Regulatory Impact Statement

New regulatory regime for psychoactive substances

Agency Disclosure Statement

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

It provides an analysis of options for new legislation to address the rapid growth in party pills and other legal highs. These psychoactive substances can currently be sold without any restriction on their ingredients or safety profile. There are also no restrictions on where the substances can be sold, labelling, advertising, or purchase age. The options considered in this Regulatory Impact Statement relate to proposed retail restrictions which would control the way approved psychoactive products are sold. Options are also considered for some of the proposed offences and penalties for non-compliance with the new legislation.

The legislation is a new way of controlling psychoactive substances: the importation and sale of all substances not already scheduled in the Misuse of Drugs Act 1975 will be prohibited unless they meet criteria to establish a low risk of harm. There is no international model on which to base this legislation, and we do not know what kinds of displacement effects the legislation may have. For instance, there may be a decrease in the use of drugs prohibited by the Misuse of Drugs Act in preference for the new approved psychoactive products. Alternatively, there may be little interest in the approved substances.

In order to estimate the impact of offences and penalties, we have used cannabis as a comparator because of the lack of information about legal highs. The Ministry does not know if this provides a reliable figure on which to model costs. Additionally, we do not know if people will change their behaviour with the new framework; for instance people may choose cannabis over an unapproved synthetic cannabis product. Until agencies are able to monitor offending under the new legislation compared to the Misuse of Drugs Act, we will not know the impact of the offences, and costs to the criminal justice sector.

The Ministry of Justice has modelled potential costs to the criminal justice sector on the basis of ten cases a year. However, for some years, the figure may be much higher. Police has provided information about a recent case concerning substances that could have been covered by the new regime involving 27 people with separate information to be laid for each. However, other years may have far fewer cases.

The Ministry has considered options for price control but lacks information on which to choose a preferred option. As we do not know what the consumer price sensitivity to approved products would be, it is difficult to model the extent to which demand might be affected by price. Also, without an active market for approved products at this time, it is impossible to know what a reasonable price per dose of approved product should be.

The majority of the retail restrictions proposed are the same as those in the Misuse of Drugs (Restricted substances) Regulations 2008. However, these regulations were introduced following the classification of BZP as a controlled drug and since then there have been no restricted substances. This means that there is no experience of the retail restrictions being implemented.

The proposed retail restrictions will impose a cost on industry: both the retailers of psychoactive products, and the manufacturers and distributors. Costs include licensing, labelling and packaging, and potential loss of earnings through restrictions on outlets. The

Ministry considers that these costs would be justified on public safety grounds as the restrictions are proposed to minimise the visibility of products to people not looking for them and restrict access by children.

The proposed offences and penalties for importation, manufacture, and supply are strict liability offences, which means that the prosecution only needs to prove the act of offending and not any knowledge or recklessness in relation to the act. Strict liability offences appear to limit the presumption of innocence affirmed in section 25(c) of the New Zealand Bill of Rights Act 1990, because they require the defendant to prove a defence (such a reasonable excuse) to escape liability. The proposed penalty level of two years is consistent with a strict liability offence. A full Bill of Rights vet will be carried out once the legislation is drafted.

Don Gray Deputy Director-General Policy Business Unit

Introduction

- 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. On 8 September 2011, the Government responded to the report's recommendations and agreed to legislation for psychoactive substances posing a low risk of harm, requiring a supplier or manufacturer to apply to a regulator for approval before a substance could be made available (CAB Min CBC (11)59/CBC(11) 8/19).
- 3. On 2 July 2012, Cabinet agreed to a number of policy proposals in relation to the new legislation (SOC(12)12/3 refers). A Regulatory Impact Statement was prepared at that time, setting out in detail the problem to be addressed by the new legislation and the status quo.¹
- 4. On 2 July 2012, Cabinet also agreed to separate report-backs on three issues: costs and fee-setting for the new regime, offences and penalties, and options for retail restrictions.

Status quo

- 5. On 2 July 2012, Cabinet agreed to the following aspects for new legislation to control psychoactive substances:
 - a. to establish a pre-market approval regulatory regime for substances taken for the primary purpose of inducing a psychoactive effect
 - b. that approval should be considered for manufactured products rather than individual active ingredients, on the basis of consistent toxicological and behavioural data
 - c. to establish a new regulator within the Ministry of Health to administer the regime
 - d. that the regulator will be funded through full cost recovery
 - e. that the importation of active ingredients will be regulated by the Hazardous Substances and New Organisms Act 1996, and the importation of manufactured products will be regulated under the new legislation
 - f. that unapproved substances will be prohibited imports under the Customs and Excise Act 1996
 - g. that there will be transitional provisions following enactment to permit the continued availability of some psychoactive products provided they are undergoing assessment by the regulator
 - h. that a policy review of the regulatory scheme will be carried out five years after commencement.

¹ The RIS New Regulatory Regime for Psychoactive Substances can be found on the Ministry of Health website http://www.health.govt.nz/about-ministry/legislation-and-regulation/regulatory-impact-statements/new-regulatory-regime-psychoactive-substances

6. Cabinet authorised the Associate Minister of Health to issue drafting instructions to Parliamentary Counsel to give effect to the recommendations. It is intended that the legislation is introduced by the end of 2012 and enacted by August 2013.

Problem definition

- 7. Currently, there is no mechanism to prevent psychoactive substances not already scheduled in the Misuse of Drugs Act 1975 (MoDA), or structurally similar analogues, from being sold. Existing legislative controls rely upon the Government identifying that a potentially harmful substance is being sold and then reacting accordingly.
- 8. This means that there is a delay between a substance being marketed and any controls being placed on its availability. For a substance to be scheduled in the MoDA, which prohibits its importation, manufacture, supply, and possession, the Expert Advisory Committee on Drugs provides the Minister of Health with evidence-based advice on the level of harm. In the case of new psychoactive substances, there is often little information about use and harms on which to base advice.
- 9. Drug legislation has been ineffective in dealing with the rapid growth in synthetic psychoactive substances that can be synthesised to remain one step ahead of legislation. It is also inconsistent with the way other products are regulated: medicines, novel foods, and hazardous substances are subject to pre-market assessment and approval.
- 10. Psychoactive substances can currently be sold without restrictions on their purchase age, place of sale, advertising or packaging, and without accurate information for consumers. With other psychoactive substances, particularly alcohol and tobacco, the Government restricts access by young people, and manages demand 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.
- 11. Cabinet has agreed a legislative solution to the problem is to introduce a pre-market approval regime for low-risk psychoactive substances. This new legal regime and the proposed provisions require offences and penalties in order to deter and address failure to comply with the new regime. The regime will also need to establish powers for enforcement agents to investigate potential non-compliance.

Objective

12. The overarching 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.

Regulatory Impact Analysis

- 13. This Regulatory Impact Analysis considers the following issues:
 - offences and penalties (Part A)
 - retail restrictions for approved products (Part B)

Part A - Offences and penalties

- 14. Currently, there is no regulatory framework for psychoactive substances that are not controlled by the Misuse of Drugs Act or by temporary class drug notices. The new legislation will establish restrictions on importation, manufacture, and supply of unapproved and approved psychoactive substances. Without a framework of offences, there would be no incentive to comply with the provisions of the legislation. It would also be inconsistent with the way that alcohol, tobacco, and drugs controlled under the MoDA are regulated.
- 15. The new regime requires appropriate offences and penalties for criminal breaches and regulatory non-compliance to ensure a sufficient level of deterrence against offending. Police and Customs will need to have adequate powers to address the illegal import, manufacturing, dealing, supply, and intention to supply, of unapproved substances. The new regulator established under the legislation will need powers to investigate licensing breaches and other regulatory non-compliance, and offences and penalties will be required for these breaches.

Objectives

- 16. The overall objective is to minimise non-compliance with the new regime and ensure penalties act as a deterrent against offending. Other objectives include:
 - consistency with other similar pieces of legislation such as the MoDA and Hazardous Substances and New Organisms Act 1996 (HSNO)
 - adequate provision for enforcement agencies to investigate and address criminal activity and regulatory non-compliance
 - to minimise the impact on the public from harms associated with sanctions, such as imprisonment or criminal record, by ensuring a proportionate and fair approach
 - to minimise the resource burden on enforcement agencies

Options

- 17. A table has been developed by the Ministry of Justice with proposed offences and penalties for all breaches under the legislation (attachment one). This framework differentiates between offending with unapproved substances and offending with approved products. The maximum penalties for offences relating to both types of substances are therefore different.
- 18. In terms of regulatory breaches, such as failure to meet standards of the manufacturing code of conduct and failure to report adverse events, the Ministry has not considered alternative options but supports the Ministry of Justice's proposed offences and penalties as these are in line with similar regimes, such as the regulation of hazardous substances.
- 19. The Ministry has, in consultation with the Ministry of Justice, New Zealand Police, and the New Zealand Customs Service, considered options in relation to offences and penalty levels for criminal offending in relation to unapproved substances.

Criminal activity in relation to unapproved substances

Importation, supply, and manufacturing offences

20. The offences proposed are largely the same as those for controlled drugs in the MoDA in relation to dealing offences (importation, manufacturing, sale and supply). However, the proposed maximum penalty is lower. It will be illegal to import, manufacture, or supply an unapproved substance without a licence. A licence will be needed, for instance, for the importation of small quantities of unapproved substances for testing.

Option one – the same offences and penalties as for Class C MoDA drugs

- 21. The Ministries of Health and Justice, New Zealand Police, and the New Zealand Customs Service initially considered dealing offences in line with the offences and penalties for Class C controlled drugs in the MoDA. This was because we proposed to bring analogue substances within the new legislation. Analogues are substances that have been demonstrated to have a chemical structure similar to a controlled drug. They are treated as Class C controlled drugs with a maximum sentence of 8 years imprisonment.
- 22. The analogue provisions have proved useful as they prevent a person subtly altering a controlled drug and being able to sell it without any restrictions. However, the Law Commission considers that the provisions are problematic because the definition of an analogue is based only on the chemical structure and not on the effect on the brain or the harm posed by the substance. This means that substances which pose no risk of harm could be captured by the analogue provisions. The Law Commission also considers that the definition of "substantially similar" leaves room for ambiguity.
- 23. In order to repeal the analogue provisions in the MoDA and bring analogues into the new legislation, enforcement agencies considered it important that the penalties remained the same as currently available under the MoDA, namely 8 years. This reflects a concern about analogues that have been an important focus for enforcement activity in recent years. Police advised us that organised criminal groups have dealt in substances that are not scheduled under the MoDA, but are analogues of substances that are. The 12 month investigation and seizures of large quantities of drugs, cash and weapons in Operation Ark in 2011 depended on these analogue provisions. A priority for enforcement agencies is that there is a consistent deterrent to prevent a person trying to game the system by claiming to have acted under the new regime.
- 24. The reason this option is not supported is because, in order for the offences to carry an 8 year penalty, they would need to include intent. This means that the prosecution would have to prove both the act (eg dealing), and that the defendant acted knowingly or recklessly. Enforcement agencies consider that this would make the offences unworkable as it would allow for defendants to claim that they thought a substance to be a herbal remedy, or that they did not know it was psychoactive. It may be so hard to prove intent under the new regime, that the offences could be unenforceable.
- 25. If we made this a strict liability offence, which means the prosecution would not have to prove a person's knowledge or recklessness, it would have significant implications under the New Zealand Bill of Rights Act 1990 (BORA). A sentence of eight years without the right to offer an explanation or excuse is a clear breach of the right not to be arbitrarily detained (sec 22).
- 26. This option would meet the objectives of being consistent with the MoDA and providing a deterrent to the sort of large-scale offending that we know occurs with respect to

analogue substances. However, we consider that, either there would be a negative impact on the operational activities of enforcement agencies, or it would create serious BORA issues for defendants.

Option two - strict liability offence with a two year maximum penalty

- 27. The preferred option is for a strict liability offence with the onus on the defendant to provide a reasonable excuse for committing the offence. However, the proposed maximum penalty is two years imprisonment.
- 28. The Law Commission recommended penalties in line with offences in the Hazardous Substances and New Organisms Act 1996 (HSNO), namely: a maximum sentence of three months' imprisonment for an individual or a \$500,000 fine for a body corporate.
- 29. Agencies agree that HSNO-equivalent penalties are appropriate for regulatory noncompliance (considered below). However, for dealing in unapproved substances, enforcement agencies consider that maximum term of imprisonment should be higher than for approved products. Unapproved substances will include new and unknown substances with unknown health risks, and the penalties need to deter against dealing in these substances.
- 30. The preferred option is for analogue provisions to remain in the MoDA. The offences under the new legislation would apply unless it was subsequently demonstrated that a substance was an analogue of a controlled drug. If a person has imported, manufactured or supplied a controlled drug, or an analogue of a controlled drug, they will be dealt with under the MoDA.
- 31. It is possible that there will be situations where a person will insist that they thought they were importing, manufacturing or supplying an unapproved substance (which would carry a lesser penalty to substances under the MoDA). It is therefore proposed that the legislation is drafted to ensure that a person cannot claim that they thought they were dealing in an unapproved substance. In that case, the person would be tried in accordance with the MoDA regime and the prosecution would be required to prove intent as established by MoDA case law (such as knowledge of the offending).
- 32. While the analogue provisions are problematic, retaining them in the MoDA provides enforcement agencies with a more serious deterrent if it can be demonstrated that an unapproved substance is a controlled drug analogue. These agencies have expressed concern about any changes to their ability to investigate, enforce and deter offending with analogues.

Intent to supply offence

- 33. It is proposed that there is an offence to possess an unapproved substance with the intention to supply. The prosecution would be required to demonstrate intention to supply based on evidence including equipment, packaging, and the quantity found in possession.
- 34. This offence is different to the possession for supply offence in the MoDA which provides a presumption for supply when a person is in possession of a controlled drug over a certain amount. The default quantity for the majority of drugs is 56g, but it is 28g for cannabis and 2.5mg for LSD.²

² The presumption for supply provision has been criticised as being contrary to the Bill of Rights Act 1990 as it reverses the onus of guilt, presuming someone to be guilty of the offence unless they can prove otherwise.

35. Unlike the MoDA, which lists each controlled drug in its schedules, the new regime will make any and all psychoactive substances unapproved unless approved by the regulator. It would be impractical to determine specific quantities without a list of substances. In addition, a default quantity would be inadequate as it would not be suitable for very potent substances, such as LSD.

Enforcement powers

- 36. Enforcement agencies will have powers to investigate, search, and seize unapproved substances under the Search and Surveillance Act 2012. For example, it will be possible to obtain a search warrant in relation to the commission of an imprisonable offence. It would also be allowed to conduct a warrantless search where there reasonable grounds to suspect that an offence has been committed and that, if the search is not conducted immediately, evidential material could be lost or altered.
- 37. A consequential amendment to the Search and Surveillance Act 2012 will be necessary to allow for trespass surveillance, such as intercepts. Although this generally has a penalty threshold of seven years, the Ministry supports this as we understand that until the surveillance is carried out, enforcement agencies would not know if the substances involved were controlled drugs, analogues of controlled drugs, or unapproved. This is consistent with the approach for trespass surveillance for firearms.

Impacts of the preferred option

- 38. The proposed two year penalty is relatively high for a strict liability offence. Strict liability offences appear to limit the presumption of innocence affirmed in section 25(c) of the BORA, because they require the defendant to prove a defence (such a reasonable excuse) to escape liability. The penalty level is one factor that determines whether the limitation is reasonable. Therefore, this proposal has the potential to be inconsistent with the principles in the BORA.
- 39. The BORA issues would be less serious than under option one, however, the full implications of option two will not be known until the legislation has been drafted.
- 40. The proposed offences and penalties for the importation, manufacture, supply and intent to supply will be "category 3" offences in accordance with the Criminal Procedure Act 2011. This means that these offences will progress through the District Court. The defendant will not have the option to elect trial by jury.
- 41. There is insufficient information available to determine the likely number of offences of importation, manufacture or supply of unapproved substances committed that would progress through the court system. This is because the regime is designed to deal with substances that are either currently unregulated or have been temporarily classified. Agencies will be in a better position to evaluate the situation once the new regime is in effect. The Ministry of Justice will track the number of cases progressing through the court system via its computerised Case Management System.

The Law Commission in its review of the MoDA recommended an alternative to the current provision, and the Government will consider this recommendation during the policy work for a new Misuse of Drugs Act. The recommendation is that there would be two possession offences: simple possession and aggravated possession, with penalties set higher for aggravated possession.

- 42. There is insufficient legal high data to estimate the potential impacts to the criminal justice sector. The Ministry of Justice looked at BZP cases from 2008 (when BZP was scheduled as a Class C controlled drug in the MoDA). BZP cases fell and ecstasy cases increased. There may be a similar shift from currently available party pills to controlled drugs, once party pills become unapproved substances. However there is no evidence around displacement effects and Justice chose not to use this data. Justice has instead used cannabis offending data for 2011 (a meaningful average could not be extracted from five year data owing to considerable fluctuations).
- 43. In order to calculate potential costs, the Ministry of Justice has assumed that there will be no impact on behaviours relating to the importation, manufacture, and supply of cannabis (and other controlled drugs). The assumption is that manufacturers and suppliers of unapproved substances would not move their operations to controlled drugs. However, this is an assumption and if profit margins are better and risks the same, there may be a shift in behaviour.
- 44. New Zealand Police does not consider the financial implications will be significant. However, Police is unable to provide an estimate of the costs of prosecutions. This is because each case depends on a number of factors that determines how much time goes into a prosecution. Factors include file preparation, information gathering, and dealing with witnesses and will depend upon the complexity of the case. Police also notes that prosecutorial work is driven largely by the availability of judicial time and how quickly a Judge may dispose of a case. Police provided, as an example, the difference between family violence cases in Waitakere, where 18% of cases have over 10 court appearances, compared to 8.1% in Manukau.
- 45. The Ministry of Justice and Corrections have based their costs on a maximum of 10 cases per offence type, resulting in the following estimated court cases and sentence types imposed from convictions. These figures are based on the proportions relating to 2011 cannabis offending:

	Charge Convictions	Case convictions	Case Sentences (from cases)	Average length of custodial Sentence (in year terms)	Community service	Home detention	Community detention	Intens -ive super vision
IMPORTATION	10	10	0	0	0	0	10	0
MANUFACTURE	6	6	2	0	2	1	1	0
SUPPLY	6	7	2	0	2	2	1	0
POSSESSION WITH INTENT TO SUPPLY	7	7	1	0	2	2	1	0

Court costs

- 46. Any costs for the courts would depend on a number of factors, including the length of court hearings and trials, frequency of court events, outcomes of the trials, staff resources, complexity of the issues being raised (assuming expert scientific evidence may be required for new substances). Therefore, it is difficult to make a proper assessment.
- 47. However, based on broad cost estimates relating to other category 3 offences and modelling for 10 people per offence type, total costs for importation, manufacture, supply and possession with intent to supply should not exceed \$130,500. More accurate costs will become apparent once the regime has been implemented. Therefore, this figure is to be treated as a guideline cost until further notice.

Corrections costs

- 48. On the basis of estimations by the Ministry of Justice on potential volumes of charges, Corrections has estimated that an additional four prison beds would be required per annum at an annual cost of \$177,000. There would be an additional 18 community sentence years at a cost of \$118,000 per annum (based on the average cost of home detention, community detention, intensive supervision, supervision community work, parole and release conditions). This is a total cost to Corrections of \$295,000 per annum.
- 49. However, Corrections estimates do not take into account any displacement. For instance, there may be no additional offending but instead offending may be spread across both the MoDA and the new legislation
- 50. Agencies have advised that the estimated increase in costs can be met within baselines. The costs were not seen as an impediment to enforcement.

Personal possession (without intent to supply)

51. There are three options for addressing the possession of unapproved substances with no intent to supply, for instance the possession of small quantities of an unapproved substance.

Option one - no offence for possession

- 52. The temporary class drug notice provisions of the MoDA do not have a possession offence, and a personal possession offence was not recommended by the Law Commission for the new legislation.
- 53. The benefit of not having an offence is that there would be no harms to the offender associated with criminal sanctions, such as negative impacts on travel and employment opportunities. There would also be no additional cost implications for Police and the courts.
- 54. Without a possession offence, however, there would be no provision for Police to confiscate unapproved and potentially unsafe substances. It is not possible for legislation to permit the seizure of unapproved substances without this power being linked to an offence, as if it is not, it will constitute an unreasonable seizure and breach the New Zealand Bill of Rights Act 1990 (sec 21). As this legislation is primarily aimed at protecting public safety, all agencies agree that the power to confiscate unapproved substances is necessary. Hospital discharge data collated by the Ministry reports only a

small number of cases of hospitalisations for "legal highs" (37 between 2009-2011).³ Although the harms to the individual may be small, the Ministry supports there being an offence, proportionate to the potential harm, in order to reduce the risk of someone taking a potentially harmful substance, by Police having the power to confiscate substances the safety of which has not been assessed. For that reason, the Ministry does not agree with the Law Commission that there should be no offence.

Option two – a summary offence carrying a maximum fine of \$500

- 55. A criminal offence for possession would be consistent with the MoDA which has a possession offence for controlled drugs. These are the substances listed in Schedules 1-3 (Classes A, B, and C) of the MoDA. The penalties for possession offences are set in accordance with the risk of harm associated with each Schedule. Schedule 1 (Class A) drugs carry a maximum penalty of 6 months imprisonment and/or a \$1000 fine. Possession of Schedule 2 and Schedule 3 (Class B and Class C) drugs carries a maximum prison sentence of 3 months and/or a fine of \$500. In addition, Police have a discretionary policy to use alternative resolutions, such as diversion and pre-charge warnings, in relation to Class C possession offences under the MoDA.
- 56. The Ministry understands that it is highly unusual for someone to receive a custodial sentence for personal possession of Class C drugs⁴ and that the average fine imposed by the courts is currently less than \$250.⁵ The Ministry considers that including a maximum term of imprisonment would be disproportionate for this offence.
- 57. If this option is considered appropriate for the new legislation, the offence will be based on those available under the Summary Offences Act, which carry a monetary penalty. For example, a defendant would be charged with committing an offence of possession of an unapproved substance without a reasonable excuse. This means that the onus would be on the defendant to provide a reasonable excuse for the product to be in their possession. The penalty would be a maximum \$500 fine.
- 58. The police would have the discretion to either charge the person for this offence or issue them with a pre-charge warning. This is the same as for cannabis offences. Where a person has been convicted for possession of an unapproved substance, this conviction will be entered on their criminal record.
- 59. As with the dealing offences above, there is insufficient information available to make a solid estimate of the likely number of breaches and subsequent charges or cases that will occur from making possession an offence.
- 60. The Ministry of Justice has estimated 700 breaches per annum for possession.⁶ This figure is derived from an assumption of a similar prevalence of use for unapproved

³ The Regulatory Impact Statement prepared for the Cabinet consideration of the new regime for psychoactive substances in June 2012 summarises this data in greater detail.

⁴ From 2002 – 2011, only (on average) 8.4% of possession/use of cannabis offences resulted in a custodial sentence and in 2011 it was 7%. The most common sentence is therefore a fine (40% in 2011), followed by community service (30% in 2011) and custodial sentences.

⁵ The average fine imposed on a person for possession of cannabis from 1996 - 2011 was \$202. The average fine imposed in 2011 was \$227.

⁶ a. 2011 Court data on cannabis possession charges and cases:

i. There were 4798 charges for possession of cannabis in 2011

ii. Seventy-six percent (or 3,637) of the 4798 charges resulted in a conviction.

iii. Approximately 80% of case convictions (not charge convictions) resulted in a sentence being imposed (eg, custodial, community service, home detention, or fine) as opposed to conviction and discharge without a

substances as cannabis (15%) and then increasing cannabis charges by 15%. However, this figure does not take into account a shift in behaviour from cannabis or other controlled drugs to approved products, or an increase in controlled drug offending. However, this figure allows us to apply the potential proportion, based on cannabis charges, that result in a pre-charge warning (around 180), resulting in around 520 cases progressing through to the courts. An estimated 395 of those will result in a conviction and 316 in a fine being imposed.

- 61. It costs the Ministry of Justice on average 26c per dollar of fine collected. This is for generally offending and not drug specific offending. Therefore, if 320 fines are imposed then the cost of collecting these fines will be maximum \$130 (for a \$500 fine), with a total of \$41,600 for 320 fines at \$500, or on average \$18,880 (based on the average \$227). Therefore the cost of collecting a fine would be in the approximate range of \$18,880 to \$41,600.
- 62. The costs to the courts for 520 cases progressing through the courts have been estimated at around \$550,000 per year.

Option three – an infringement offence with a set infringement fee

- 63. The third option is an offence of possession of an unapproved substance, where a person is liable to pay an infringement fee. As with the second option, the health benefit of this option would be that Police could confiscate unapproved and potentially harmful substances. This is the preferred option.
- 64. A person receiving an infringement notice would be required to pay the amount within 28 days, otherwise, the matter would progress to the court for a hearing. The person would not be liable for a conviction on their criminal record for not paying their fee. However, they could receive a conviction for non-payment of a court fine (as a different offence).
- 65. As noted above, the average fine currently being imposed by the courts for possession of cannabis was \$227 in 2011 and the Ministry supports an infringement fee of \$300. It is close to the average amount being imposed by the courts. It is high enough to serve as deterrence for users without being too unaffordable for the offender or for Collections to collect.
- 66. If an estimated 700 breaches are committed then these breaches will result in infringement fees to be collected by the Ministry of Justice's Collections Unit. If it costs 26c per dollar collected then the cost of collecting a \$300 fee is \$78. Therefore, the total cost of collecting a \$300 fee will be \$54,600.
- 67. The Ministry is unable to estimate how many of those infringements are likely to progress through to the courts.

sentence. This figure represents the likely number of charges resulting in a sentence and therefore could be used as an indication of the estimated number of fines that would be imposed by the court iv. The average fine imposed was \$227 with the maximum available being \$500.

b.The 2008 Health Survey of Users (as a representative of clientele of unapproved substances)

i.11.3% of the population use stimulants monthly and 15% of the population use cannabis monthly

c.Police pre-charge warning data - (20% of breaches resulted in a warning from the period September 2010 to June 2012 and 26% for the year ending June 2012).

Court and Collections costs

68. As with dealing offences above, any costs to the courts and Collections Unit for options 2 and 3 would depend on a number of factors, including the length of court hearings and trials, frequency of court events, outcomes of the trials, staff resources, complexity of the issues being raised (assuming expert scientific evidence may be required for new substances).

Enforcement powers

- 69. If the offence was a summary offence, an officer would have the power to arrest (without a warrant) any person whom they have good cause to suspect of having an unapproved substance in their possession. This is in line with the powers to arrest in the Summary Offences Act for summary offences carrying a fine only (for instance, section 4 offensive behaviour, and sale of spraycans to persons under 18 years).
- 70. If a person has been found in possession of an unapproved substance and refuses to provide the officer with their particulars, it would be difficult for an officer to charge them with the offence or issue an infringement notice. The person could then be charged with wilful obstruction, hindering or resisting an officer. The proposed maximum penalty for commission of this offence is 3 months imprisonment or a maximum \$500 fine. This is the same as the maximum available under the MoDA.
- 71. For either a summary offence or an infringement, an officer would have the power to confiscate but would not have the same warrantless powers to search a person as available under the Search and Surveillance Act. That Act provides powers for dealing offences (as above) and offences that carry imprisonment offences (such as, possession under the MoDA).

Impact to agencies of the options for possession

- 72. If possession was not an offence, there would be minimal impact on enforcement agencies and no impact on the courts. Police would continue to have powers under the MoDA to seize an unknown substance, but only if they suspected it of being a controlled drug.
- 73. The costs for the three options, based on the assumption that there are 700 breaches each year, are set out in the following table.

Possession offences

Costs	No offence	Fine max \$500	Infringement \$3007[1]	Costs
Police	No breaches	Breaches: 700	Breaches: 700	Costs of issuing notices?
		Pre charge warnings: 180	No pre-charge warnings	Costs of issuing pre-charge warnings?
		Prosecutions: 520		Costs of prosecutions?
Courts	0	Prosecutions: 520		Case costs: \$550,000 (for 520 cases) Approx
		Charges resulting in a conviction: 395		
Collections	0	Fines	Infringements	Maximum cost of collecting 700 infringements: approx \$54,600
			700	
		Fines imposed: 320		Estimated cost of collecting fines: approx \$18,800 to \$41,600

Impact on individuals

- 74. If there was a summary offence for possession, there would be impacts to individuals in terms of the harms from the sanction. For instance, a criminal record would affect employment and travel opportunities. Police would be able to use the discretionary alternative resolutions such as pre-charge warnings for a summary offence, as they currently do for Class C possession offences under the MoDA. This would lessen the impact of a potential criminal offence, but possibly only in around 25% of cases.
- 75. While an infringement ensures that an individual does not receive a criminal record, there is potential for this to have a discriminatory impact on those with less ability to pay the fee, which could lead to increased interaction with the justice sector. We recommend a fee of \$300, which would be a fixed amount. A summary offences fine is set by the court and the average Class C possession fine is less than half the maximum \$500. The Ministry considers that \$300 is sufficiently high to be a deterrent without being disproportionately high.

Conclusion – options for possession

	Criminal offence with fine	Infringement with a fee	No possession offence
Consistent with other Leg.	MoDA controlled drugs (without imprisonment penalty)	Alcohol offences under new legislation	Temporary class drug notice Tobacco (ie contraband) Counterfeit medicines
Enforcement powers	Power to confiscate. Power to arrest. Can use alternative resolution including diversion and pre-charge warning	Power to confiscate. No arrest powers for infringement so additional criminal offence required for failing to provide details with a fine and the power to arrest.	No power to search and confiscate (unless reasonable cause to believe that MoDA drugs is involved – if found to be an unapproved substance, then charges would have to be dropped)
Impact on public	Unlike the MoDA, there will be no list of substances that are illegal to possess. This would create uncertainty for individuals who have a right to be certain about charges/penalties as a result of behaviour. Maximum fine of \$500 for possession consistent with Class C controlled drugs. Potential for a criminal record which would impact employment and travel opportunities - however pre-charge warning likely to be used in some cases	Similar issue of uncertainty for the public Fee could be around the same as the average fine for Class C which is less than \$250 No conviction or criminal record but could discriminate against those unable to pay the fee which would bring them into contact with the courts. Time to pay arrangements may be put in place to manage payments.	No legal or financial impact on consumers
Minimise harm	Unapproved substances could be dangerous. Having a possession offence allows for confiscation and may have a deterrent effect. However, some substances may be completely harmless and individuals could face a possible criminal record	Would have power to confiscate avoiding potential harms from untested substances. Individual would not be subject to criminal record and therefore not face employment and travel limitation. Police would not have access to diversion or pre-	Police would have no power to confiscate unapproved substances which could have health implications as these are untested and potentially harmful. But there would be no negative impact from potential criminalisation of possession offence (depending upon penalty)

	Criminal offence with fine	Infringement with a fee	No possession offence
	limiting employment and travel opportunities. Diversion could be used to encourage people into some kind of treatment intervention	charge warnings. It is likely that a fee is charged more often than a fine would be	
Impact on enforcement agencies	Impacts on Police and courts depending upon penalties. Police: operational and enforcement Courts and legal aid May be impractical for Police to enforce as no list of unapproved substances. However, any pure chemical that is not packaged in a dose form would likely be either a controlled drug or an unapproved substance.	Impact on Police, and to some extent courts if challenged or people refuse to/or unable to pay fees.	No additional resource implications for Police but may be difficult to distinguish between unidentified unapproved substance and controlled drug. Police could still act under s.18 of MoDA if reasonable cause that a controlled drug in possession. There is a risk that this would be used too freely.

Conclusion

- 76. The Ministry prefers option three, the infringement fee, as the most proportionate response to personal possession, which would avoid harms associated with criminal sanctions. An infringement is consistent with the approach to alcohol and allows for the confiscation of unapproved substances mitigating their potential harm to the individual. The Ministry of Justice and New Zealand Police also support this option.
- 77. In addition, the Ministry notes that, unlike the MoDA, the new legislation would not list unapproved substances in schedules, and most would not have been assessed for potential harm as is the case with drugs scheduled in the MoDA. This creates uncertainty for individuals. A person has the right to be certain about the likely charges and likely penalties for which they are liable as a result of their behaviour. Some unapproved substances could be harmless and the consequences of being charged with an offence may outweigh any potential health benefit. As explained previously in this paper, there has only been a small number of health problems associated with party pills and other legal highs. A summary offence for possession may be a disproportionate response, particularly as a conviction would result in a criminal record.

Regulatory breaches in relation to approved products

- 78. There will also need to be offences for regulatory non-compliance for approved products and licensing offences. The proposed offences are largely consistent with provisions under the Hazardous Substances and New Organisms Act 1996 and the Medicines Act 1981. These are set out in the table of offences developed by the Ministry of Justice and attached to the Cabinet paper. The Ministry has not considered any alternatives and supports the offences proposed.
- 79. The proposed offences include an offence to knowingly or recklessly import, manufacture, or supply an approved substance in breach of specific conditions of licence, or without a licence. An offence for possession of an approved product with intent to supply, without a licence, is also proposed. There will also be offences relating to knowingly or recklessly include false or misleading information in an application or to omit any adverse information, or for failing to report any new information.
- 80. The proposed maximum penalty for committing these regulatory offences is 3 months imprisonment and/or \$500,000. This option retains judicial discretion to determine the most appropriate sentence in each case. It will also ensure against any difficulties prosecutors have in determining whether to charge an individual or a company for commission of the offence.

Enforcement powers

- 81. An officer will be required to obtain a warrant to enter a place to inspect, search and seize where there are reasonable grounds to believe the commission of a regulatory breach relating to an approved substance. This is similar to the powers available under the Alcohol Reform Bill.
- 82. An officer will have the power to enter a commercial property to inspect compliance with the law where there are reasonable grounds to believe a breach has been committed.

Impacts to the criminal justice sector for regulatory non-compliance

- 83. Offences for regulatory breaches in relation to approved products will be "category 2" offences for progression through the courts. This means that these offences will progress through the District Court. The defendant will not have the option to elect trial by jury. A judge will preside over these cases.
- 84. There is insufficient information available currently on the likely volume of cases, however this will be monitored by the Ministry of Justice and the regulator established under the new legislation.

Consequential amendments to the Misuse of Drugs Act 1975

- 85. The new regime will make two of the provisions of the MoDA redundant.
- 86. The restricted substance provisions brought into force by the Misuse of Drugs Amendment Act 2005 were intended to provide a regulatory regime for the sale of substances considered by the EACD to pose a lower than moderate risk of harm. The new regime makes the restricted substances regime superfluous by providing a similar regulatory scheme with retail restrictions largely based on those agreed for restricted substances. The principal difference is that the restricted substances legislation, as with other provisions in the MoDA, is reactive, requiring the Government to schedule substances once it becomes aware of them. Also the approval of products for the new regime will not be carried out by the EACD but managed by a new regulator and based on the approval process for new medicines.
- 87. The temporary class drug notices provide an emergency mechanism to prohibit for a 12month period the importation, manufacture, sale and supply of substances listed by a notice in the *Gazette*. With the introduction of the new regime, the temporary notices will be unnecessary as all psychoactive substances will be brought automatically within the scope of the regime. The Government will no longer be required to react to the emergence of new substances and issue a notice, as anything unapproved will, by default, be controlled. Before the legislation is enacted, the EACD will consider all substances currently under a temporary notice to assess whether permanent scheduling in the MoDA is appropriate.

Part B - Retail restrictions

- 88. Currently, psychoactive products such as party pills can be sold without any restrictions on purchase age, place of sale, or advertising. This means they can be accessed by young people who are arguably not mature enough to make the decisions to limit the potential harms of psychoactive substances. For example, decisions about the dosage that an individual can tolerate, and whether they can safely drive whilst under a product's influence. There are no labelling requirements advising of these risks and no controls over where psychoactive products can be bought. This situation is inconsistent with the approach taken with other psychoactive substances such as alcohol and tobacco.
- 89. In our view, the status quo does not effectively reduce the potential for legally-available psychoactive products to cause adverse reactions. This view is informed by hospital presentations attributable to the use of similar products over the past 10 years. Generally, these have been low level presentations that are mainly due to over consumption and anxiety about an unexpected strength of effect. Retail restrictions can address this by ensuring that products are appropriately labelled and only marketed at, and available to, those old enough to make an informed decision about their use.

Objectives

- 90. The primary objective of restrictions on the retail of approved psychoactive products is to mitigate any harms resulting from their legal availability. Other objectives are:
 - to be consistent with restrictions on other psychoactive products such as alcohol and tobacco,
 - cost effectiveness,
 - proportionality with the harms of the approved products,
 - effectiveness in reducing exposure and visibility of products to those not actively looking for them,
 - to address public concern about the wide availability of these products, especially to children.

Options

- 91. The controls proposed are modelled on those previously made by the Misuse of Drugs Amendment Act 2005 and Misuse of Drugs (Restricted Substances) Regulations 2008, together with the recommendations of the Law Commission contained in its report *Controlling and Regulating Drugs: A Review of the Misuse of Drugs Act 1975.*
- 92. These restrictions also take into account New Zealand's experience with the legal sale of psychoactive substances (for example, the unrestricted sale of benzylpiperazine (BZP) from 2000 2005, and the regulated sale of BZP from 2005 2008). The Ministry has also considered the unrestricted sale of 1-3 dimethylamylamine (DMAA) from 2008 2011, and the sale of legal cannabis-like substances as herbal smoking products in 2010 and 2011.

Mechanism to give effect to retail restrictions

93. The Law Commission recommended that there should be a number of generic statutory conditions in primary legislation that apply to all approved substances. We agree. The Ministry considered recommending regulation-making powers to use in due course when more is known about the market. However, we consider that including these controls in primary legislation will provide greater clarity regarding the expectations for this industry.

Enforcement and compliance monitoring for retail restrictions

- 94. The Ministry considers that the regional public health services throughout New Zealand are the best fit to undertake a compliance monitoring role for retail restrictions. There are 12 District Health Board-owned Public Health Units (PHUs) and a range of non-government organisations that also carry out this function in New Zealand. For the sake of simplicity, this analysis will refer to any provider of these services as a PHU.
- 95. We have considered alternatives to PHUs including a dedicated monitoring capability for the new regulator, or for New Zealand Police to undertake this role. The new regulator will need audit and compliance resource, however a dedicated monitoring capability for the regulator would require additional staffing at a time when the Ministry of Health is operating within a FTE cap, and would likely incur large travel expenses in order to undertake this role nationwide. The Ministry has its own enforcement capability and this could be used as appropriate for the new legislation in addition to PHUs. However, certainly for the first two to five years, the Ministry does not consider a dedicated enforcement role to be necessary. Likewise, we do not think Police are appropriate for regulatory enforcement.

CRITERIA	OPTIONS				
CRITERIA	Public Health Units	New Zealand Police	The new regulator		
Cost effective	\checkmark	Partial	×		
Proportionate	\checkmark	×	\checkmark		
Effective	\checkmark	\checkmark	Partial		
Existing expertise	\checkmark	Partial	×		

Who should check for compliance with retail restrictions?

- 96. PHUs already employ officers designated by the Ministry of Health for enforcement of tobacco restrictions. This includes controlled purchase operations. PHUs have also been responsible for monitoring to ensure that synthetic cannabis-like products are compliant with the minimum purchase age restriction of 18 years for herbal smoking products. We think that adapting this practice to meet the needs of approved psychoactive products is the most rational fit for the new regime.
- 97. In 2010 the Ministry of Health spent \$8.5 million on contracts with PHU's tobacco control services. Around 40% of this figure (\$3.4 million) was expected to fund compliance and enforcement activities. However, we expect the cost of enforcing approved psychoactive products will be significantly less than \$3.4 million. This is because there will be far fewer premises selling approved products. We estimate that enforcement and compliance monitoring for approved products will cost less than 10% of the cost of enforcing tobacco. The cost modelling carried out for the Cabinet Paper estimates a maximum of \$120,000 per annum on enforcement activity; this can be met through cost recovery. A better estimate of enforcement costs will be possible once the legislation is drafted.

Proposed restrictions

98. In May 2012, the Ministry conducted targeted consultation with government agencies, industry representatives, and technical experts about retail restrictions. There was general support for the proposed restrictions, but also some suggestions that have been summarised in this document.

Controls on the minimum purchase age of approved products

- 99. We agree with the recommendation of the Law Commission that age restrictions are required for all products approved under the regime. The Ministry considers that restriction on the legal purchase age for approved products reflects a young person's maturity to make decisions around substance use.
- 100. A minimum purchase age would be consistent with the approach taken for other legally-available psychoactive products, such as alcohol and tobacco, and would also take into account public concerns about access to these products by young people.
- 101. We think it is appropriate to align the legal purchase age for approved products with the legal purchase age for alcohol, namely 18 years. Aligning the minimum purchase age for each would also provide consistency between the two frameworks and make it clear that people under the age of 18 should not be consuming any psychoactive product.

Impact

- 102. This restriction is unlikely to have a significant impact on users or industry. This is because it is already an offence to sell herbal smoking products to people under the age of 18 and nearly all manufacturers of party pills already voluntarily restrict their sale to those over the age of 18. A requirement for a minimum purchase age is therefore unlikely to significantly change current access to these products. However, it will have some impact on retailers that are non-compliant with the current voluntary measures.
- 103. We consulted with industry on this restriction. Industry supported a minimum purchase age for approved products. We were asked to consider alternatives such as whether there could be a variety of age restricted bands for different products, e.g. R18, R21 or R25 as appropriate. We consider that there needs to be single legal purchase age to reduce ambiguity.

Advertising and promotion of approved products

- 104. There has been significant public concern about the unrestricted advertising of previously legal psychoactive products. We agree with the view of the Law Commission that it is desirable to prevent a high level of commercialisation of approved products. To achieve this, the Ministry considers that the level of regulation governing the advertising of these products should more closely resemble that of tobacco than alcohol.
- 105. The Ministry supports the following restrictions:
 - a. The advertising of products approved under the regime should be prohibited except at the point of sale, either within the premises where they are sold or supplied, or on internet sites from which they are sold or supplied
 - b. The advertising of approved products must not contain themes that are particularly appealing to children
 - c. Point of sale advertising should be confined to material that communicates objective product information, including the characteristics of the product, the manner of its production and its price. This restriction should also apply to advertising on websites selling these products
 - d. The promotion of psychoactive substances, including sponsorship, should be prohibited in all media

- e. Incentives to encourage people to purchase approved products, such as promotional gifts or free-of-charge supply by retailers, should be prohibited
- f. Advertising or promotion must not convey that the product is safe.
- 106. These restrictions are supported in order that people not intending to use approved psychoactive products are not exposed to advertising encouraging them to do so. This is especially true for people under the legal purchase age. The Ministry considers that those who do wish to use these products should still be able to access objective product information within a premise selling them. Consumers should also be protected from false claims about the product's effects or safety.

Impact

- 107. These restrictions will significantly change existing arrangements. Industry is not currently subjected to any restrictions on the advertising of psychoactive substances.
- 108. Despite the extent of this change, the Ministry does not consider these restrictions will have a significant impact on industry. This is because the nature of the market will shift from one that is saturated with products attempting to establish a point of difference, to one where individual products are approved based on their respective merits. We think it is reasonable to assume that advertising will be less important for market share under the new model than the previous one. It is possible that some events, such as dance parties, which may rely on income from sponsorship, could see a lack of revenue as a result of these restrictions. However, on the whole, the Ministry estimates that the impacts for industry will be low.
- 109. This proposal will have some impact on consumers who may find it more difficult to identify a retailer of psychoactive products.
- 110. A Bill of Rights Act assessment of this proposal may raise some issues in relation to the industry's freedom of expression. A complete assessment of this, including a view as to whether any limitations can be justified, will be possible when the legislation is drafted.

Place of sale restrictions

- 111. The availability of previously uncontrolled psychoactive products from a wide range of retailers has caused public concern about the visibility of these products and their availability to children. There is also some evidence that ease of availability of these products has contributed to their increased use. This might have resulted in an increase in harms.
- 112. We think that place of sale restrictions are required in conjunction with advertising restrictions to minimise exposure for those not actively looking for these products. For example, a restriction prohibiting the advertising of approved products except within premises that sell them, would not be effective unless the type of premises that are eligible to sell these products is also restricted.
- 113. It is our view that the sale or supply of approved products should be prohibited from the following places:
 - a. premises that have an on-licence for the sale of alcohol;
 - b. petrol stations;
 - c. non-fixed premises such as vehicles, tents and mobile street carts;

- d. places children or minors gather (such as schools, recreational facilities and sports facilities);
- e. dairies and general grocery stores.
- 114. These restrictions have mostly been carried over from those made by the Misuse of Drugs (Restricted Substances) Regulations 2008, and recommended by the Law Commission. However, there are two changes. First, we think that places with an offlicence for the sale of alcohol should not be disqualified from selling these products. Second we support a new restriction specifying that dairies and general grocery stores should not be eligible to sell approved products.
- 115. There is not a strong evidence base to justify prohibiting the sale of these products from dairies or general grocery stores. While there is evidence linking the general availability of these products with increased use, we are not aware of any evidence that suggests availability from dairies or general grocery stores specifically increases harms. However, we think that owing to their location in the community and trade in items with appeal to young people, dairies and general grocery stores are not a good fit for the sale of these products.
- 116. In regards to alcohol retailers, we think there is good reason to prohibit the sale of these products from premises with an on-licence, in order to discourage the opportunistic sale of these products. People under the influence of alcohol, even at low levels, are arguably more likely to make reckless decisions about the use of other psychoactive products. As the use of alcohol and approved products together will generally be more harmful than using either alone, these consumers could suffer adverse reactions as a result of this availability.
- 117. However, the case is not as strong for off-licences. People buying alcohol from bottle stores are arguably less likely to have already consumed alcohol at the time of purchase than people buying alcohol from on-licences. Furthermore, off-licences have systems in place to verify purchase age, and are less likely to be places visited by children. We think it is reasonable to allow the sale of approved products from these premises.

Impact

- 118. As many as 1,000 dairies could be viewed as being affected by this restriction as this is the number of outlets roughly estimated to have traded in synthetic cannabis-like products prior to the temporary class drug notices. However, since the introduction of temporary notices in 2011, significantly fewer dairies have been trading in these products. The Ministry estimates that around 50 dairies may be affected.
- 119. Some pubs and other on-licensed premises that trade in these products could be affected. However, the Ministry expects the numbers that choose to sell psychoactive products will be low.
- 120. The proposed restrictions would have a small impact on consumers' access to psychoactive products.
- 121. We considered alternatives to this approach such as allowing the sale of approved products at dairies and general grocery stores providing certain conditions were met. For example, products should not be displayed near the point of sale (to stop impulse purchases) nor prominently displayed near food and other common household items (to minimise normalising the product) nor sold near products that would be attractive to children. On balance, we think that allowing dairies and general grocery stores to sell

approved products increases exposure to them by children. As advertising will be allowed within a premise selling these products, the object of the advertising restrictions will be compromised should premises frequented by children be allowed to sell them. We therefore do not consider that dairies and general grocery stores are suitable premises for the sale of approved psychoactive products.

122. We acknowledge that a dairy or general grocery store is going to be difficult to define. However, the policy intent is clear. We propose to work through the viability of this restriction with Parliamentary Counsel during the drafting of the Bill.

Packaging of approved products

- 123. Noting previous cases of accidental ingestion of legal psychoactive products by children, the Ministry supports the continuation of the following restriction:
 - a. Approved products must be packaged and stored in child-proof and tamper proof containers.
- 124. This is consistent with packaging of other substances that may be injurious to health, such as poisons and some medicines.

Impact

125. There may be a cost to manufacturers to comply with this requirement. However, these costs are likely to be small, and are warranted by the need to reduce the risk to children, by making containers child-proof. We have consulted with industry of the impact of this restriction and no concerns were raised.

Labelling of approved products

- 126. The Ministry supports labelling requirements for all approved products in order for the user to make an informed decision regarding their use and to know where they may seek help should they experience adverse effects.
 - a. All approved products should be labelled with a list documenting active ingredients, as well as contact details for the National Poisons Centre and the product's sponsor
 - b. Labels should be prominent on all approved products cautioning against their use during pregnancy
 - c. Labels should be prominent on all approved products cautioning against driving or operating machinery whilst under the product's influence.

Impact

- 127. Requiring manufacturers to list the active ingredients on their products might affect trade secrets. It is likely that other manufacturers will try to copy a product's formula once its active ingredients are listed. However, when industry was consulted on this proposal no concerns were raised. We think it is reasonable to infer from this that the impact will be small.
- 128. These requirements will have a positive impact for consumers. Foods and medical products are required to disclose the ingredients and additives they contain so consumers can make an informed choice about their use and avoid ingredients they know to cause them adverse reactions. We think the same considerations should apply to approved psychoactive products. For example, some consumers may have uncommon reactions to certain substances that cannot be identified in pre-market

testing. Disclosing a product's active ingredients would allow consumers to avoid the substances that they know to cause these reactions.

We do not know that any particular product will be risky to use while pregnant, and we do not intend to require products to be tested on pregnant women. As no such testing will be done, and we know that some psychoactives do have adverse effects if used during pregnancy, a label advising against their use is appropriate.

129. Similarly, any psychoactive substance can be reasonably assumed to impair perception, making it unsafe to drive or operate machinery. A warning on the label is appropriate.

Alternative options raised in consultation

"A restricted psychoactives user licence"

- 130. We were asked to consider whether people could be licensed to use and possess certain quantities of psychoactive substances. This would involve testing people for preexisting risk factors such as mental illness, cardiovascular disease, or problems in the way they metabolise active substances. People who did not fall into restricted categories could then be issued a licence allowing them to purchase approved psychoactive products.
- 131. We do not recommend this approach as it would be administratively complex and disproportionate. Given that the intent is for only low-risk psychoactive products to be approved, the Ministry does not think that it is necessary to screen individuals for these risks.

"A vertically integrated model of distribution"

- 132. We were also asked to consider a vertically integrated system keeping individual records of each consumer, documented medical history, and risk factors identified. It was suggested that each consumer could be assigned a case worker with skills in the area of alcohol and other drugs clinical assessment. Consumer purchasing patterns would be individually monitored with clinician contact and medical check-ups for high level uses. Consumers would have access to a support desk with 24 hour access, psychological evaluations, and targeted nutrition education.
- 133. Again the Ministry considers that this would be administratively complex and have considerable resource implications, as well as privacy implications for consumers.

Conclusion on marketing restrictions

The proposed package of retail restrictions is proportionate to the risks of products that have passed the safety tests and does not impose unreasonable costs on industry, according to industry members. It is a clear improvement on the status quo, where novel psychoactive substances are readily available, including to children, and with no safety, ingredient information.

Price Controls

134. Previously, there has been no mechanism to influence the price of legally-available psychoactive products in New Zealand. Operating within a competitive marketplace, manufacturers have been known to heavily discount their products. For example, in 2011 there were bulk specials on synthetic cannabis-like products which resulted in

between 100 and 200 doses of the drug, each lasting around 60 minutes, sold by retail for \$300.

- 135. Likewise, party pills have been sold by retail between \$4 \$5 a dose, and bags of pure active ingredients containing the substance 1,3-dimethylamylamine (DMAA) have been sold by retail for around \$2 a dose when purchased in large quantities.
- 136. Having psychoactive products available this cheaply is likely to have increased their use and potentially their harms. There may be merit in using price as a mechanism to moderate the demand for these products. Price controls are also consistent with the approach taken in relation to alcohol and tobacco, and may return some revenue to the Crown.
- 137. However, the Ministry does not recommend price controls at this time because of the lack of information required to justify their imposition. For example, we do not know what the consumer price sensitivity is to these products, and therefore it is difficult to model the extent to which demand might be affected by an increased price. Also, without an active market for approved products at this time, it is impossible to know what a reasonable price per dose of approved product should be.
- 138. We expect that approved products will initially be expensive. This is because industry will need to recoup the costs of research and development, toxicity testing, and fees. However, in time it is likely that the price of approved products will reduce as costs are recovered and market competition increases.
- 139. We think excise may be the better long term option to address this problem as it is consistent with the approach taken for alcohol and tobacco and would return revenue to the crown.
- 140. Establishing an excise regime would require amendment to the Customs and Excise Act 1996, a price per dose or quantity to be established (consistent with the approach taken to setting excise on alcohol and tobacco), and additional resources for the New Zealand Customs Service to establish a licensing regime and for enforcement and auditing of manufacturers.
- 141. The Government has agreed that this regulatory scheme be reviewed five years after commencement. We think price controls should be considered at this time, or sooner if circumstances dictate.

Consultation

- 142. The Ministry has worked with other government agencies on considering the options for offences and penalties and retail restrictions, namely: the Ministry of Justice, New Zealand Police, the New Zealand Customs Service, the Ministry for Business, Innovation and Employment, and the Treasury.
- 143. The Ministry has met with key industry members and ran a targeted consultation in May 2012 on the retail restrictions. Industry members were broadly supportive of the proposals, and their input is reflected in this regulatory impact statement.

Monitoring, evaluation and review

- 144. The Ministry of Justice will track the number of criminal cases progressing through the court system via its computerised Case Management System to assess the impact of the proposed penalties on the criminal justice system.
- 145. Police and Customs data will provide information on activity around unapproved substances and potential displacement effects of the new legislation. Tracking offending under the MoDA in addition to the new legislation should enable agencies to identify notable behaviour shifts in relation to approved, unapproved, and controlled drugs.
- 146. The Ministry will monitor retail restrictions through the Public Health Units and internal enforcement teams.