

Regulatory Impact Statement

Government Response to the Law Commission's Report "Controlling and Regulating Drugs – a review of the Misuse of Drugs Act 1975"

Agency Disclosure Statement

The Associate Minister of Health has agreed that, in light of the truncated timeframes arising from the forthcoming general election and the need for further detailed policy work on many of the issues, the Government Response will be limited to in-principle decisions on the need for new legislation. For other recommendations, such as those relating to the detail of the legislation, greater clarity about the potential impacts is required before any Government commitment can be made. Many of the proposed changes would have flow-on effects for the justice sector which require modelling by Justice and Police on the likely cost and resource impacts.

The most urgent concern for the Government is to address problems with the regulation of psychoactive substances emerging in the burgeoning legal high market. Government has signalled its intention to introduce a regime for psychoactive substances along the lines of the regime proposed by the Law Commission. Cabinet approval is being sought for in-principle agreement to develop a new regulatory regime to control these psychoactive substances in advance of the development of a new Misuse of Drugs Act. Priority will be given to policy work on the options for its implementation.

Until further policy work is completed, the Ministry is unable to calculate with any accuracy the costs of establishing a regulatory regime. There are no data on the demand for legally-available psychoactive substances. There are also scarce data on the number of applications a regulatory regime would be likely to consider. The Ministry has estimated that the workload of the regulator for the regime is likely to be far less than a hundred applications per annum but this figure is based on an estimation of the "legal high" market at its height of legal availability and may not reflect the true scale of future applications.

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Introduction - the Law Commission Review

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. Under Cabinet Office Circular CO(09)1, Government has 120 working days to respond to the Law Commission's recommendations. This would give the Government until mid October 2011 to consider all of the 144 recommendations. In light of the forthcoming election, it is recommended that the Government provide a response in early September 2011. The proposed response is limited to an 'in-principle' agreement for the need for new legislation and for a new regulatory regime for psychoactive substances. It will be necessary to carry out more detailed policy consideration before taking a position on other recommendations.
4. The proposals analysed in this RIS respond to the Law Commission's recommendations in relation to the regulatory regime for psychoactive substances and the Misuse of Drugs Act classification system (Recommendations 1, 2 and 46). The Ministry has not carried out regulatory impact analysis on the following issues, pending further policy work:
 - a) Classification of controlled drugs including recommendations relating to establishing a new expert committee, abolishing the current sub-schedules in the ABC system, developing new schedules for precursors, and abolishing the Order in Council provision.
 - b) Supply offences including recommendations relating to the presumption for supply provisions and addressing profit at sentencing.
 - c) Personal possession offences including abolishing the possession of utensils offence and the mandatory cautioning scheme.
 - d) Enforcement offences including warrantless searches and the detention of someone suspected of having drugs within their body.
 - e) Interaction with other legislation including the Medicines Act 1981, ministerial powers, and regulations made under the Misuse of Drugs Act.

Existing arrangements and status quo

New Psychoactive Substances

5. Over the last ten years, there has been a burgeoning market in “legal highs” which are psychoactive substances not scheduled as controlled drugs in the Act. The current mechanisms for dealing with these substances are:
 - a) The Smoke-free Environments Act 1990 prohibits the sale of herbal smoking products, such as synthetic cannabinomimetic substances, to people aged under 18;
 - b) The analogue provisions of the Act state that substances which are structurally similar to controlled drugs are analogues of these drugs and automatically classified as Class C controlled drugs;
 - c) The Expert Advisory Committee on Drugs (EACD) is a statutory body established under the Act to provide advice to the Minister of Health on drug classification matters. The EACD assesses drugs brought to its attention and can recommend either control under the Act or as restricted substances under the Misuse of Drugs Amendment Act 2005 (MODAA 2005) which places restrictions on the sale of listed substances. There are no restricted substances currently listed in the MODAA 2005. There was a technical inconsistency between the MODAA and the Hazardous Substances and New Organisms Act 1996 (HSNO). This conflict has now been resolved with the enactment of the Misuse of Drugs Amendment Act 2011.
 - d) The temporary class drug notices introduced by the Misuse of Drugs Amendment Act 2011 provide a mechanism for prohibiting the importation, manufacture, sale and supply of substances listed by a notice in the *Gazette*. Sixteen synthetic cannabinomimetic substances have been listed since the provision came into effect in August 2011.

The Misuse of Drugs Act 1975 – ABC classification system

6. The Act classifies controlled drugs in three controlled drug schedules according to the potential risk of harm from each substance. The ABC classification system sets maximum penalties in the Act relative to the harm posed to individuals and society by controlled drugs. Class A drugs 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 maximum penalties assigned to each class are commensurate with the level of harm attributed to the drugs each class contains. For example, the supply of Class A drugs has a maximum penalty of life imprisonment while the supply of Class C drugs to a minor has a maximum penalty of eight years imprisonment. Two of the schedules are also divided into sub-schedules which primarily relate to prescribing rights and storage requirements.
7. There is also a separate schedule for precursor substances, which are chemicals that can be used to manufacture controlled drugs.

Problem definition

New Psychoactive Substances

8. One of the most significant problems identified with the Act, and a catalyst for the Law Commission's review, was the lack of effective mechanisms for dealing with substances which pose a risk of harm but do not meet the criteria to be controlled drugs.
9. The Law Commission raised concerns about the reactive nature of drug control in that new psychoactive substances can be manufactured, imported and sold with minimal restriction until they are proven to be harmful and scheduled as either controlled drugs (prohibited drugs) or as restricted substances (available subject to restrictions) under the Act. There is a delay from identifying a new substance, acquiring and collating evidence of harm and finally scheduling drugs under the Act. The Law Commission considered that in this period potentially harmful substances could be marketed and sold.
10. The Law Commission identifies 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.
11. Psychoactive is a term which applies to a substance which "affects the mind", coming from the Greek term psyche meaning self, soul or life. The Law Commission defines psychoactive substances as substances "manufactured for the primary purpose of being administered, ingested, inhaled or injected in order to induce a psychoactive response". The Law Commission, in its report, uses the terms "new psychoactive substances". However, the Ministry considers that the problems identified by the Law Commission are not exclusively limited to "new" substances. In this regulatory impact statement, the Ministry refers to "psychoactive substances".
12. For historical and cultural reasons, psychoactive substances have been regulated in different ways. For instance, alcohol and tobacco are regulated but legally available and heroin which used to be available on prescription is now a prohibited substance.
13. The global response to psychoactive substances other than alcohol, tobacco and caffeine is dealt with by three United Nations (UN) conventions which New Zealand has ratified. New Zealand's obligations under these conventions are met by scheduling substances under international control in the Act. The EACD assesses substances to determine their level of harm according to criteria including risk of dependence and death, and public health harms. On the basis of this assessment the EACD recommends a classification to the Minister of Health.
14. 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, scant or no evidence is available. This leads to delays whilst available 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 harm could remain uncontrolled until such time as adequate evidence is available.

15. 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.
16. Other substances are not considered to pose a sufficient level of harm to warrant scheduling as controlled drugs in the Act. These are substances which the EACD has assessed as providing a psychoactive effect but without risk of dependence, overdose or other acute harms, and which are not listed in the UN conventions. The EACD has recommended that these low-risk substances are controlled in the MODAA 2005¹.
17. Although some of the emerging substances may be assessed as posing a low risk of harm to the user once sufficient evidence becomes available, controls are still required. One of the ingredients in legally-available party pills, DMAA, was associated with a number of hospital admissions for seizures when used as a pure powder. The EACD has assessed DMAA and does not consider it to pose a moderate risk of harm warranting scheduling as a controlled drug under the Act and recommended that it should be restricted under the MODAA 2005. This could allow it to be sold under conditions including controls on its formulation.
18. Whilst there is clearly a demand for legally-available psychoactive substances, the Ministry has no data on the prevalence of use. Before BZP was made a controlled drug and BZP-based party pills removed from the legal market, survey data reported that 13.5% of New Zealanders aged between 16 and 64 had tried them.² New Zealand research identified health harms associated with BZP use, including seizures. BZP was scheduled as a Class C controlled drug under the Act in 2008 following an assessment by the EACD and agreement that it posed a moderate risk of harm.
19. The Ministry estimates that at the height of their popularity and legal availability there have been around 100 party pills and smokable products referred to as “legal highs”. There are approximately 10 major importers and manufacturers in New Zealand and a large number of retailers, including specialist stores and other outlets such as dairies. Owing to the nature of synthetic drug manufacture, a substance which is prohibited or restricted by Government can relatively easily be replaced by different substances with similar chemical structures. The industry has demonstrated significant agility in adapting product lines in response to the identification of analogue substances or legal changes. Government must therefore repeat the process of assessing the harm and scheduling.
20. The existing tools for dealing with uncontrolled psychoactive substances have not provided an adequate response to the market for “legal highs”:

¹ There are no substances scheduled as restricted substances in the MODAA 2005 due to the technical conflict with the HSNO recently resolved by the enactment of the Misuse of Drugs Amendment Act 2011.

² Ministry of Health. 2010. *Drug Use in New Zealand: key results of the 2007/08 New Zealand Alcohol and Drug Use Survey*. Wellington: Ministry of Health.

- a) Analogue provisions
The analogue provisions have proved a useful tool in preventing those chemicals proven to be substantially similar to controlled drugs being marketed. Although some new substances are automatically defined as controlled drugs under the analogue provisions of the Act, these provisions are considered by the Law Commission to be flawed. This is 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 too much room for ambiguity.
- b) Restricted substances regime
The MODAA 2005 restricted substances regime allows for robust controls to be placed on psychoactive substances assessed as posing less than a moderate risk of harm. Controls can be put on place of sale, marketing, purchase age and packaging. However, the onus remains with Government to react to the emergence of new substances. Any drug within the restricted substances provisions has to be assessed by the EACD and then scheduled in the MODAA 2005. The restricted substances regime addresses some problems by regulating availability ensuring that age restrictions and some safety controls are in place. The regime does not, however, prevent substances being sold on the market while their harm is being assessed and appropriate scheduling undertaken.
- c) Temporary class drug notices
The new temporary class drug notices introduced by Parliament in August 2011 allow Government to deal urgently with uncontrolled psychoactive substances. These can be used to control substances for a 12-month period while they are assessed by an expert committee and a decision is made about the appropriate scheduling, which could be as a prohibited drug or as a restricted substance depending upon the level of harm. The Ministry does not consider this to be an effective long-term strategy. It deals with immediate concerns but postpones the need to assess harm and make permanent classification decisions. The Ministry considers that for some new substances, there is unlikely to be sufficient evidence available for the expert committee to consider within the 12-month period. Moreover, the temporary class drug notices do not resolve the onus issue with the Government continually being required to react to the emergence of new substances. In the case of GHB, for instance, the first hospital admissions were reported in 1999 before Government became aware of the popularity of this substance. The temporary class drug notices provide an emergency solution where there are safety issues but they are not an evidence-based approach to drug control and reduce rather than eradicate the time delay problem.
- d) Hazardous substances regime
In theory the Hazardous Substances and New Organisms Act 1996 (HSNO) could be used to control psychoactive substances as a psychoactive substance could be defined as toxic under the HSNO. HSNO requires approval for toxic substances before they reach the

market but this legislation was not designed to control psychoactive substances and has never been used for this purpose.

21. The Ministry agrees with the Law Commission's assessment that the problems with the status quo are unacceptable.

Classification System

22. The Law Commission has considered criticisms of the ABC classification system for determining maximum penalties for controlled drugs including examining the situation in the UK which has a similar system for scheduling drugs. Criticisms include the failure of an ABC system to deter harmful drug use, the arbitrary nature of classification, and failure to take into account drug-taking behaviour.
23. The Law Commission acknowledges that there is no evidence that a higher drug classification, such as a Class A classification, has a deterrent effect on drug offending and use.
24. The Law Commission considers that establishing clear boundaries between the different classes of drugs is difficult and acknowledges that the ABC system is criticised for inaccurate classifications. There are also criticisms that decisions are not evidence-based either because of a lack of robust evidence or because they are vulnerable to political influence. There has been considerable public interest in the relationship between the UK Government and its expert drug committee.
25. The ABC system does not take into account drug-taking behaviour or the context of drug use such as mode of administration, frequency of use, or individual personal factors.
26. The Ministry agrees with the Law Commission that the current ABC system is not a flawless means of determining penalties

Objectives

27. The objectives of the proposals analysed in this RIS are as follows:
 - a) Psychoactive substances regime
To ensure the legislative regime is capable of dealing with the rapidly evolving market in new drugs, balancing the risk of harm to individuals and society with the demand for access to such drugs. The regime should:
 - Provide a mechanism for effectively regulating new psychoactive substances before they reach the market;
 - Provide public confidence about the safety profile of the psychoactive substances legally available for sale;
 - Place controls on the availability of psychoactive substances, 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, giving the industry long-term financial confidence and reducing the risk that people will seek them through the black market;

- Establish an enduring regime to replace interim measures, analogue and restricted substances provisions.
- b) Classification system
 To ensure that the process or mechanism of determining penalties for drug use:
- Reflects the relative harm posed to individuals and society by different controlled drugs;
 - Is workable, efficient and effective; and
 - Is flexible and allows for sentencing discretion.

Regulatory Impact Analysis

The new regulatory regime for psychoactive substances

Options

Objective	Option 1 Temporary Class Notices	Option 2 Outlet restrictions	Option 3 Reverse onus	Option 4 HSNO
1. Provide a mechanism for effectively regulating new psychoactive substances before they reach the market	x	x	✓	✓
2. Provide public confidence about the safety profile of the psychoactive substances legally available for sale	x	x	✓	✓
3. Place controls on the availability of psychoactive substances, including purchase age and place of sale	✓ Control through prohibition	Partial – controls on place of sale only	✓	Partial - HSNO not currently fit for purpose would require amendment
4. Provide information for consumers on product contents, dose and potency	x	x	✓	Partial - HSNO would need amendment
5. Provide certainty on the status of psychoactive substances, giving the industry long-term financial confidence and reducing the risk that people will seek them through the black market	x	✓	✓	✓
6. Establish an enduring regime to replace interim measures, analogue and restricted substances provisions	x	x	✓	✓

Option 1 – extended use of the temporary class drug notices

28. The first option would be to revise the temporary class drug notices recently put in place. Temporary notices are an emergency response to the unregulated sale of potentially harmful psychoactive substances. Currently seven days' notice is given by *Gazette* before the importation, manufacture, sale and supply of specified substances are prohibited for 12 months. To reduce the time products are on the market once they had been identified, it would be possible to make the notice take immediate effect or come into effect the following day. It would also be possible to include analogue provisions with the notice provisions so that any substance structurally similar to a substance listed in the *Gazette* would automatically be prohibited for a 12-month period.

Costs and benefits of option 1

29. As this is a small change to the status quo, there would be limited costs to Government in terms of having a notice in the *Gazette* take immediate effect. There would be no additional costs for enforcement. There would be a cost to Government in identifying analogue substances in terms of laboratory testing to establish that a substance is structurally similar. There would be costs to retailers and distributors as there would be very little time to react to a notice and return stock to the manufacturer. However, the cost would not be significantly different to the costs facing industry now. As possession of drugs captured by the temporary class drug notices is not illegal, the public would not be significantly affected by a change of this nature to the status quo.
30. This would address one of the problems identified by the Law Commission, namely the unregulated sale of potentially harmful psychoactive substances. However, this option would potentially criminalise manufacturers, distributors and retailers unable to react in time to the issuing of notices. It also still requires the Government to first identify and then take action to deal with psychoactive substances. In addition there will remain the need for more permanent controls to be put in place at the end of the 12-month notice period. The Government has considered temporary bans are only an interim measure until an enduring regime along the lines proposed by the Law Commission has been developed.
31. The Ministry considered, in its advice to Government, that there should be a seven day period between gazetting and the notice coming into effect in order to provide sufficient time for industry to remove products from sale. The Ministry would not support reducing this timeframe. The analogue provisions have been criticised by the Law Commission as flawed and this option does not address the problems identified by the Law Commission. The Ministry does not consider this option to be an improvement on the status quo, and therefore does not support it.

Option 2 – Prohibiting the sale of psychoactive substances from certain outlets

32. It would be possible to prohibit the sale of psychoactive substances from specified outlets, in particular dairies, or limit sale to R18 shops only. One of the concerns of Government and the public has been the sale of legal highs from dairies and the visibility of these products to children. This would not

prohibit the availability of these products altogether but restrict place of sale. In the case of pharmaceutical products, the Medicines Act 1981 specifies the types of medicines and formulations which can be sold from supermarkets and those that are pharmacy-only. The restricted substances regime in the MODAA 2005 allows for regulations to be made prohibiting the sale of listed substances from premises which also sell alcohol or outlets near schools.

Costs and benefits of option 2

33. The benefit of this option would be reduced visibility of psychoactive substances for young people. There would be costs to industry from lost earnings, particularly affecting retailers prohibited from marketing psychoactive substances. There would also be a cost to the public in terms of reduced availability.
34. There would be considerable difficulty in adequately defining the outlets which would be covered by this option. Dairies could be defined by size or by the products they sell but this is unlikely to accurately capture all outlets as the alcohol reform process has shown. This option addresses part of the problem with uncontrolled availability but only in relation to place of sale. It does not remove the onus from Government to identify potentially harmful substances from sale.
35. The Ministry does not consider this a satisfactory solution to the two problems identified by the Law Commission.

Option 3 – reverse onus regime

36. The Law Commission has recommended a pre-approval regulatory regime for psychoactive substances. The regime requires sponsors (namely importers, manufacturers and distributors) to demonstrate that products they wish to market do not pose an undue risk of harm to the user before they can be marketed. This proposed regime reverses the onus of proof from the Government to the sponsor.

Costs and benefits of option 3

Regulator

37. The Law Commission has considered the role of a regulator to conduct the pre-approval process and recommended a separate regulatory authority. The Ministry agrees that a regulator will be required to administer the pre-approval process, but decisions are not sought at this stage. The options for a regulator include: a new stand-alone authority, the function being carried out by an existing regulator, or the establishment of a separate regulatory authority as part of an existing agency.
38. A new regulatory regime would put the onus on a sponsor to apply for approval to market a product. There would be a cost associated with this application in terms of the pre-approval evidence to be provided to the regulator such as laboratory test results and in fees payable to a regulator. The new regulator/regulatory regime would incur costs in terms of

administration, expert advice, audit and enforcement. These will be recovered in part from application and licence fees.

39. Cost recovery (pre-market and partial post-market) through fees paid by the industry would be consistent with Treasury and Audit Office principles and guidelines for charging for government services. This would result in substance assessment and compliance, audit, surveillance and monitoring costs being recovered from applicants, and the Crown funding the costs of policy advice and enforcement.
40. It is important to set fees which are not so high as to deter industry from applying for an approval which might lead to substances ending up on the black market.
41. The Ministry estimates that there are likely to be fewer than 100 applications per annum. This figure is based on an estimation that the market, at the height of popularity and legal availability of psychoactive substances, did not exceed 100 products. As each separate product would need an approval, incurring compliance costs and fees, the Ministry considers that industry is likely to reduce the number of products subject to approval. The Ministry is unable to estimate at this time how long an application to assess a psychoactive substance would take as it is not clear to what extent the industry will be in a position to provide evidence-based assessments of harm but it is unlikely to be as comprehensive a process as for hazardous substances which have the potential to cause significant environmental damage.
42. Based on the functions likely to be carried out by any regulator, and compared to an equivalent regulator/regulatory regime (for instance the Environmental Protection Authority's (EPA) management of the HSNO pre-approval process), we estimate the magnitude of costs for applicants are not likely to exceed \$10,000. The EPA charges around \$5,000 for substances similar to substances which it has already approved. The EPA estimates that these assessments take on average 56 hours to complete with an hourly rate of \$115. For a comprehensive assessment, the EPA charges \$17,250. The EPA carried out six of these last year and they took on average 220 hours to complete. The Ministry considers that the approval process for the new regime is likely to resemble the shorter assessment process carried out by the EPA rather than the comprehensive assessment for a potentially highly toxic or explosive hazardous substance.

Impact on industry

43. Currently there are few controls on the sale of psychoactive substances which are not controlled drugs, medicines or captured by the new temporary class drug notices.
44. The proposed reverse onus in the new regime would have a significant impact on importers, manufacturers, distributors and retailers.
45. The proposed regime would ensure that no product could be sold or supplied without first being approved by a regulator. A product sponsor (importer, manufacturer and/or distributor) would need to demonstrate that a product posed a low risk of harm by providing evidence likely to include toxicological and pharmacological data before approval would be granted. This will entail

costs for the sponsor in laboratory testing to provide evidence of the risk profile for each product and potential loss of earnings whilst this process is on-going. If the sponsor is unable to provide adequate information to the regulator, the product would not be approved and its sale would be prohibited.

46. In addition to the cost to the sponsor in acquiring evidence to demonstrate a product is low-risk, the regulator is likely to charge a fee to assess the application for approval. Fees are unlikely to exceed those for the assessment of hazardous substances which potentially pose significant harms to people and the environment.
47. The Law Commission has recommended that each product would require a separate approval to ensure that each product and/or each variation according to potency has been assessed and demonstrated not to pose undue risk to users. Owing to the cost to industry of completing the approval process for each product, it is probable that a limited number of products would be marketed potentially affecting the earnings of manufacturers and retailers, as well as potentially reducing product choice for consumers.
48. There will be cost and compliance implications for manufacturers in addition to the approval process. There will be packaging requirements such as tamper-proof and child-proof packages, warning labels and health information requirements for each product.
49. There will also be a number of cost implications for retailers. The Law Commission has proposed that restrictions are put on places of sale to minimise exposure for children. For instance, restrictions may be placed preventing supply from outlets near schools or places where children gather. Petrol stations, pharmacies and outlets which sell alcohol may also be prohibited from stocking these products. This would result in a loss of potential earnings for these retailers.
50. There are potential benefits to importers, manufacturers and retailers from the introduction of a new regulatory regime. The existence of a statutory regime with a formal approval process should give industry greater long-term financial confidence once products have been approved. For a number of years, there has been uncertainty as to the status of “legal highs” and the threat of prohibition. Consideration will need to be given to the impact of an approval on manufacturers and their competitors and whether approval for one product would apply to all products with the same ingredients. It may be necessary to allow a successful sponsor exclusive access to the market for a period of time before opening up the market to competitors seeking to market a product with the same ingredients to allow the original sponsor to recoup the costs of their application.

Impact on the public

51. There are potential costs and benefits to the public from the proposed regime. The Ministry considers that significant benefit to the public will be achieved through greater confidence about the ingredients and safety of a product compared to the status quo. Any product which is legally available will have been assessed to ensure it does not pose undue risk and all products will contain information about contents, recommended dose and potency. The regime is likely to restrict sales to those 18 and over and may limit the

exposure of children to the products as restrictions may be placed on selling the products from outlets near schools or where children gather.

52. Given the findings from drug use surveys about the prevalence of illegal drug use, it is evident that there is a demand for psychoactive substances that exists despite the legal status or the threat of penalties. A potential benefit from the introduction of the proposed new regime would be the existence of a legal market for low-risk substances. Whilst products may be harder to acquire as they may only be available in certain outlets than in an unregulated market, the public would have greater confidence about what they are buying. This may reduce the risk that people will seek these products from the black market, and the associated risk of interaction with a criminal supply chain, risks of prosecution, and interaction with the criminal justice sector.
53. There are potential costs for the public if the regime is too restrictive and only a limited number of products are available.

Option 4 – Hazardous Substances and New Organisms Act

54. The HSNO operates a pre-approval regime for the importation of toxic chemicals and other hazardous substances. It would be theoretically possible for the EPA to treat psychoactive substances in the same way as other hazardous substances. The importation and manufacture of psychoactive substances not already covered by other legislation, such as the Act, would be prohibited until approval had been granted by the EPA. The HSNO does not directly control the sale and supply of hazardous substances (with the exception of fireworks) but no unapproved substance can be distributed or sold and there are controls over packaging which could be extended for psychoactive substances.

Costs and benefits of option 4

55. The costs for using the HSNO would include the need to recruit specialised technical experts at the EPA to assess substances not currently approved by the EPA. There would be an increased administrative workload, licensing, audit and enforcement. The Ministry of Health estimates that there would be no more than 100 approval applications for psychoactive substances per annum. The EPA assessed a total of 75 substances in 2010/11 so this could potentially double their workload. However, the assessment of psychoactive substances is unlikely to be as time-consuming as the process for many hazardous substances. The costs could in part be recovered through fees charged to the sponsor.
56. The costs to industry would include charges for approval which range from approximately \$5,000 to over \$17,000 per application according to the current fees charged by the EPA. There would also be costs in providing adequate evidence for the approval process and compliance costs arising from requirements for packaging and labelling.
57. There would be benefits to the public in terms of confidence about the safety profile of approved products.
58. The Ministry has previously considered using the HSNO to control unregulated psychoactive substances and the Law Commission also considered it as an option. The Law Commission concluded that it was not fit

for purpose as the approval criteria are designed to manage the risks of chemicals or risks to the environment and not recreational drugs. The Law Commission considers that there is too much ambiguity around what is captured by the HSNO and substances which are at the margins, such as substances taken orally which could be defined as health supplements which would fall outside. To make the HSNO workable and manage the risks that substances might not be captured by the regime, some changes would probably need to be made to the legislation.

59. The Ministry does not support this option as the costs in adapting the HSNO to include psychoactive substances would probably approximate a new regime which was specifically designed for psychoactive substances and fit for purpose. The Ministry considers that HSNO has a role in managing the risks of bulk chemicals being imported into New Zealand for the purpose of manufacturing psychoactive drugs but the Ministry does not consider it suitable for regulating the retail of psychoactive substances.

Preferred option

60. In the Ministry's opinion, the only viable option to address both of the problems identified by the Law Commission, as outlined in paragraph 10, is to introduce a new regime where psychoactive products cannot be marketed until they are demonstrated not to pose undue risk (a 'reverse onus' regime). The Ministry's preferred option is option 3.

Classification system

Options

Objective	Option 1 Single Maximum penalty	Option 2 Two-tier system	Option 3 Multi-tier system	Option 4 ABC system
1. Reflects relative harm posed to individuals and society by different controlled drugs	x	✓	✓	✓
2. Is workable, efficient and effective	✓	x	x	✓
3. Is flexible and allows for sentence discretion	✓	✓ Some discretion	x	✓ Some discretion

61. As part of its review of the Act, the Law Commission considered whether the ABC system was the most effective means of determining penalties. It considered the following options:

Option 1 – a single maximum penalty for all drugs

62. This system would replace the three-tiered arrangement of substances and maximum penalties with a single maximum penalty for all substances. This would allow Judges to determine sentences according to a range of factors

including the amount of a drug in an offender's possession. This assumes that someone dealing commercial quantities of cannabis (currently Class C) is equally culpable as someone dealing a commercial quantity of methamphetamine (currently Class A).

Costs and benefits of option 1

63. The benefit of this option would be to avoid the difficulties in agreeing a level of harm for each substance. There would be less work for the EACD as recommendations on substances would be limited to whether or not they should be scheduled in the Act but there would be no need for the consideration of the different levels of harm.
64. The option would be very flexible and leave sentencing entirely to the discretion of the judiciary. The Law Commission considers that Judges should have Parliamentary guidance for sentencing based on the relative levels of harm of drugs. The Law Commission considers that penalties should reflect the seriousness of the offence and that the more harmful the drug the more serious the offence.
65. The Ministry agrees that maximum penalties should be commensurate with the potential risk of harm for each drug.

Option 2 – a two-tier system

66. This option would split drugs into two classes: seriously harmful and moderately harmful drugs.

Costs and benefits of option 2

67. The benefit of this option would be a simpler process for classifying drugs but, unlike the first option, drug classification would reflect the relative harm to the user and society. However, the Law Commission considers that there needs to be an intermediate class as there are a number of substances which would not easily fit in one of two categories. There may be a cost to the public as the Law Commission considered this option might lead to a misconception that there are “hard” and “soft” drugs.
68. The Law Commission did not consider this option an improvement on the status quo and the Ministry of Health agrees.

Option 3 – a multi-tiered system

69. This would establish a matrix of drug classifications.

Costs and benefits of option 3

70. This option would allow far greater nuance in the classification of drugs. However, the Law Commission considered that increasing the number of schedules would make it harder for an expert committee to categorise drugs and have a potential negative impact on the sentencing process by creating a large number of offences with little between them in terms of culpability. It would leave minimal discretion to the judge at sentencing compared to the other options. The Ministry of Health agrees.

Option 4 – retain the ABC system

71. The Law Commission concluded that the current arrangement of an ABC classification ranking drugs according to moderate, high and very high risk of harm was the most workable system. The Law Commission has therefore recommended maintaining three controlled drug schedules to reflect the differing levels of harm posed by each substance and to determine the maximum penalties associated with offences related to them.

Costs and benefits of option 4

72. The benefit of the ABC system is that it provides greater flexibility than a two-tier system without the need for very precise nuanced decisions of a multi-tier system. It is also familiar to the New Zealand public.
73. The Law Commission acknowledges that the ABC system has been criticised but considers that there is a broad consensus amongst experts internationally on the relative harms of most drugs to enable evidence-based scheduling.
74. Retaining the existing scheduling system should have no additional compliance or cost implications as it is the status quo.
75. The Ministry agrees with the Law Commission that the flaws are not sufficiently significant to warrant the establishment of a new classification system. The Ministry agrees that the ABC system is the most appropriate option for classifying controlled drugs.

Consultation

76. The Law Commission produced an Issues Paper as part of its review of the Misuse of Drugs Act, summarising problems and proposing possible solutions. The Law Commission consulted widely on the Issues Paper, receiving over 3,800 submissions and has incorporated many of the views of submitters in its final report.
77. The Ministry of Health was the lead agency for the Government response but worked closely with other agencies through an inter-agency working group, consisting of officials from Justice, Police and the Customs Service. These agencies collaborated on the development of the Cabinet Paper. Other agencies have been involved as appropriate. These agencies include: the Treasury, the Ministry of Economic Development, Te Puni Kōkiri, the Ministry for the Environment, and the Department of Prime Minister and Cabinet.

Conclusions and recommendations

78. The Law Commission has reviewed the Misuse of Drugs Act 1975 and made 144 recommendations for the development of new legislation. Owing to the forthcoming election and consequent truncated timeframes, the Government will defer taking a position on most recommendations until careful consideration can be given to the cost, resource, and other impacts of the proposed changes.

79. The Government plans to give priority to the establishment of a new regulatory regime for psychoactive substances as stand-alone legislation. The recommended approach is to agree in-principle to the recommendation for a new regime with detailed policy work on its development and implementation to take place as a priority.
80. The Ministry welcomes the Law Commission's assessment of the problems with the current legislation and supports the need for a new Misuse of Drugs Act. It is recommended that Cabinet support in-principle the need for a new act which would retain the ABC classification system whilst reserving its position on the other elements of the proposed new Misuse of Drugs Act and the Law Commission's other recommendations.

Implementation and next steps

81. The Government has signalled its intention to implement a new regime for psychoactive substances along the lines of the regime proposed by the Law Commission. Whilst there is agreement on the problem and the need for action, the details of how the regime will be implemented need further policy work. The details of how best to implement a pre-approval process will be worked out fully following targeted and public consultation during the policy development for the new regime.
82. It is proposed that Cabinet agree in-principle to a new regime for low-risk psychoactive substances requiring pre-market approval by a regulator. In the policy work to develop the new scheme a RIS will be prepared and the regulatory impact of the following issues will be considered in detail:
 - a) The criteria for a substance to be considered low-risk. The Law Commission has recommended that the criteria include not just the benefits and harms of the substance but also whether regulatory controls would be effective and the likely consequences of prohibition. Determining criteria will have a significant impact on the workability of the regime. If the inclusion criteria are too narrow and no substances are approved, there is a risk that substances may end up on the black market;
 - b) Evidential requirements to demonstrate low-risk;
 - c) Trade implications including the consequences for the Trans Tasman Mutual Recognition Act;
 - d) Restrictions, including restrictions on purchase age, place of sale, advertising, labelling;
 - e) Impact on criminal justice system, including potential costs and savings for Police, the Courts and Corrections.
83. It is also proposed that Cabinet agree in principle to the need for a new Misuse of Drugs Act which retains the ABC classification system. As a regulatory regime for psychoactive substances is a priority for Government, the development of a new Act would commence once the new regime is in place.

84. The other recommendations of the Law Commission around the contents of new legislation will be considered as part of the policy development for a new Misuse of Drugs Act and the Government will carry out consultation on a draft Bill. Full regulatory impact analysis and a RIS will be prepared during the development of the legislation.