the legislation five years following enactment. There will also need to be a review of the fee structure sooner than this.
144. In order to monitor the health effects of the new legislation, there are a number of data sources the Ministry can draw upon. New hospital codes will be created for each approved product and better coding for unapproved substances. The Ministry will also continue to monitor the free text used for hospital discharges. Data from the Poisons Centre and the Centre for Adverse Reactions Monitoring will also be reviewed for self-reported adverse events.
145. Supply of both approved and unapproved substances can be monitored from Police and Customs data. It is proposed that Customs provide the new regulator with a monthly report of all imports which meet the import requirements for tracking. The different stages of importation and manufacture will be licensed by the regulator and will be audited as part of surveillance.
146. Police data will provide information on activity around unapproved substances and illegal drugs and would help indicate displacement issues if there is a spike or decline in supply of these substances.
147. Demand and prevalence will be measured through existing surveys managed by the Ministry. This will provide information on both the use of legally available psychoactive substances and illegal drugs.