Ref: H201806049

Dear [Name]

Response to your request for official information

I refer to your request of 6 September 2018 under the Official Information Act 1982 (the Act) for:

"1. All advice regarding sentencing and penalties given to the Minister of Health by the Ministry of Health over the past six years.
2. A copy of any drafts pertaining to the departmental report on the Psychoactive Substances Amendment Bill produced by the Ministry of Health before the finalised version of the report.
3. All communications with the Minister of Health’s Office and the Ministry of Health regarding the departmental report on the Psychoactive Substances Amendment Bill.
4. A copy of all advice provided to the Minister of Health over the last 6 years relating to the connection between the harm caused by Psychoactive Substances and sentencing and penalties."

The information relating to this request is itemised in the table Appendix One, with copies of documents attached in Appendix Two.

I have decided to withhold some information under various sections of the Act, and specific grounds are noted in the document table and within each document where information has been withheld.

I trust this information fulfils your request. You have the right, under section 28 of the Act, to ask the Ombudsman to review my decision to withhold information under this request.

Yours sincerely,

John Doyle
Acting General Manager
System Strategy and Policy, Regulatory Policy
Appendix One

1. All advice regarding sentencing and penalties given to the Minister of Health by the Ministry of Health over the past six years

<table>
<thead>
<tr>
<th>Document No.</th>
<th>Date</th>
<th>Title</th>
<th>Decision</th>
</tr>
</thead>
<tbody>
<tr>
<td>04</td>
<td>5 Dec 2017</td>
<td>Misuse of Drugs (Medicinal Cannabis) Amendment Bill Legislation Paper</td>
<td>The document is withheld under section 18(d) of the Act as it is already publicly available at the following link <a href="https://www.health.govt.nz/our-work/regulation-health-and-disability-system/medicines-control/medicinal-cannabis/misuse-drugs-medicinal-cannabis-amendment-bill/advice-governments-medicinal-cannabis-100-day-commitment">https://www.health.govt.nz/our-work/regulation-health-and-disability-system/medicines-control/medicinal-cannabis/misuse-drugs-medicinal-cannabis-amendment-bill/advice-governments-medicinal-cannabis-100-day-commitment</a></td>
</tr>
<tr>
<td>05</td>
<td>7 Sept 2018</td>
<td>Drugs Utensils Notice and Vaporisers</td>
<td>Withheld in full under section 9(2)(f)(iv) to maintain the constitutional conventions for the time being which protect the confidentiality of advice tendered by Ministers of the Crown and officials.</td>
</tr>
<tr>
<td>06</td>
<td>24 Nov 2017</td>
<td>Medicinal Cannabis 100-Day Action Cabinet Paper</td>
<td>The document is withheld under section 18(d) of the Act as it is already publicly available at the following link <a href="https://www.health.govt.nz/our-work/regulation-health-and-disability-system/medicines-control/medicinal-cannabis/misuse-drugs-medicinal-cannabis-amendment-bill/advice-governments-medicinal-cannabis-100-day-commitment">https://www.health.govt.nz/our-work/regulation-health-and-disability-system/medicines-control/medicinal-cannabis/misuse-drugs-medicinal-cannabis-amendment-bill/advice-governments-medicinal-cannabis-100-day-commitment</a></td>
</tr>
<tr>
<td>08</td>
<td>5 April 2018</td>
<td>Review of the Psychoactive Substances Act 2013</td>
<td>Withheld in full under section 9(2)(f)(iv) to maintain the constitutional conventions for the time being which protect the confidentiality of advice tendered by Ministers of the Crown and officials.</td>
</tr>
<tr>
<td>Document No.</td>
<td>Date</td>
<td>Title</td>
<td>Decision</td>
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</tbody>
</table>
| 09           | 23 August 2018 | Advice to Justice Committee on the Psychoactive Substances (Increasing Penalty for Supply and Distribution) Amendment Bill | Partially released.  
Redactions made under section 9(2)(a) of the Act to protect the privacy of natural persons.  
The attachment to this document is withheld under section 18(d) of the Act as it is already publicly available at the following link  
Redactions made under section 9(2)(a) of the Act to protect the privacy of natural persons. |
Redactions made under section 9(2)(a) of the Act to protect the privacy of natural persons. |
| 12           | 24 January 2014 | Cabinet Approval for Consultation on Psychoactive Substances Regulations                   | Partially released.  
Redactions made under section 9(2)(a) of the Act to protect the privacy of natural persons. |
| 13           | 24 May 2013  | Advice to the Health Committee about the Psychoactive Substances Bill                       | Partially released.  
Redactions made under section 9(2)(a) of the Act to protect the privacy of natural persons. |
Redactions made under section 9(2)(a) of the Act to protect the privacy of natural persons. |
Redactions made under section 9(2)(a) of the Act to protect the privacy of natural persons. |
2. A copy of any drafts pertaining to the departmental report on the Psychoactive Substances Amendment Bill produced by the Ministry of Health before the finalised version of the report.

3. All communications with the Minister of Health’s Office and the Ministry of Health regarding the departmental report on the Psychoactive Substances Amendment Bill.

<table>
<thead>
<tr>
<th>Document No.</th>
<th>Date</th>
<th>Title</th>
<th>Decision</th>
</tr>
</thead>
<tbody>
<tr>
<td>16</td>
<td>1 June 2012</td>
<td>Summary of Proposals for the New Regime to Control Low-Risk Psychoactive Substances</td>
<td>Partially released. Redactions made under section 9(2)(a) of the Act to protect the privacy of natural persons.</td>
</tr>
</tbody>
</table>
Health report

Hon Dr Jonathan Coleman (Minister of Health)

New National Drug Policy and Review of the Misuse of Drugs Act 1975

Executive summary

i. This paper provides you with an overview of the development of a new National Drug Policy (NDP), and the related review of the Misuse of Drugs Act 1975 (MoDA), and outlines the decisions we will be seeking of you and Cabinet over the next few months to progress these.

ii. The NDP is government's overarching framework for action on alcohol and other drugs (AOD). The purpose of the NDP is to provide a cohesive approach to minimising AOD-related harm by setting common goals and committing to joined-up cross-government action. Collective government action is essential to achieving good outcomes in this area.

iii. The NDP also provides direction to people and organisations outside of government who work to minimise AOD-related harm.

iv. The development of a new NDP is led by the Ministry of Health, in partnership with the Inter-Agency Committee on Drugs. Public consultation via a discussion document on what a new NDP should look like was undertaken between December 2013 and February 2014. Significant progress has since been made to develop the NDP, including to scope proposals for action. One of the more significant proposals for action will be to review the MoDA. This aligns with the Law Commission's 2011 report Controlling and Regulating Drugs, which made 144 recommendations for a new law to replace the MoDA.

v. We propose to seek decisions from you and Cabinet regarding the NDP and the review of the MoDA in the coming months.

The Ministry recommends that you:

a) Note the Ministry of Health is currently leading the development of a new National Drug Policy (NDP) and scoping a review of the Misuse of Drugs Act 1975 (MoDA)

b) Note the Ministry intends to provide you with:

   i) in November 2014, a Health Report and draft Cabinet paper seeking the mandate to proceed with a review of the MoDA and to set its scope

   ii) in December 2014, a Health Report seeking decisions on the draft NDP, including proposals for action over the next 5 years and a proposal for stakeholder engagement to finalise the NDP

   iii) in early 2015, subject to your agreement, a draft Cabinet paper seeking approval to either publish or consult on the final NDP.
**Health Report number: 20141271**

### Ministry of Health contacts

<table>
<thead>
<tr>
<th>Name</th>
<th>Position</th>
<th>Phone</th>
<th>Cellphone</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paula Martin</td>
<td>Group Manager, Sector &amp; Services Policy</td>
<td>(04) 816 2668</td>
<td>s 9(2)(a)</td>
</tr>
<tr>
<td>Dr John Crawshaw</td>
<td>Director of Mental Health</td>
<td>(04) 496 2304</td>
<td>s 9(2)(a)</td>
</tr>
</tbody>
</table>

### Minister's feedback on quality of report

- Very poor (1)
- Poor (2)
- Neutral (3)
- Good (4)
- Very good (5)

Good (4)
New National Drug Policy and Review of the Misuse of Drugs Act 1975

Purpose

1. This paper provides an overview of the development of a new National Drug Policy (NDP) and a proposal to review the Misuse of Drugs Act 1975.

The NDP ensures a cohesive and joined-up approach to minimising AOD-related harm

2. The NDP is government's overarching framework for action on alcohol and other drugs (AOD). The purpose of the NDP is to provide a cohesive approach to minimising AOD-related harm by setting common goals and shared actions across government to maximise impact. It also provides direction to people and organisations outside of government who work to minimise AOD-related harm. Additionally, the NDP aligns with and mutually reinforces the Mental Health and Addiction Service Development Plan 2012-2017 "Rising to the Challenge".

3. Many of the issues government agencies work on are impacted in some way by AOD misuse, the impacts of which include: physical and mental health; crime; family violence; neglect of children; inability to sustain employment resulting in benefit dependency; and poor educational outcomes. As well as the impact on people's lives and on New Zealand's society, the financial cost to the government is substantial. The benefits of minimising AOD-related harm are also significant if the prevalence of AOD misuse is reduced, and help for those who need it increased, then, as well as improved health outcomes, gains can be expected across all Better Public Services result areas: reducing long-term welfare dependence, supporting vulnerable children, boosting skills and employment, reducing crime, and improving interaction with government.

4. The existing NDP organises work to minimise AOD-related harm in New Zealand into three areas or 'pillars':

   a. Supply Control — which aims to prevent or reduce harm by restricting the availability of AOD. This pillar focuses on controlling New Zealand's borders to prevent illegal drugs being imported, and shutting down domestic cultivation, manufacture and supply. It also focuses on the regulation of supply of alcohol, tobacco and other legal drugs.

   b. Demand Reduction — which aims to reduce individuals' desire to use AOD. This pillar focuses on activities that delay or prevent uptake and reduce problematic use through education, health promotion, and influencing the environmental factors that can contribute to the use of AOD, including price, advertising and sponsorship.

   c. Problem Limitation — which aims to reduce harm that is already occurring. This pillar focuses on prevention through early intervention, treatment interventions and support for people in recovery, as well as harm reduction activities that result in safer equipment and environments for AOD use, such as needle exchanges.

The new NDP builds on previous NDPs, while ensuring it remains modern and directs action to areas of most need

5. The Ministry of Health is leading the cross-government development of the NDP. This work is governed by the Inter-Agency Committee on Drugs.

---

1 Other drugs include tobacco, illegal and other substances used recreationally such as diverted medicines, approved psychoactive products and butane

2 Inter Agency Committee on Drugs (IACD) membership comprises: the Ministry of Health (chair), New Zealand Police, National Drug Intelligence Bureau, New Zealand Customs Service, Department of Prime Minister and Cabinet, Department of Corrections, Ministry of Education, Ministry of Social Development, and the Accident Compensation Corporation. IACD meets at Chief Executive, Tier 3-management and Working Group level. The Working Group additionally comprises Te Puni Kōkiri and the Health Promotion Agency.
6. This NDP will build on previous NDPs to ensure focus is directed at areas of most need, and opportunities for gain through cross-government coordination are maximised. In particular, it:

- continues the principle of harm minimisation using the three pillar structure of supply control, demand reduction and problem limitation
- adopts a broader definition of harm by extending the focus to include families and communities who are also impacted by individual AOD use
- sets out priority actions over the next five years to minimise AOD-related harm.

7. Public consultation on what a new NDP should look like was undertaken from December 2013-February 2014, and 120 submissions were received. Common themes from these submissions were:

a. the NDP should focus on engendering social change and creating a culture whereby harmful use of AOD is no longer seen as "cool" or acceptable
b. a need to destigmatise AOD problems so the public see them as a health issue (rather than a moral failing) in order to facilitate better access to treatment
c. a greater focus is needed on reducing alcohol-related harm
d. a need for improved support for communities and young people, and better access to a greater range of treatment options
e. to expand the definition of 'harm' to include harm to people other than those who use AOD
f. the importance of genuine cross-agency integration and cooperation, and consistency across sectors.

Significant progress has been made to develop the NDP

8. The draft NDP is being structured in three parts:

a. Where are we now? – Outlines the context of AOD use in New Zealand (prevalence, drivers of AOD use and nature and magnitude of AOD-related harm and trends) and introduces harm-minimisation and the three strategies.
b. Where do we want to be? – Describes the desired future state and provides a structure for action over the next five years.
c. How do we get there and measure progress? – Identifies indicators and other measures to track progress and sets out governance arrangements for reporting and decision-making.

9. Action plans are currently being scoped by cross-agency working groups under four main headings.

a. Improving what we know – to ensure the highest priority issues are targeted effectively by basing the identification and response on good evidence, and measure progress with robust indicators.
b. Building on what works – to facilitate ongoing improvement, rather than disruptive reconfiguration, through improved collaboration, knowledge sharing, and supporting successful and innovative initiatives.
c. Shifting thinking and behaviour – to change the mind set of individuals, communities, organisations and leaders on how we use and respond to AOD.
d. Getting the legal balance right – to ensure legislation and its implementation is effective and relevant in both preventing the uptake and use of AOD and minimising harm from AOD.
Health Report number: 20141271

10. By the end of 2014 we will provide you with a Health Report seeking decisions on the draft NDP – including proposals for action over the next 5 years and proposed stakeholder engagement to finalise the NDP.

11. Subject to your agreement, in early 2015 we will then provide you with a draft Cabinet paper seeking agreement to either publish or consult on the final NDP.

The Misuse of Drugs Act 1975 is not fit-for-purpose in the current environment

12. One of the more significant NDP actions that would be led by the Ministry of Health is the Review of the Misuse of Drugs Act 1975 (MoDA).

13. The Law Commission’s 2011 report Controlling and Regulating Drugs – A Review of the Misuse of Drugs Act 1975 made recommendations for new legislation to replace MoDA. This is because current legislation is outdated, inaccessible and poorly aligned with other newer legislation and the NDP. The Law Commission’s recommendations aim to modernise legislation and better align it with minimising the health and social harms of drug use. To date, priority has been given to recommendations that relate to new psychoactive substances and the establishment of drug courts.

14. In May 2014 officials met with Associate Minister of Health Hon Peter Dunne to discuss the timing and process to complete a review of the MoDA. Mr Dunne asked that work on the review be initiated with the expectation that a paper seeking the mandate to proceed with the review and to set its scope be considered by Cabinet Social Policy Committee in November 2014.

15. Progressing of the review of MoDA under the NDP umbrella will ensure a coordinated approach to development of the scope, resourcing and priority of the review across the key government agencies. This will be reflected in the Cabinet Social Policy Committee paper.

16. This timeframe will see the Cabinet being asked to agree to the MoDA review commencing before it considers the overall NDP in 2015. However:
   - there is a strong case for the case for reviewing the MoDA even if the NDP work was not occurring
   - the MoDA review will be a substantial exercise that will not be completed before Cabinet takes final decisions on the NDP in 2015 – and these decisions will be able to be reflected in the recommendations of the MoDA review.

17. Additionally, work is underway to develop new therapeutic legislation to replace the Medicines Act 1981. It is worth considering advancing both in an integrated fashion as the MoDA includes provisions relating to the therapeutic use of controlled drugs which may sit better within the therapeutic legislation.

18. In November 2014 we will provide you with a Health Report and draft Cabinet paper seeking the mandate to proceed with a review of the MoDA and to set its scope.

END.
Health report

Hon Peter Dunne (Associate Minister of Health)
cc Hon Tony Ryall (Minister of Health)

Review of the Misuse of Drugs Act 1975

Executive summary

i. At your regular drug policy meeting with officials held on 19 March you asked for advice on the timing and process to complete the review of the Misuse of Drugs Act 1975. This briefing provides you with that advice.

ii. In April 2011 the Law Commission made 144 recommendations for a new law to control and regulate drugs. Following progress with the enactment of the Psychoactive Substances Act 2013 and the establishment of drug court pilots, there are 96 of these recommendations left to be considered. This will require a review of the Misuse of Drugs Act 1975.

iii. This Health Report sets out the Ministry's advice on suggested time frames and process to complete the Misuse of Drugs Act review. We expect that a Bill to replace the Misuse of Drugs Act could be ready for introduction to the House in December 2015.

The Ministry recommends that you:

a) Note that if policy work was to commence now, a Bill to replace the Misuse of Drugs Act 1975 could be introduced in December 2015

b) Discuss our suggestions around the timing and process for this project at your regular drug policy meeting with officials on 30 April 2014.

Ministry of Health contacts

<table>
<thead>
<tr>
<th>Nick Goodwin</th>
<th>Mark Heffernan</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acting Manager, Policy</td>
<td>Senior Policy Analyst</td>
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<td>Phone</td>
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</table>

Minister's feedback on quality of report

| Very poor (1) | Poor (2) | Neutral (3) | Good (4) | Very good (5) |

Page 1 of 4
Advice

1. At your regular drug policy meeting with officials held on 19 March you asked for advice on the timing and process to complete the review of the Misuse of Drugs Act 1975 (The Review). This briefing provides you with that advice.

2. The review is founded on the Law Commission's report Controlling and Regulating Drugs (The Report). In April 2011, the Law Commission published The Report which made 144 recommendations for a new law to replace the Misuse of Drugs Act 1975. The Government responded to The Report in September 2011. The Government's approach has been to prioritise the aspects of The Report that relate to new psychoactive substances and the establishment of drug courts. Both of these matters are now complete in terms of addressing the Law Commission's recommendations, but implementation is ongoing.

3. There are 96 recommendations of the Law Commission that are still to be addressed. There are also an unknown number of other issues that were either not covered in the Law Commission's analysis or might have arisen in the three years since the Law Commission gave their advice, which if addressed would ensure The Review considers a broader range of issues than The Report alone.

4. Of the 96 remaining recommendations the Ministry has judged 20 to be of high importance, 33 to be of medium importance and 43 of lesser importance. In forming this view we made a judgement about the effects our current law might have on people who use drugs in instances where the Law Commission has recommended a different approach. This is only preliminary analysis and the Ministry expects that other Government agencies or non-governmental organisations may rank these issues differently.

5. Examples of the type of matters the Law Commission recommended include:
   a. Whether the Bill of Rights Act limitations in the current MoDA that presume someone to be guilty of supplying a drug, based solely on the quantity of the drug they are caught in possession of, remain tenable
   b. Whether there should be a system of mandatory cautioning and referral to a treatment need assessment in place of criminal penalties for possession and use of small quantities of controlled drugs
   c. Whether the possession of controlled drug utensils, such as pipes, should continue to be an offence
   d. Whether a presumption against imprisonment for social dealing should be introduced. Social dealing means the supply of drugs that is not motivated by profit such as the sharing of small quantities between friends
   e. Whether the historical classifications of controlled drugs, made prior to the establishment of the Expert Advisory Committee on Drugs, should be revisited.

Timing and process for the review

Preparation

6. The Ministry anticipates that preparation for The Review will take four months. This will enable the Ministry to gather adequate information to inform The Review. In particular, the Ministry will consider how circumstances may have changed in New Zealand and internationally in the three year period since the Law Commission presented its recommendations. The Ministry will also use this period to ascertain what other matters government agencies think should be addressed through This Review that were not covered off in The Report.
7. The Ministry expects that a paper seeking the mandate to proceed with the review and to set its scope could be considered by Cabinet Social Policy Committee (SOC) in November 2014. This timeframe takes into account other commitments in this area such as the refresh of the National Drug Policy, the ongoing allocation of Drivers of Crime monies and work to reconvene a meeting of the Expert Advisory Committee on Drugs.

Policy development

8. Once a mandate to proceed with the review of the MoDA has been obtained, the Ministry suggests that a working group comprising of the Ministries of Health and Justice together with New Zealand Police and the New Zealand Customs Service should be convened to work through these issues under the guidance of the Inter-Agency Committee on Drugs.

9. Based on the complexity and range of issues that will need to be considered in The Review the Ministry suggests allowing around 10 months for agencies to work through the required policy decisions and present them for Cabinet's consideration. Based on this timeframe, and allowing 3 months for Parliamentary Counsel to draft replacement legislation, we think it would be possible to introduce a Bill to the House in December 2015.

10. A more detailed plan for this project is attached as Appendix One to this report. It sets out proposed timing for this project and includes all stages through to the enactment of replacement legislation.

Output Plan

11. As discussed with you previously, work on the MoDA review has not been prioritised in this financial year though it remains in our output plan. Advice is currently being drafted to request a formal change to this output from the Minister of Health in line with the revised timeframes incorporated in this Health Report.

Next steps

12. You may wish to discuss our suggested approach to the review of the MoDA at your next regular drug policy meeting with officials on Wednesday 30 April 2014.

END.
Appendix One: Timing and milestones for the review of the Misuse of Drugs Act 1975 if this project was initiated in May 2014.

<table>
<thead>
<tr>
<th>Output</th>
<th>Date</th>
<th>Detail</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preparatory Work</td>
<td>May – September 2014</td>
<td>A stocktake of what has changed in the time since the Law Commission presented its recommendations and what other matters government agencies want addressed through the review that were not covered off by the Law Commission’s report</td>
</tr>
<tr>
<td>Cabinet Paper (SOC)</td>
<td>November 2014</td>
<td>Seeking agreement from Cabinet: • to go ahead with the review • to set the review’s scope noting any significant developments in the time since the Law Commission’s report was published • to a Legislative Bid, in principle, for a Bill to replace the Misuse of Drugs Act</td>
</tr>
<tr>
<td>Legislative Bid</td>
<td>January 2015</td>
<td>Seeking priority for a replacement Misuse of Drugs Bill on the 2015 Legislative Programme</td>
</tr>
<tr>
<td>Cabinet paper and RIS (SOC)</td>
<td>September 2015</td>
<td>Seeking agreement from Cabinet: • to all policy proposals for a new law to control and regulate drugs • to issue drafting instructions to Parliamentary Counsel to drafting the new legislation</td>
</tr>
<tr>
<td>Drafting</td>
<td>September – November 2015</td>
<td>During this period the Ministry would: • assist Parliamentary Counsel with drafting • start planning for implementation of the new Law</td>
</tr>
<tr>
<td>Cabinet paper (LEG)</td>
<td>November 2015</td>
<td>Seeking approval to introduce the Bill to the House.</td>
</tr>
<tr>
<td>First Reading</td>
<td>December 2015</td>
<td>N/A</td>
</tr>
<tr>
<td>Select Committee</td>
<td>December 2015 – May 2016</td>
<td>The Ministry would lead this process with support from the Ministry of Justice, New Zealand Police and the New Zealand Customs Service.</td>
</tr>
<tr>
<td>Second Reading</td>
<td>May 2016</td>
<td>N/A</td>
</tr>
<tr>
<td>Committee of the Whole House</td>
<td>May – July 2016</td>
<td>We would expect a large number of Supplementary Order Papers on this Bill and have allocated time for their response accordingly.</td>
</tr>
<tr>
<td>Third Reading</td>
<td>July 2016</td>
<td>N/A</td>
</tr>
<tr>
<td>Enactment</td>
<td>July 2017</td>
<td>At this stage we suggest allowing a year following Royal Assent to plan for implementation. More detailed advice on this would be possible when the content of Bill is known.</td>
</tr>
</tbody>
</table>
Review of the Misuse of Drugs Act 1975

To: Hon Peter Dunne (Associate Minister of Health)

Copy to: Hon Dr Jonathan Coleman (Minister of Health)

Purpose

This paper responds to your request for advice on a review of the Misuse of Drugs Act 1975.

Key points

- The context for the review has changed:
  - changes to therapeutic use provisions will need to be considered alongside the new therapeutic products regime being developed following the decision not to proceed with ANZTPA
  - there is no clear consensus on whether changes to criminal justice provisions are needed to support harm minimisation
  - a review of the psychoactive substances regime is scheduled for 2018.

- The Ministry recommends a phased approach to reviewing the Act and has identified opportunities to coordinate the review of the Act with other work underway. The proposed actions could be included in the National Alcohol and Other Drug Policy which is not yet finalised.

- We propose controls on legitimate use be considered in advance of other work, with advice to you by June 2015, with changes given effect as part of the broader legislative framework for therapeutic products. This approach will enable decisions about legislative design to be coherent, regulatory efficiencies to be identified and the interface between regimes to be clear.

- We propose a review of the classification framework for controlled drugs, and a Justice-led review of the impact of the criminal justice provisions, reporting by December 2017, with any resulting changes being given effect alongside the legislative response to the 2018 Psychoactive Substances Act review.

- This approach would see the Law Commission recommendations addressed over the next five years.

Contacts:
Paula Martin, Group Manager, Sector & Services Policy
Hannah Cameron, Manager, Sector & Services Policy
Review of the Misuse of Drugs Act 1975

Recommendations

The Ministry recommends that you:

a) Agree to a phased approach to reviewing the Misuse of Drugs Act consisting of three discrete pieces of policy work:

1. Advice on regulating legitimate uses of controlled drugs by June 2015, including classification as medicines, to allow some or all changes to be given effect through the new therapeutic products legislation

2. Review of the classification framework for controlled drugs be undertaken by December 2017 (to allow any legislative change to be considered alongside the Psychoactive Substances Act review in 2018)

3. The application of offences and penalties be reviewed by the Ministry of Justice, with advice provided by December 2017 (subject to agreement by the Minister of Justice)

b) Meet with officials to discuss this report.

Minister’s feedback on quality of report

<table>
<thead>
<tr>
<th>Very poor (1)</th>
<th>Poor (2)</th>
<th>Neutral (3)</th>
<th>Good (4)</th>
<th>Very good (5)</th>
</tr>
</thead>
</table>

[Signature]

Don Gray
Deputy Director-General
Policy Business Unit

Minister’s signature
Date:

17-12-14
The Misuse of Drugs Act

1. The Misuse of Drugs Act 1975 governs the use of controlled drugs in New Zealand. It recognises the need for controlled drugs for therapeutic purposes, while ensuring controls on the supply and use of controlled drugs for non-therapeutic uses. It has a strong supply control and law enforcement focus treating drug use largely as a criminal justice rather than a health matter.

2. A review of the Act has been signalled since 2007 when a previous Government invited the Law Commission to review the Act and the penalties imposed under it. At the time there was significant concern about the rapidly evolving market for synthetic psychoactive substances.

3. In 2011 the Law Commission made 144 recommendations for new legislation to replace the Act. The Law Commission argued that the Act:
   • should more clearly reflect the National Drug Policy's harm minimisation approach
   • address an inconsistency with the Bill of Rights Act 1990
   • was out-dated and not-fit for purpose.

4. The Government response to the Law Commission's report was to agree in principle to a review of the Act and to prioritise development of legislation to address the psychoactive substances issue.

5. In April 2014 the Ministry advised you that we would scope a review of the Misuse of Drugs Act with a view to preparing advice for the Cabinet Social Policy Committee in November, setting out the provisions to be considered in a review, and likely timeframes. The initial advice assumed a stand-alone Misuse of Drugs Amendment Bill to be introduced to the House in December 2015.

6. During the scoping project, the context for therapeutic regulation changed with the decision not to proceed with ANZTPA, and we identified a number of challenges with the concept of a stand-alone Misuse of Drugs Amendment Bill:
   • any review will need to ensure the provisions are consistent with the new therapeutic legislation necessary now ANZTPA will not proceed
   • there is a lack of a clear consensus on the changes that are required to build a criminal justice system focused on harm minimisation, and the role that legislation should play in a longer term cultural shift across the system
   • the psychoactive substances regime is now part of the regulatory landscape.

Proposed approach to further changes

7. The Ministry recommends a phased approach to reviewing the Misuse of Drugs Act. The Act covers four main functions and there are possible options for review under each. The four functions are:
   • control of legitimate uses of controlled drugs: prescribing, licensing and labelling
   • classification of controlled drugs: the ABC classification system, an Expert Advisory Committee on Drugs, and the process for classification of drugs
   • offences and penalties for the criminal use of controlled drugs
   • surveillance and detection provisions. The Search and Surveillance Act 2012 has addressed the majority of the Law Commission's recommendations. Further review of this area is not recommended at this stage, and is not discussed in this paper.

8. We propose discrete pieces of policy work on the three areas identified for review:

1. Advice on regulating legitimate uses of controlled drugs by June 2015, to line up with the potential for some or all changes being given effect through the new therapeutic products legislation
2. Review of the classification framework for controlled drugs is undertaken in 2017 to allow any legislative change to be considered alongside the outcome of the Psychoactive Substances Act review in 2018.

3. The application of offences and penalties reviewed by the Ministry of Justice, with advice provided by December 2017.

9. These actions could be set out in the final National Alcohol and Other Drug Policy which is currently being finalised (see Health Report number 20141488). Legislative changes agreed from reviews of classifications and the applications of offences and penalties could be progressed with any legislative response to the review of the Psychoactive Substances Act 2013. We propose reporting on those reviews by December 2017 to ensure they can inform the statutory review of the psychoactive substances regime, required by July 2018.

Three areas for review

Legitimate uses of controlled drugs

10. Control of legitimate uses of controlled drugs is the most complex element of controlled drug regulation, including detailed rules around licencing and prescribing. The complexity of the provisions, and the fact that they differ slightly from the Medicines Act requirements has been the subject of complaints by health practitioners for some time.

11. Regulating legitimate uses of controlled drugs within a framework designed to control criminal uses of the drugs can result in more regulation and stronger penalties than is justified. The Law Commission considered the dual exemption provisions for prescribing controlled drugs in the Misuse of Drugs Act and the Medicines Act 1981 duplicates requirements and is difficult to understand. It is also arguable that the regulation of industrial hemp is overly rigorous and time consuming.

12. We recommend a review of the controls on legitimate (therapeutic and industrial) use of controlled drugs. This project would report to you in June 2015, to make recommendations on changes around legitimate uses of controlled drugs, for example, licensing, prescribing and classification as medicines. This timing would allow changes to be progressed through the therapeutic legislation project.

Classification system for controlled drugs

13. The classification provisions within the Act include:

- the ABC classification system
- the Expert Advisory Committee on Drugs (provides advice to the Minister of Health on new drug classifications and amendments to existing classifications)
- the process for making and amending classification decisions.

14. There is a strong similarity between the controlled drugs and psychoactive substances regimes in terms of assessing the harm and determining the controls required for particular drugs. The objective is to ensure the classification system across both regimes is fit-for-purpose and informed by current evidence, and the decision making processes are efficient and transparent.

15. The Ministry recommends any review of these provisions be considered alongside the outcome of the Psychoactive Substances Act review in 2018 to inform options to streamline processes and resources between the two regimes. This work would be undertaken in 2017.

Offences and penalties for criminal use of controlled drugs

16. The Act's strong supply control and law enforcement focus is perceived by some stakeholders to be inconsistent with the harm-minimisation principles of the guiding national policy. This is despite the current law allowing innovative approaches such as Alcohol and Other Drug Treatment Courts and using warnings for low level offending. We do not yet have good information on how alternative provisions are being used, and for whom. If a shift in the approach...
taken by the criminal justice system is desired, a range of levers are available, including change in operation and enforcement policy as well as legislative change.

17. The Ministry has identified the potential for a Ministry of Justice-led project to review innovative approaches to harm minimisation in the criminal justice sector. This project would focus on reviewing how the provisions are applied, rather than the offences and penalties themselves. Ministry of Justice officials have indicated they are comfortable with the proposal, and plan to provide advice to their Minister on this approach in the New Year.

18. The proposed review could also include existing government and NGO policies and programmes, such as the Youth Crime Action Plan to identify opportunities to reduce drug-related harm and identify barriers to achieving the desired outcomes. This review would also give us useful data on possession for supply offences, where the Supreme Court has found an inconsistency with the Bill of Rights Act, but the impact of this, while believed by the Law Society to be inconsequential, is unclear.

19. Specific actions and timing of stages of the review would need to be agreed with the Minister of Justice. We propose that finalising this review by 2017 would allow for any legislative changes to be considered alongside the 2018 review of the Psychoactive Substances Act.

Next Steps

20. We suggest a meeting with officials to discuss your preferred approach, noting that this work programme will need to be considered alongside other priorities.

END.
Memorandum: Psychoactive Substances (Increasing Penalty for Supply and Distribution) Amendment Bill

To: Hon Dr David Clark, Minister of Health

Purpose

1. The Psychoactive Substances (Increasing Penalty for Supply and Distribution) Amendment Bill (the Bill) is expected to be read for the first time on Members day on 21 February 2018. This memorandum provides you with background information.

Comment

2. The Bill is on the provisional Order Paper for 20 February, expected to be read on Members’ day on 21 February.

3. The Bill was introduced on 1 February 2018. The Member in charge is Simeon Brown, National MP for Pakuranga.

4. The Bill amends the Psychoactive Substances Act 2013 to increase the penalty for selling or supplying psychoactive substances that are not approved products. It increases the penalty from 2 years to 8 years. The increase is intended to ensure that those who supply illegal psychoactive drugs onto the market face the same penalty as they would if they were supplying a Class C Drug under the Misuse of Drugs Act 1975.

5. Note that in 2016/17 145 people were convicted of possession, sale and/or supply of psychoactive substances, including synthetic cannabis (further breakdown has not been published).

6. We believe the Bill is contrary to Government aspirations for a humane and effective justice system and reducing the prison population. We are not aware of any evidence that increased penalties will lead to reduced drug-related harm.

7. Government has also indicated they are looking to review the Misuse of Drugs Act, taking a health-based approach. This will be an opportunity for a broader review of offences and penalties including consideration of penalties both available and awarded.

8. The Psychoactive Substances Act requires a review of the Act in 2018 and officials will propose the scope and method of this review by April 2018.

END.

Contacts: Hannah Cameron, Deputy Chief Policy Officer, Strategy and Policy
Helen Fielding, Senior Policy Advisor, Strategy and Policy
Health Report: Advice to Justice Committee on the Psychoactive Substances (Increasing Penalty for Supply and Distribution) Amendment Bill

Date: 27 August 2018
Report No: 20181785
File Number: AD62-14-2018

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Contact for Telephone Discussion (if required)

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<tr>
<td>John Doyle</td>
<td>Acting General Manager, Regulatory Policy, Strategy and Policy</td>
<td>s 9(2)(a)</td>
<td>1st Contact</td>
</tr>
<tr>
<td>Emma Hindson</td>
<td>Manager, Prevention, Strategy and Policy</td>
<td>s 9(2)(a)</td>
<td>2nd Contact</td>
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Actions for the Minister's Office Staff

Return the signed report to Ministry of Health

Feedback on the quality of the report
Advice to Justice Committee on the Psychoactive Substances (Increasing Penalty for Supply and Distribution) Amendment Bill

To: Hon Dr David Clark, Minister of Health

Purpose

This report:
- provides you with a copy of the departmental report on the Psychoactive Substances (Increasing Penalty for Supply and Distribution) Amendment Bill. The Ministry of Health intends to present the report to the Justice Committee on 6 September 2018.
- seeks your agreement that the Ministry of Health will advise the committee that any changes to penalties in the Act should be considered as part of a wider work programme.

Key points
- The Bill is a Private Members Bill. Simeon Brown, National MP for Pakuranga, is the Member in charge.
- The Bill amends the Psychoactive Substances Act 2013 to increase the penalty for selling or supplying psychoactive substances that are not approved products in line with those applied for supplying a Class C controlled drug under the Misuse of Drugs Act 1975.
- The Ministry of Health is advising the Justice Committee. We have consulted with the Ministry of Justice in the preparation of the departmental report.
- We believe the Bill is contrary to the Government’s commitment to reform the criminal justice system to make it more humane and effective, and to reduce the prison population. There is insufficient evidence that increased penalties will lead to reduced drug-related harm.
- Government has indicated it will take a health-based approach to drug use. This will be an opportunity for a broader review of offences and penalties including consideration of penalties.
- The majority of submitters did not support the Bill on the grounds that prohibition of drugs does not work and drug use should be treated as a health issue, rather than a criminal issue.
- It is the view of the Ministry that any changes to penalties in the Act should be considered as part of a wider work programme.
Recommendations

The Ministry recommends that you:

a) **note** the attached departmental report for the Psychoactive Substances (Increasing Penalty for Supply and Distribution) Amendment Bill.

b) **note** that the Ministry will advise the Justice Committee that we recommend that Parliament does not consider penalties in the Psychoactive Substances Act in isolation from other drug related legislation and a wider work programme.

c) **note** that the Ministry will present the attached departmental report to the Justice Committee on 6 September 2018.

Todd Kriebile  
Chief Strategy and Policy Officer  
Strategy and Policy

Minister’s signature:

Date:
Psychoactive Substances (Increasing Penalty for Supply and Distribution) Amendment Bill

Departmental Report

Prepared by the Ministry of Health

6 September 2018
Introduction

1. This report provides an overview of submissions on the Psychoactive Substances (Increasing Penalty for Supply and Distribution) Amendment Bill (the Bill). The Bill intends to increase the penalty associated with the supply of non-approved products in line with the penalties for the supply of Class C drugs.

2. The Ministry of Justice has been consulted in the development of this report. The Parliamentary Counsel Office has been informed.

3. This report provides advice on the proposed amendment to the Psychoactive Substances Act 2013.

Submissions Received

4. The Committee received 78 written submissions on the Bill.

5. There were 18 submissions in support of the Bill and 53 submissions opposing the Bill. A further seven submissions are unclear.


7. There were 64 individual submissions and 14 submissions from organisations, including five health or treatment related organisations, three justice sector related organisations (including lobbyists), three local government or local business groups, two industry related organisations and one research organisation.

8. Some submissions appear to be form submissions. Of the individual submissions, 21 repeat similar statements including:
   • there is a lack of evidence that longer prison sentences contribute to reduced harm
   • that prohibition of drugs causes harm
   • that being tough on crime does not work
   • all drug use should be treated as a health issue rather than a criminal issue.

   Similar themes appear in other written submissions.

9. The submissions in support of the Bill generally argue that drug dealers should be punished, that penalties should be aligned with cannabis offences, and that this increase in penalties should be included along with a range of other interventions.

Comment

10. The Bill would amend Section 70(3)(a) of the Psychoactive Substances Act 2013 to replace "2 years" with "8 years". The intention of the Bill is to increase the penalty associated with the supply of non-approved products in line with the penalties for the supply of Class C drugs under section 6(2)(c) of the Misuse of Drugs Act 1975.

11. Increases in penalties do not necessarily produce a corresponding deterrent effect. The international and domestic evidence does not support the contention that increased penalties result in reduced incidences of offending. Instead the majority of the deterrent effect is considered to be tied to the certainty of response to offending, rather than the severity of punishment. While there is strong evidence for the general
deterrent power of a criminal justice system, increases in the severity of penalties do not necessarily produce a corresponding increase in deterrence.

12. There is a broad range of psychoactive substances. While some may pose a greater risk of harm than Class C drugs, others may pose a lesser risk of harm. The maximum penalty for supplying Class C drugs is 8 years imprisonment.

- Recent reports indicate the Coroner is currently investigating 40 – 45 deaths provisionally linked to synthetic cannabis, suggesting a higher risk of harm than Class C substances.
- The Psychoactive Substances Act 2013 regulates substances that pose no more than a low risk of harm, and the Misuse of Drugs Act regulates drugs by classifying drugs according to the level of risk they pose. Substances that have a high risk of harm may be scheduled under the Misuse of Drugs Act as they come to light.

13. Government has indicated it will take a health-based approach to drug use, and reform the criminal justice system to make it more safe and effective, and to reduce the prison population. This will be an opportunity for a broader review of offences and penalties in drug related legislation.

Security classification: In-Confidence

Memorandum: Second Reading of Psychoactive Substances (Increasing Penalty for Supply and Distribution) Amendment Bill - Talking Points

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<tr>
<td>Emma Hindson</td>
<td>Manager, System Strategy and Policy</td>
<td>3.9(2)(a)</td>
<td>1st Contact</td>
</tr>
<tr>
<td>Helen Fielding</td>
<td>Senior Analyst, System Strategy and Policy</td>
<td>3.9(2)(a)</td>
<td>2nd Contact</td>
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Actions for the Minister’s Office Staff

Return the signed report to Ministry of Health

Note any feedback on the quality of the report
Talking points: Psychoactive Substances (Increasing Penalty for Supply and Distribution) Amendment Bill Second Reading

To: Hon Dr David Clark, Minister of Health

Purpose
This briefing provides you with information and talking points for the second reading of the Psychoactive Substances (Increasing Penalty for Supply and Distribution) Amendment Bill, due to take place tomorrow, 17 October 2018.

Key points
- The Bill is a Private Members Bill. Simeon Brown, National MP for Pakuranga, is the Member in charge.
- The Bill amends the Psychoactive Substances Act 2013 to increase the penalty for selling or supplying psychoactive substances that are not approved products from 2 years to 8 years. The increase is intended to ensure that those who supply illegal psychoactive drugs onto the market face the same penalty as they would if they were supplying a Class C Drug under the Misuse of Drugs Act 1975.
- The Bill passed its first reading on 21 March 2018 and was referred to the Justice Committee. The Committee presented its report to the House on 20 September 2018.
- The Committee did not reach agreement on whether to recommend that the Bill be passed. Their report is attached to this memo.
- The majority of submitters did not support the Bill on the grounds that prohibition of drugs does not work and drug use should be treated as a health issue, rather than a criminal issue.
- Ministry of Health officials believe there is insufficient evidence that increased penalties will lead to reduced drug-related harm.
- Government has indicated it will take a health-based approach to drug use, and reform the criminal justice system to make it more safe and effective, and to reduce the prison population. This will be an opportunity for a broader review of offences and penalties in drug related legislation, and the Ministry of Health recommends that any changes to penalties in the Psychoactive Substances Act should be considered as part of this wider work programme.
- The Bill's second reading is due to take place on 17 October 2018. Talking points are included in this memo.
Talking points: Psychoactive Substances (Increasing Penalty for Supply and Distribution) Amendment Bill Second Reading

Recommendations

The Ministry recommends that you:

a) note the talking points included for your speech at the second reading.

John Doyle
Acting Manager Regulatory Policy
System Strategy and Policy

Minister's signature:

Date:
Talking points: Psychoactive Substances (Increasing Penalty for Supply and Distribution) Amendment Bill Second Reading

Further information

Current law
1. The Psychoactive Substances Act 2013 prohibits any substance that has a psychoactive effect that hasn’t been approved. It establishes a regulatory regime for substances that pose no more than a low risk of harm.

2. Substances that have a high risk of harm can be scheduled under the Misuse of Drugs Act 1975. This process can take up to a year. The Misuse of Drugs Act regulates scheduled drugs by classifying them according to the level of risk they pose. It allows access and use of drugs for legitimate purposes such as medicines, and generally prohibits all other use.

3. There is a broad range of psychoactive substances, with new ones being created constantly. The risk of taking these substances is highly variable, with some only having minor effects, and some at the other end of the spectrum causing death.

4. The Coroner has investigated 40 to 45 deaths that are provisionally linked to the use of synthetic cannabis. You are currently working to get these classified as Class A, which will increase the police search and surveillance powers available.

Psychoactive Substances (Increasing Penalty for Supply and Distribution) Amendment Bill
5. The intent of the bill is to align the penalty for non-approved substances in the Psychoactive Substances Act with the penalty for Class C drugs in the Misuse of Drugs Act. The alignment would allow for longer sentences and provide more flexibility for judges when sentencing. It is intended as a deterrent to the sale and supply of new or modified non-approved substances.

6. The bill proposes to amend the penalty in section 70(3)(a) of the Psychoactive Substances Act, under which a person who sells, supplies, or possesses a substance with the intent to sell or supply is liable to a term of imprisonment not exceeding 2 years. This would align with the penalty in section 6(2)(c) of the Misuse of Drugs Act, which sets out a penalty of imprisonment for a term not exceeding 8 years in respect of the sale, production, or supply of Class C drugs.

7. While the member’s bill increases the penalty for supplying and distributing psychoactive substances, it has no effect on search and surveillance powers that apply to psychoactive substances.

Proactive Release
8. The Ministry intends to publish this memo under its proactive release policy.
Talking points: Psychoactive Substances (Increasing Penalty for Supply and Distribution) Amendment Bill Second Reading

Talking points

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END.
Health report

Hon Todd McClay, Associate Minister of Health
cc Hon Tony Ryall, Minister of Health

Psychoactive Substances Act: Implementation, communications and enforcement

Executive summary

i. The Psychoactive Substances Bill is anticipated to be enacted on 11 July 2013. On enactment, the Ministry of Health becomes the regulator of psychoactive substances. Its role will be to consider applications for new psychoactive products, license industry participants (e.g. manufacturers, importers, wholesalers and retailers), monitor industry activity and contribute to enforcement (with New Zealand Police).

ii. The Ministry's systems and processes are being developed in time for the Bill's commencement, to ensure the Ministry regulatory roles are achieved. These include: preparing a communications plan; establishing a website; establishing an interim product approval and licensing process; developing forms and guidelines for interim product approvals and licences; and preparing for compliance and enforcement activity with Police.

iii. This report recommends that you note how the Bill will be implemented on its commencement. It includes a table updating you with the Ministry's preparation of operational requirements, a communications plan, information on compliance and enforcement activities to be undertaken in conjunction with Police, and a draft media statement intended for release by the Ministry upon enactment of the Bill (Appendix A).

iv. In the 28 days following commencement, the Ministry will focus on considering interim product approvals and licences. The Ministry will also commence development of the Regulations and product testing guidelines to support the Act. DHB public health officers will undertake on-going compliance activity, as guided by local police. The Ministry is preparing a letter for you to the Minister of Police outlining activity to be jointly undertaken between DHBs and police.

The Ministry recommends that you:

a) Note that the Psychoactive Substances Bill is due to be enacted on 11 July 2013 and that the Ministry is developing systems and processes in its role as the new regulator in time for the Bill's commencement;

b) Note that the Ministry has developed a communications plan for the Bill's commencement, which includes a draft media release;

c) Note that the Ministry is working with Police to undertake compliance and enforcement with the new legislation to start immediately on the Bill's commencement;

d) Note that the Ministry will provide a draft of the proposed website for the new regulatory authority by 5 July 2013

Dr Stewart Jessamine
Group Manager, Medsafe
Clinical Leadership, Protection & Regulation

Minister's signature

Date 10/7/13
Ministry of Health contacts

<table>
<thead>
<tr>
<th>Dr Stewart Jessamine</th>
<th>Bruce Atmore</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group Manager, Medsafe</td>
<td>Principal Advisor, New Regulators Establishment Unit</td>
</tr>
<tr>
<td>Phone 04 819 6874</td>
<td>Phone 04 816 4386</td>
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Minister's feedback on quality of report

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END.
Advice

The Ministry work plan includes five functions to be completed by the Bill’s enactment. The functions and status are set out below:

**Operational requirements**

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**Communication plan**

There is a need to communicate the immediate and longer-term effects of the Act and its Regulations.

**Communication objectives**

- Make clear the immediate effects of the enactment of the law – in particular how enforcement is to occur
- Provide information about the Act as a whole and its key provisions
Health Report number: 20130890

- Explain how the subsequent stages will work (with day 28, and the implementation date of new regulations as key milestones)
- Ensure consistent communication with other agencies around the Act — primarily Police — and Ministers
- Handle media and public queries around the Act, which initially are expected to focus on enforcement issues
- Support confidence in the Act as a decisive measure that overcomes issues created by previous regulatory measures.

Background

- The Act overcomes a problem being experienced world-wide of trying to effectively regulate novel psychoactive substances.
- The Act reverses the responsibility for proving that psychoactive products, such as party pills, are safe. No new product will be legally available in New Zealand unless it has been shown to cause no more than a low risk of harm to the person using it.
- The Act will immediately remove the most pressing risks of psychoactive products being sold in local dairies and to under 18 year olds.
- The Bill will have an immediate effect. As soon as the Bill becomes law:
  - Sale of psychoactive products will be banned in dairies, convenience and grocery stores, supermarkets, service stations and anywhere that has an alcohol on-licence
  - No-one under 18 years of age will be permitted to purchase or possess psychoactive products
  - Advertising of psychoactive products will be strictly controlled — only permitted at the point of sale
  - All products must have health warnings
  - Neither advertising nor labelling will be allowed to appeal to youth
  - The regulatory authority will be able to withdraw a product from the market if any adverse effects are reported
  - New offences are created for breaches of requirements under the Act.

- The Government has reiterated that animals will only be used for psychoactive product safety testing when it is essential, and that animal testing will be reduced, refined and replaced wherever practicable.

Communication will include the following audiences:

- Associate Minister and Minister of Health (briefings ahead of and as the Act is enforced, liaison around communications and media issues as they arise)
- Director-General of Health (as above)
- Police (on-going regular liaison at agency level — co-ordination of communication messaging at time of enactment and beyond)
- DHB and their Public Health Units
- News media (media statement and spokesperson available for interviews; provision of other information primarily via Ministry website)
- General public (via media publicity, website, and provision of information about how the public can report possible breaches and other concerns)
- Retailers affected from commencement (pre-enactment pamphleting by police; on-site visits by police / Public Health Unit staff in days following enactment)
- Retailers still able to trade, under transitional provisions (liaison by police / Public Health Unit staff)
Psychoactive substances industry (on-going regular liaison by Ministry).

What these audiences probably think about this issue:

There will be considerable initial media and public interest on the immediate impact of the Act – and the accelerated introduction of the Act (faster than previously publicised timelines) will mean minimal chance to explain it before it becomes in force.

Most initial coverage will likely centre on those retailers who knowingly or unknowingly continue to trade. Strong media and public interest is highly likely to unearth such instances before initial enforcement measures have taken full effect. A speedy response to such complaints will help build confidence in the new Act’s enforcement.

There will also be interest in whether a black market has been created.

There will be interest in who is still able to trade and what they can trade – so there will be a need to succinctly explain what the transitional period means. There may be some perception that it is “business as usual” for retailers.

The 28-day period and the time through to the completion of regulations will likely see coverage more focussed on how the new testing regime will operate and how the industry is adapting to that. The question of animal testing is likely to be of on-going interest as part of this.

We will reach those audiences by taking these initiatives:

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<td>CLPR regulatory team</td>
<td>On-going</td>
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<tr>
<td>Liaison with Associate Minister’s office around communications (cc’ing Minister Ryall’s office) including assisting with any separate ministerial media release.</td>
<td>MoH comms team</td>
<td>On-going</td>
</tr>
<tr>
<td>Internal liaison (primarily Office of DG) around communications.</td>
<td></td>
<td>On-going</td>
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<tr>
<td>Press release by Ministry (including directing media for more information to the Ministry website) - including attributable spokesperson for media interviews.</td>
<td>MoH comms team</td>
<td>Day of enactment (Possible) on Day 28 (Probable) on completion of regulations</td>
</tr>
<tr>
<td>MoH website – Material on Act provisions, key points, and brief FAQs (aimed at media and members of the public)</td>
<td>CLPR team / MoH comms team / MoH web team</td>
<td>ASAP before enactment target date by 5 July</td>
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<td>Liaison with Public Health Units to ensure they are aware of the Act’s arrival, and to facilitate enforcement in conjunction with local police equivalents</td>
<td>CLPR team</td>
<td>Before enactment and on-going</td>
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<tr>
<td>Liaison with DHB communications managers (key messages and FAQs)</td>
<td>MoH comms team</td>
<td>Before enactment</td>
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<tr>
<td>Liaison with police</td>
<td>CLPR team</td>
<td>On-going</td>
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<tr>
<td>Liaison with Police over communications and key messages (especially enforcement) and any joint media initiatives (possible photo opportunity)</td>
<td>MoH comms team</td>
<td>Before enactment and initial 28-days</td>
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<td>Handling of media inquiries prior to and beyond enactment of the law</td>
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<td>- Website</td>
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<td>DHB PHUs / CLPR team</td>
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<td>Retailers banned from Day One:</td>
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<td>Police pamphlet to known traders</td>
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<td>Has / is occurring nationwide</td>
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<tr>
<td>Enforcement action</td>
<td>Police / PHU</td>
<td>On-going from day one</td>
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<td>Key message from spokesperson that they should cease trading or face prosecution and penalties.</td>
<td>MoH comms team</td>
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<td>Retailers still able to trade under interim measures</td>
<td>Police / PHU liaison</td>
<td>On-going</td>
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<tr>
<td>Psychoactive substances industry</td>
<td>CLPR team</td>
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Key messages

1. This is a world-leading approach to a global problem of trying to effectively regulate novel psychoactive substances.

2. The Act will immediately remove the most pressing risks of psychoactive products being sold in local dairies and convenience stores, and to under 18-year-olds.

3. Other businesses have up to 28 days from commencement to seek an interim licence to trade.

4. The interim licences only cover the period until the completion of regulations later this year, including those detailing the new Psychoactive Substances Regulatory Authority within the Ministry of Health.

5. From 28 days after commencement, all non-licensed businesses must also cease trading in psychoactive substances and all non-approved products must be removed from the distribution chain.
6. Once the Regulations are in place, manufacturers of products with interim approvals will be required to submit an application for approval to the Authority as soon as practicable or their licence will be revoked.

7. While companies are collecting the information required for applications, products with interim approvals will continue to be available for sale as long as evidence from use in the community indicates they pose no more than a low risk of harm. If reports of harm occur, the Act allows immediate banning and removal from the market.

8. The Government has reiterated that animals will only be used for psychoactive product safety testing when it is essential, and that animal testing will be reduced, refined and replaced wherever practicable.

9. Police and health officials are working together on enforcement and welcome the public reporting of any possible breaches.

Ministry spokesperson

The Ministry spokesperson is Dr Stewart Jessamine, Group Manager, Medsafe.

Compliance and enforcement action

Police to lead

The Ministry has been meeting with New Zealand Police to discuss compliance and enforcement activities in relation to the new legislation. Local police are leading the response before and after the legislation comes into effect, with the assistance of DHB public health units. The Ministry has provided Police with a list of public health managers as first points of contact.

The key focus for police immediately following enactment is to ensure that all currently unregulated psychoactive products are removed from prohibited premises, such as dairies, convenience and grocery stores. Subsequent operations will focus on enforcing the prohibition of sales of psychoactive products to, and by, under 18 year olds and compliance with other product and licensing restrictions and requirements by the remaining retailers still permitted to trade in them during the interim period and under the Regulations.

Police headquarters has developed a leaflet warning retailers that it will soon be illegal for dairies and convenience stores to sell psychoactive products such as synthetic cannabis or party pills. Local police districts have commenced a mass delivery ahead of the legislation being passed.

Police has also assigned operational responsibility to twelve District Prevention Managers and issued good practice guidelines for officers visiting retail outlets once the Act is in force. Police will investigate deliberate breaches of the Act and prosecution will be considered on a case by case basis. Police have also assumed responsibility for the disposal or destruction of stock surrendered by retailers, in line with current standard practices.

Role of DHBs

The Ministry has communicated with DHB public health unit managers on the key provisions of the new legislation and encouraged strong cooperation with police District Prevention Managers. While enforcement powers under the new legislation will not be available to public health officers until the Regulations are developed, DHBs still have an important monitoring and compliance role in the interim.

Police are requesting that smoke-free or other public health officers accompany them on retailer visits where possible. A number of DHBs already maintain good working relationships with local
police, which have been enhanced recently by responding to public concern about the sale of legal highs from dairies and convenience stores. DHB smoke-free officers have also carried out a number of controlled purchase operations to ensure retailers are not selling synthetic cannabis to under 18s.

The Ministry is confident DHB officers will provide good support to local police in joint operations by providing information about the new legislation to retailers, including what to do with prohibited stock and by passing on illegal activity or reported breaches for police follow up.

The Ministry is preparing a letter for you to the Minister of Police, Hon Anne Tolley, outlining the undertaking by DHB public health units to assist local police with monitoring and enforcement.

DHBs are also working with local police to develop a list of retailers who may be permitted to continue trading in psychoactive products in the interim period following enactment and after the Regulations are in place. The list should prove useful for later compliance and enforcement activity and to assist with monitoring of the market.
Appendix A

Draft media release Ministry of Health July xx 2013

Psychoactive Substances Act now law

A law that allows regulation of psychoactive substances and products in New Zealand is now in effect.

The Psychoactive Substances Act immediately curtails aspects of current product retailing and establishes a Psychoactive Substances Regulatory Authority within the Ministry of Health.

The Authority will be responsible for ensuring products meet adequate safety requirements before they can be distributed in New Zealand. It will also license importers, distributors, and retailers to ensure products are not supplied to minors.

Dr Stewart Jessamine, Group Manager Medsafe, says the most immediate effect of the law is that dairies, supermarkets, service stations, or anywhere with an alcohol on-licence are no longer allowed to sell psychoactive substances. No-one under 18 years of age will be permitted to purchase or possess psychoactive products.

"This change is from day one, and police and health officers are working together to ensure that those retailers understand they should remove products from their shelves as they can no longer trade in these substances. To do so places them at risk of prosecution and substantial penalties."

Dr Jessamine says: "Retailers permitted by the law to sell such products, and their manufacturers are required to comply with requirements during a transition period between the passage of the Act and the passage of the Psychoactive Substances Regulations expected towards the end of this year."

During this time, distributors and manufacturers have 28 days to obtain interim approval:

- A product manufacturer will be required to apply for an interim approval for each product they make. This will require the manufacturer to certify that it has been on the market for more than 3 months and that no harm has been reported. A condition is that all products will be required to carry labelling describing the product ingredients and specified warning statements;

- Permitted retailers and wholesalers of psychoactive substances will be required to apply for interim licences to sell products in each location they operate. The licence will limit their ability to advertise products to within their premises, restrict sale to persons aged 18 years and over; and to store product for sale behind the counter such that self-selection is not possible.

While dairies, supermarkets, service stations, or anywhere with an alcohol on-licence are immediately prohibited from selling psychoactive substances, from 28 days after enactment, all non-licensed businesses must also cease trading in psychoactive substances. All non-approved products must be removed from the distribution chain.

Dr Jessamine says: "Interim licences only cover the period to passage of the regulations. Once regulations are in place, manufacturers of products with interim approval will be required to submit an application for approval to the Authority within 18 months. This application will contain information demonstrating that the product poses no more than a low risk of harm. Within two
years I expect that only products that have gone through the full Regulatory Authority process will be able to be sold”.

"While companies are collecting the information required for applications, products with interim approval will continue to be available for sale as long as evidence from use in the community indicates they pose no more than a low risk of harm. If reports of harm occur, the Act allows a product to be immediate banned and removed from the market.”

More details on the Act can be found here (LINK to Ministry website, including FAQ)

For further information, contact Kevin McCarthy, senior media advisor, 021 832 459.
Health report

Hon Todd McClay, Associate Minister of Health
cc Hon Tony Ryall, Minister of Health
Cabinet approval for consultation on Psychoactive Substances Regulations

Executive summary

i. The Psychoactive Substances Act 2013 requires you to consult affected parties on draft regulations, and Cabinet approval is required before consultation can begin. A draft consultation document and supporting draft Cabinet paper are attached for your approval.

ii. These documents can be lodged with the Cabinet Social Policy Committee following your approval. Lodging the attached papers on 5 February is likely to enable the first part of regulations to be in place from July 2014, by which time the interim arrangements will have been in place for a year.

iii. This paper recommends consultation on the regulatory proposals is followed by a two-phase implementation process designed so that local approved product policies can be finalised by territorial authorities and implemented before the full retail regulatory provisions are put in place. Given current progress by territorial authorities, it is likely that phase two of the regulations relating to retail aspects will not be in place until 2015.

iv. While there are risks with extending the implementation timeframe for the retail regime (such as delaying the implementation of a more rigorous full regime), these are outweighed by the risks of the regulations running ahead of the development of local approved products policies and of multiple consultations which could be confusing for stakeholders and would create unnecessary duplication.

The Ministry recommends that you:

a) Note section 101(2) the Psychoactive Substances Act 2013 requires you to consult substantially affected parties on any proposed regulations.

b) Note Cabinet approval is required before any consultation document is released

c) Agree to a single consultation on all regulatory proposals to avoid confusion and duplication, and save time and money

d) Agree to a two-phase implementation approach, where pre-market parts of the regulations are promulgated as soon as reasonably practicable, but retail aspects of the regulations come into effect after territorial authorities have developed local approved products policies

e) Agree to the content of the attached draft consultation document and accompanying Cabinet paper

f) Forward the attached draft consultation document and accompanying Cabinet paper to the Cabinet Social Policy Committee by 5 February 2014.

Don Mackie
Chief Medical Officer
Clinical Leadership, Protection and Regulation

[Signature]

Minister’s signature

Date 26/1/14
Ministry of Health contacts

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<thead>
<tr>
<th>Name</th>
<th>Title and Unit</th>
<th>Phone</th>
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<td>Senior Advisor, New Regulators Establishment Unit</td>
<td>04 816 4486</td>
<td>9(2)(a)</td>
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<tr>
<td>Donald Hannah</td>
<td>Manager, New Regulators Establishment Unit</td>
<td>04 816 2682</td>
<td>9(2)(a)</td>
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Minister's feedback on quality of report

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Draft documents are attached for your approval

1. Under section 101(2) of the Psychoactive Substances Act 2013, you are required to consult any person or organisation that you consider representative of the interests of persons likely to be substantially affected by proposed regulations. Cabinet approval is required before any consultation documents are released.

2. Two papers are attached to this report for your approval, a draft:
   a. Cabinet paper
   b. consultation document.

3. This report also seeks your approval of the consultation and implementation approach to the Psychoactive Substances Regulations.

One consultation is recommended

4. The regulations end the transitional period, bringing the full licensing regime into force. By lodging papers with the first Cabinet Social Policy Committee meeting of the year, and proceeding with the consultation and drafting process, the first stage of regulations could be passed by July 2014 and the transitional period for all aspects of the regime (except retail) completed by August 2014.

5. We recommend one consultation on all regulatory matters, but a phased approach to the implementation of the regulations, with retail licensing not coming into effect until after territorial authorities have their local approved products policies (LAPPs) in place. Another way to approach this matter is to run two consultations; the first on pre-market issues such as importing, manufacturing and wholesaling psychoactive substances and products, including labelling and packaging, and the second on retail matters, such as advertising and retail licence applications. A single consultation will:
   a. ensure the legal requirement to consult is met
   b. allow the scheme to be consulted on in its entirety, and for submitters to comment on the whole scheme
   c. avoid confusion for stakeholders that may arise from conducting two consultations
   d. save the extra costs and time associated with a second consultation, in particular for territorial authorities
   e. still allow for a phased approach to the implementation of the regulations.

A two phase implementation is recommended

6. Officials recommend a single consultation, followed by a phased implementation of the regulations. Phase one of implementation would have all pre-market matters including importing, manufacturing and wholesaling of psychoactive substances and products, including labelling and packaging, in place by July 2014.

7. The Act is designed to allow territorial authorities, in consultation with their communities, to determine where psychoactive products can be sold within the council district. It would be inefficient and expensive for the Psychoactive Substances Regulatory Authority (the Authority), councils and applicants to process retail licence applications before local policies are known.

8. Therefore, we recommend that phase two of the implementation covers all aspects of the retail market. This phased process would help ensure a managed approach to retail licences that follows territorial authorities approving their policies, and would allow the Authority to continue to work with territorial authorities to ensure we have an integrated licensing system.

9. Once consultation on the retail regulations is concluded, the process for promulgating these regulations in a second step will be quicker than if a further consultation was required. The
Health Report number: 20131684

Authority proposes to clearly signal the proposed phased implementation approach with territorial authorities, their communities and licence applicants so that community and industry expectations are clear.

10. Regulations relating to infringement offences do not require consultation under the Act, and proposals will be developed in conjunction with New Zealand Police.

Local authority progress on LAPPs

11. A recent scan of territorial authority progress on LAPPs by the Authority revealed that 42 of the 65 authorities (or 65%) had not yet taken any action although not all areas have retail outlets within them. Of the remaining 23:
   a. three had a LAPP in effect (Hastings District Council, Napier City Council, Tasman District Council)
   b. one had closed their consultation on a draft policy (Nelson City Council)
   c. six had policies out for consultation (several councils in the Waikato area, plus Palmerston North and Hutt City Councils)
   d. two were considering a policy
   e. eleven were developing a policy.

12. In some areas, for example Waikato, Wairarapa and the West Coast, territorial authorities are considering joint policies with neighbouring councils. The Authority is encouraging this approach which is permitted under the Act. Areas with policies out for consultation might be expected to have LAPPs in place by mid-2014, but other areas will take longer, given that they have not begun their processes (the Act requires authorities to run a special consultative procedure under the Local Government Act). Accordingly, it is likely to be 2015 before the retail aspects of the regulations move from the interim into the full regime.

Risks

13. There are some risks in taking a phased approach to implementation, including:
   a. a short-term interim retail scheme may potentially run for over a year, delaying the implementation of more rigorous full regulatory controls
   b. a delay in gathering revenue from the retail licence applications
   c. a potential drop in the number of retail outlets because no new interim licences can now be issued - meaning that once the full scheme is in place, the number of retail outlets may rise
   d. perceptions that this public-facing aspect of the scheme is less stringently regulated than other aspects of the scheme.

14. These risks are being mitigated by appropriate implementation and enforcement of the interim regime. The delay in revenue gathering will not create any additional cost to the Crown, but will have some effect on the phasing of cost recovery. All matters apart from the retail aspects will move to the full regime. Product manufacture is already subject to Code of Manufacturing Practice requirements which focus on product quality. Risks will also be mitigated as an increasing number of territorial authorities develop their LAPPs during this period. Communications can manage expectations and public concern about retail aspects.

15. The risks of a phased approach are outweighed by the risks generated by implementing all of the regulations at once, and especially ahead of LAPPs, because the full impact of local policies on the licensing regime will not be evident and may clash with licencing decisions once they are.
Next steps

16. If you approve the approach to consultation and implementation approach to the regulations, officials recommend Psychoactive Substances Regulations Consultation is put on the agenda for the Cabinet Social Policy Committee 12 February meeting.

17. If Cabinet agrees to the release of the consultation document, consultation could be underway on 19 February and run for one month until 21 March 2014. This will allow Cabinet approval for policy under the regulations to be sought in April and, subject to Parliamentary Counsel Office confirmation, regulations drafted ready for promulgation from July 2014.

18. A consultation communications plan will be developed by officials in conjunction with your office once dates are finalised.

END.
Advice to the Health Committee about the Psychoactive Substances Bill

Advice:

1. The Health Committee met on 15 May 2013 to consider the Departmental Report and recommendations by the Regulations Review Committee in relation to the Psychoactive Substances Bill.

2. The Committee asked the Ministry to provide written advice in response to the Regulations Review Committee's recommendations. The Committee also requested that the Ministry consider whether a definition of psychoactive effect and plain packaging should be provided for in the primary legislation.

The Ministry recommends that you:

a) Agree that the Ministry can provide the attached advice to the Health Committee by Tuesday 28 May 2013

Ministry of Health contacts

<table>
<thead>
<tr>
<th>Oliver Poppewell</th>
<th>Sara McFall</th>
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<td>Senior Policy Analyst, Sector and Services Policy</td>
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<td>Phone 04 496 2158</td>
<td>Phone 04 816 4363</td>
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Minister's feedback on quality of report

- Very poor (1)
- Poor (2)
- Neutral (3)
- Good (4)
- Very good (5)
Health Committee hearing regarding the
Psychoactive Substances Bill
29 May 2013

1. At the hearing of 15 May 2013, the Health Committee considered the Departmental Report and a report by the Regulations Review Committee on the Psychoactive Substances Bill. The Health Committee requested that officials provide advice in response to the Regulations Review Committee's recommendations. The Committee also asked the Ministry to consider whether plain packaging was justified and practical, and whether a definition of psychoactive effect should be added to the Bill.

Regulations Review Committee report

2. The Regulations Review Committee raised four issues for consideration by the Health Committee. These are:
   a. the need for powers to declare a substance to be or not to be a psychoactive substance for the purposes of the legislation;
   b. the adequacy of regulations prescribing fees and charges;
   c. the regulation-making powers under clause 83 of the Bill;
   d. and the procedure for committees.

Declaring powers

3. As drafted, under clause 81, the Governor-General may make regulations by Order in Council to declare a substance to be a psychoactive substance for the purposes of the Bill.

4. The intention of this power is to clarify interface issues, and also to address a potential loophole where manufacturers market products as not for human consumption: for instance as plant food or incense. Manufacturers or distributors may argue that their products fall outside the definition in clause 9, by claiming the products are not intended to be used by individuals to induce a psychoactive effect.

5. The Ministry considers the declaring power to be justified to avoid attempts to game the system and escape regulation. The power is consistent with the declaring power in the Medicines Amendment Bill, and Natural Health and Supplementary Products Bill.

6. The purpose of the declaring power is to confirm that something falls within a particular category, and not to catch substances that fall outside this definition and bring them within the legislation. This being the case, the Regulations Review Committee has recommended removing clause 9(b)(ii) from the Bill, considering it unnecessary. However, we consider this sub-clause to be useful for the avoidance of doubt and as a reference to the declaring power in clause 81.

7. The Regulations Review Committee has also recommended that the Psychoactive Substances Expert Advisory Committee should provide advice prior to a substance being declared to be a psychoactive substance. The Ministry agrees with this recommendation.
8. As currently drafted, there is also a provision for the Governor-General to declare something not to be a psychoactive substance in the case of something inadvertently being captured by the definition in clause 9.

9. The Regulations Review Committee queried whether the test for this could be met, as it would place a substance outside regulation which is inconsistent with the purpose of the legislation, ie, to regulate psychoactive substances.

10. In the definition of psychoactive substance, there are a number of exclusions for substances regulated by other pieces of legislation. The purpose of the declaring power is to clarify under which regulatory scheme a substance should be controlled in the case of interface issues. The intention is not for some psychoactive substances to be unregulated. No change is recommended to the Bill.

Fees

11. The Regulations Review Committee queried whether the provisions for fee-setting were adequate to recover the costs of running the authority.

12. Some changes are proposed to the Bill to allow the Governor-General to make recommendations for levies, as well as fees and charges. The Ministry proposes adding additional sub-clauses to allow the authority to recover the costs of establishing the systems and processes for the regulator, and investigating and prosecuting regulatory offences against the Act.

Regulations in primary legislation

13. The Ministry agrees with the Regulations Review Committee that some of the retail regulations should be in the primary legislation.

14. The Regulations Review Committee also recommended that the regulation-making powers to set the infringement fee should be carved out from the requirement to consult. The Ministry agrees.

Procedure of appeal committees

15. The Ministry agrees with the recommendation to amend the Bill to state that the advisory and appeals committees should comply with natural justice.

Packaging and labelling

16. The Committee requested further information on whether plain packaging should be provided for in the Bill. Currently, there is a regulation-making power to provide for restrictions on labelling and packaging. The Ministry has also recommended that the primary legislation should prescribe that each pack carries a health warning but the detail of the warnings should be set out in regulations.

17. The Australian Tobacco Plain Packaging Act 2011 prohibits the use of all industry logos, brands imagery, colours and promotional text on the retail packing of tobacco products.
It does allow for the use of a brand and variant name in a standard colour, position, font size and style. The size and colour of the writing is set out in regulations, as are restrictions on other trademarks and other marks.

18. In New Zealand, it is likely that the model will be similar to the approach for tobacco health warnings. That is, that plain packaging would be prescribed in primary legislation with all the detail set out in regulations.

19. Tobacco is a fairly homogenous product with little differentiation in the base product. This is not the case with the products that will be regulated through this Bill, and distinguishing between different products will be important. It may be justifiable for product with a clear evidence of harm, such as tobacco. However, the impact of plain packaging on the ability for industry to use trade-marks may not be justified for approved products, which have been demonstrated as posing no more than a low-risk of harm. If the Committee recommends a requirement that products must be in plain packaging, the detail of colour, font size and labelling would need to go in regulations.

Definition of psychoactive effect

20. The Health Committee asked the Ministry to consider the addition of a definition of psychoactive effect. The dictionary and ordinary definition of psychoactive is "affecting the mind". It would be possible to add this definition to the interpretation section. However, it is very broad and would not add significant clarity.

21. The Ministry has looked at other definitions. These include examples of how the mind is affected such as hallucinations or disturbance in mood or perception, or the effects on brain function through chemical neurotransmitters.

22. The unintended consequence of trying to specify how the mind is affected is that it may limit the definition and allow potential loopholes. There may be a risk of challenge that the precise way a particular substance affects the mind has not been specified in legislation. The Ministry recommends no change to the definition.
Health report

Hon Peter Dunne (Associate Minister of Health)
cc Hon Tony Ryall (Minister of Health)
LEG paper for the introduction of the Psychoactive Substances Bill

Advice

1. The attached draft Cabinet Paper seeks Cabinet's authorisation to introduce the Psychoactive Substances Bill to the House. We propose that you take the paper to Cabinet Legislation Committee (LEG) on 21 February 2013.

2. The Bill provides for all the policy decisions made by Cabinet on 1 July and 1 October 2012 [CAB Min(12)35/14 and SOC Min(12)12/3 refer]. In addition to these policy decisions, during drafting we have identified other provisions that are required to make the legislation fit for purpose. These are principally additional offences and penalties required to ensure that all potential breaches of the legislation are covered. There are no substantive variations from Cabinet's decisions.

3. We are awaiting the final version of the Bill from Parliamentary Counsel Office and we will provide this to you prior to lodging papers with Cabinet Office.

4. The draft Cabinet Paper proposes that the Bill is introduced to the House on 26 February 2013 and referred to the Health Select Committee.

5. We have been formally advised by Crown Law that they may raise issues about consistency with the New Zealand Bill of Rights Act 1990. Our understanding is that these are likely to be minor, however we are expecting formal advice from Crown Law on Monday. Once we have this advice, we will address any concerns in a revised paper for LEG.

6. As you will be overseas on Monday, we propose that Mr Ryall signs the revised LEG paper and lodges the paper with Cabinet Office on Tuesday. The alternative would be to await your return and take the paper to LEG on 28 February but this would mean introducing the Bill in mid-March, following the Parliamentary recess and your return from the United Nations Commission on Narcotic Drugs. This three week delay would have an impact on the time allowed for Select Committee consideration.

The Ministry recommends that you:

a) Agree that Mr Ryall lodges the Cabinet Paper with Cabinet Office on Tuesday 19 February 2013

b) Sign the attached letter seeking permission to submit the Cabinet Paper late

c) Note the final version of the Bill will be provided to you by Friday 15 February 2013.

Don Gray
Deputy Director-General
Policy Business Unit

Minister's signature
Date 14.02.13
Health Report number: 20130153

Ministry of Health contacts

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<tr>
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Minister's feedback on quality of report

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Office of Hon Peter Dunne

MP for Ohariu
Minister of Revenue
Associate Minister of Health
Associate Minister of Conservation

Hon Gerry Brownlee
Chair
Cabinet Legislation Committee
Parliament Buildings
Wellington

Dear Mr Brownlee,

I seek your authorisation to submit a paper late to Cabinet Legislation Committee for consideration on 21 February 2013. I intend for the paper to be submitted on Tuesday 19 February 2013.

The paper seeks Cabinet's authorisation to introduce the Psychoactive Substances Bill to the House. This Bill will address the growth in unregulated psychoactive substances such as party pills.

The Bill needs to be passed by mid-August 2013 as this is when a number of the temporary class drug notices, an interim measure to restrict party pills and synthetic cannabis-like products, will permanently expire.

It is important that the Health Select Committee has adequate time to consider the details of what will be a legislative world first. If the paper is not considered by LEG until 28 February, the Bill will not be introduced until mid-March owing to the Parliamentary recess and my overseas commitments. This would reduce the time available for Select Committee consideration.

Yours sincerely,

Hon Peter Dunne
Associate Minister of Health
Consultation on Cabinet and Cabinet Committee Submissions

Certification by Department:

Guidance on consultation requirements for Cabinet/Cabinet committee papers is provided in the CabGuide (see Procedures: Consultation): [http://www.cabguide.cabinetoffice.govt.nz/procedures/consultation](http://www.cabguide.cabinetoffice.govt.nz/procedures/consultation)

**Departments/agencies consulted:** The attached submission has implications for the following departments/agencies whose views have been sought and are accurately reflected in the submission:

- The Ministry of Justice, New Zealand Customs Service, New Zealand Police, the Ministry for the Environment, the Environmental Protection Authority, the Ministry for Primary Industries, the Ministry for Business, Innovation and Employment, the Ministry of Foreign Affairs and Trade, and the Treasury.

**Departments/agencies informed:** In addition to those listed above, the following departments/agencies have an interest in the submission and have been informed:

- The Department of the Prime Minister and Cabinet

**Others consulted:** Other interested groups have been consulted as follows:

Affected industry has been consulted at different stages of policy and legislative development

**Name, Title, Department:** Don Gray, Deputy Director-General, Policy Business Unit, Ministry of Health

**Date:** 12/02/2013  
**Signature**

Certification by Minister:

Ministers should be prepared to update and amplify the advice below when the submission is discussed at Cabinet/Cabinet committee.

**The attached proposal:**

| Consultation at Ministerial level | □ has been consulted with the Minister of Finance  
(required for all submissions seeking new funding) | ✓ has been consulted with the following portfolio Ministers: HEALTH |
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Psychoactive Substances Bill: Approval for Introduction

Proposal

1. I propose that the Psychoactive Substances Bill be approved for introduction to the House of Representatives.

Policy

2. The purpose of the Bill is to regulate otherwise unregulated psychoactive substances (such as "party pills" and other "legal highs") in New Zealand.

3. On 1 July and 1 October 2012, Cabinet approved policy recommendations for a legislative framework to regulate the importation, manufacture and sale of psychoactive substances [CAB Min(12)35/14 and SOC Min(12)12/3].

4. This legislation is necessary as a permanent solution to the rapid growth in the availability of new psychoactive substances. Currently there is no mechanism to prevent these substances being imported, manufactured, or sold unless individual substances are scheduled in the Misuse of Drugs Act 1975. Existing legislative controls rely upon the Government identifying that a potentially harmful substance is being sold and then reacting accordingly. This means that there is a delay between a substance becoming publicly available and controls being placed upon it.

5. In 2011, the Government introduced temporary class drug notices that allow for emergency restrictions to be placed on new substances. The notices were designed as an interim measure and the existing notices will begin to permanently lapse in August 2013. The new legislation will provide a long-term and more effective solution as it will restrict the importation, manufacture and supply of all psychoactive substances by default, and only allow the sale of those that meet safety and manufacturing requirements. This means the Government will no longer have to demonstrate that a product is harmful before restricting it. The onus will be on manufacturers to demonstrate a product is low risk before it can be legally sold.
6. The Bill contains provisions to:
   
   a. Establish a regulatory authority within the Ministry of Health, with functions to:
      
      i. Consider and grant approvals for products,
      
      ii. Establish a code of practice for manufacturing standards,
      
      iii. Issue licences for importation, on-selling for the purpose of manufacture, and manufacture,
      
      iv. Carry out monitoring, recall, and audit functions;

   b. Establish an expert advisory committee to give technical advice to the regulator;

   c. Require importers and manufacturers of psychoactive substances to:
      
      i. Apply for a licence to carry out activities under the legislation,
      
      ii. Apply to the regulatory authority for approval before marketing a product,
      
      iii. Meet manufacturing standards,
      
      iv. Notify the regulatory authority of any adverse reactions associated with substances;

   d. Establish offences and penalties for: importing, manufacturing or selling without a licence, breaching a condition of a licence, possession of a substance that is not an approved product, sale and supply of an approved product to someone under 18 years of age, regulatory offences including for display and advertising, and failure to notify adverse reactions;

   e. Establish an appeals committee and process for appeals and disputes;

   f. Establish, through regulations: restrictions on purchase age, place of sale, free of charge distribution, advertising, labelling requirements, and warning labels;

   g. Establish a transitional provision to allow the continued sale of some psychoactive substances following enactment;

   h. Consequentially amend other legislation including:
      
      i. The Search and Surveillance Act 2012 to provide for the use of interception devices and trespass surveillance,
ii. The Misuse of Drugs Act to repeal the restricted substances and temporary class drug notices,

iii. The Hazard Substances (Minimum Degrees of Hazard) Regulations to ensure that controls under the Hazardous Substances and New Organisms Act 1996 apply when appropriate.

7. A bid for the Bill is included for the 2013 Legislation Programme, with a proposed priority 2 (to be passed in 2013).

Additions to Cabinet’s Policy Decisions

8. In the course of drafting, some additional provisions have been identified as being required. They are set out in attachment one, and summarised below.

   a. In addition to the offences and penalties agreed to by Cabinet [CAB Min (12)35/14], further offences and penalties for retail restrictions are proposed (consistent with the Misuse of Drugs Amendment Act 2005 and the Smokefree Environments Act 1990). These are for retail restrictions such as place of sale offences. I also propose strict penalties for failing to comply with a requirement to recall approved products and failing to notify adverse reactions.

   b. The draft bill contains two additional infringement offences. Firstly, I propose that supplying an approved product to someone under the age of 18 be an infringement offence. As there is a separate offence for free of charge distribution by retailers and manufacturers, this offence applies only to an individual supplying a minor an approved product. Secondly, I propose an infringement offence for the purchase of an approved product by someone under the age of 18. These activities are also offences under the Sale and Supply of Alcohol Act 2012 and the Smokefree Environments Act.

   c. Additional regulation-making powers are proposed. These are: to set the amount (up to a maximum of $500) for the three infringement offences; the form of the infringement notices; place of sale restrictions; and internet sale restrictions.

   d. I propose additional penalties for body corporates for the offences of manufacture and importation without a licence, and for supply and intent to supply a psychoactive substance that is not an approved product. This is consistent with other offences in the Bill that have separate penalties for individuals and companies.

   e. A regulatory provision is proposed to protect investment by industry in testing and the collection of data. This data protection provision is consistent with provisions for pharmaceuticals and agricultural chemicals.
Regulatory impact analysis

9. Regulatory impact statements were prepared for Cabinet policy consideration on 1 July and 1 October 2012 [CAB Min(12)35/14 and SOC Min(12)12/3 refer].

Compliance

10. The Bill is not inconsistent with:
   a. The principles of the Treaty of Waitangi
   c. The principles and guidelines set out in the Privacy Act 1993
   d. Relevant international standards and obligations

Consultation

11. The following departments and agencies have been consulted: the Ministry of Justice; New Zealand Police; New Zealand Customs Service; the Ministry for the Environment; the Environmental Protection Authority; the Ministry for Business, Innovation and Employment; the Treasury; the Ministry for Primary Industries; and the Ministry for Foreign Affairs and Trade. The Department of the Prime Minister and Cabinet has been informed.

12. Members of industry have also been consulted.

Binding on the Crown


Creating new agencies or amending law relating to existing agencies

14. The legislation does not create a new agency. A new regulatory authority will be established within the Ministry of Health.

Allocation of decision making powers

15. The Bill establishes the Psychoactive Substances Regulatory Authority and the Psychoactive Substances Appeals Committee and provides them with decision-making powers.

Associated regulations

17. The Bill will give the Governor-General the power, by Order in Council, to make regulations in order to prescribe the information required to grant licences and approve products, and prescribe restrictions on: place of sale, advertising, labelling, packaging, and other retail restrictions. The Governor-General will also be able to make regulations to set fees for licences and applications, and set the infringement fee (to a maximum of $500).

18. It is envisaged that the regulations will be around 30 clauses and of medium complexity. The regulations will be passed within six months of enactment.

Deemed regulations

19. The Bill gives the Regulator the power to establish a code of manufacturing practice, which must come into effect within a year after commencement.

Definition of Minister/department

20. Not applicable.

Commencement of legislation

21. The Bill will come into force by 13 August 2013. The legislation needs to be in force by 13 August because a number of the temporary class drug notices which prohibit the importation and sale of specified synthetic psychoactive substances will permanently lapse on that date.

Parliamentary Stages

22. It is proposed that the Bill should be introduced on 26 February 2013 and that the Bill be referred to the Health Committee for consideration.

Recommendations

23. I recommend that the Committee:

1. **Note** that a bid for the Psychoactive Substances Bill has been made in the 2013 Legislation Programme with a proposed priority 2 (to be passed in 2013).

2. **Note** that the Bill regulates currently unregulated psychoactive substances.

3. **Note** that during drafting provisions not previously agreed to by Cabinet were identified as being required [CAB Min(12)35/14 and SOC Min(12)12/3].
4. **Agree** to:

   i. additional offences and penalties for retail restrictions, and failure to comply with recall requirements and to notify adverse reactions,

   ii. infringement offences for supply of an approved product to a minor and purchase of an approved product by a minor,

   iii. additional regulation-making powers to set the infringement fee (to a maximum of $500), determine the form of the infringement notices, set place of sale and internet sale restrictions,

   iv. body corporate penalties for the offences of importation, manufacture, and supply without a licence,

   v. a data protection clause.

5. **Approve** the introduction of the Psychoactive Substances Bill, subject to final approval of the Government caucus.

6. **Agree** that the Psychoactive Substances Bill be introduced on 26 February 2013.

7. **Agree** that the Government propose that the Psychoactive Substances Bill be:

   i. Referred to the Health Committee for consideration, and

   ii. Be enacted by 13 August 2013.

---

Hon Peter Dunne  
**Associate Minister of Health**

---

Date:
## Attachment one – additional offences

<table>
<thead>
<tr>
<th>Offence relating to application for licence</th>
<th>Provides information in respect of an application for a licence that the person knows, or ought to have known, is false and misleading.</th>
<th>Term of imprisonment not exceeding 3 months; and/or Fine not exceeding $500,000</th>
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<tr>
<td>Offence relating to application for approval</td>
<td>Provides information that the person knows, or ought to have known is false or misleading; or Fails, without reasonable excuse, to provide any relevant information relating to - (i) The ingredients of the product; or (ii) The effect of the product on individuals using the product</td>
<td>Term of imprisonment not exceeding 3 months; and/or Fine not exceeding $500,000</td>
</tr>
<tr>
<td>Restrictions on selling approved products to persons under 18 years</td>
<td>Person sells an approved product to a person who is under the age of 18</td>
<td>Individual – fine not exceeding $5,000 Body corporate – fine not exceeding $10,000</td>
</tr>
<tr>
<td>Restriction on a person under 18 years purchasing an approved product</td>
<td>Person under 18 purchases an approved product</td>
<td>Infringement fine not exceeding $500.00</td>
</tr>
<tr>
<td>Restrictions on supplying approved products to persons under 18 years</td>
<td>A person supplies an approved product to a person under 18 years</td>
<td>Infringement fine not exceeding $500.00</td>
</tr>
<tr>
<td>Restriction on employing minors to sell approved products</td>
<td>A person employs a person under 18 years to sell an approved product on behalf of the person, whether at a place or by internet sale</td>
<td>Fine not exceeding $2,000</td>
</tr>
<tr>
<td>Restriction on place of sale or approved products</td>
<td>Person sells an approved product from a place that does not comply with the prescribed prohibition or restriction</td>
<td>Individual – fine not exceeding $5,000 Body corporate – fine not exceeding $10,000</td>
</tr>
<tr>
<td>Restrictions and requirements relating to Internet sales or approved products</td>
<td>Person offers an approved product for Internet sale in a way that does not comply with any prescribed restriction or prescribed requirement.</td>
<td>Individual – fine not exceeding $5,000 Body corporate – fine not exceeding $10,000</td>
</tr>
</tbody>
</table>
## Attachment one – additional offences

| Restriction on free of charge distribution and rewards of approved products | A manufacturer, importer, distributor, or retailer of an approved product:  
- Distributes an approved product free of charge;  
- Supplies an approved product to a person free of charge for subsequent distribution; or  
- in the case of a retailer, supplies an approved product to a person free of charge for the purpose of that retailer’s business  

A manufacture, importer, distributor or retailer of an approved product:  
- Offers any gift or cash rebate, or the right to participate in any contest, lottery, or game to the purchaser of an approved product in consideration for the purchase of that approved product; or  
- Offers, to any retailer, a gift or cash rebate, or the right to participate in any contest, lottery, or game, as an inducement or reward in relation to the purchase or sale of an approved product by that retailer, or the advertising or display of approved products inside that retailer’s place of business. | Individual – fine not exceeding $5,000  
Body corporate – fine not exceeding $10,000 |
|---|---|---|
| Restrictions and requirements relating to advertising approved products | Person advertises an approved product:  
- On television or on radio; or  
- In any newspaper or | Manufacturer or importer—fine not exceeding $50,000  
Any other person – a fine not exceeding $10,000 |
### Attachment one – additional offences

| Restrictions and requirements relating to labelling approved products | Person sells or supplies an approved product to which a prescribed restriction relating to labelling applies with a label that does not comply with the restriction | Individual – fine not exceeding $5,000  
Body corporate – fine not exceeding $10,000 |
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<tr>
<td>Person sells or supplies an approved product to which a prescribed requirement relating to labelling applies without a label that complies with the specified requirement.</td>
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| Restrictions and requirements relating to packaging approved products | Person sells or supplies an approved product, to which a prescribed restriction relating to packaging applies in a package that does not comply with that restriction. | Individual – fine not exceeding $5,000  
Body corporate – fine not exceeding $10,000 |
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<tr>
<td>Person sells or supplies an approved product to which a prescribed requirement relating to packaging applies which and the package does not comply with the specified requirement.</td>
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</table>
| Requirement relating to health warning | Person sells or supplies an approved product to which a prescribed requirement relating to a health warning applies without the necessary warning required to comply | Individual – fine not exceeding $5,000  
Body corporate – fine not exceeding $10,000 |
| Requirement to display signage | Person sells an approved product to which a prescribed requirement relating to signage applies without displaying the required signage to comply with the requirement | Fine not exceeding $2,000 |
| Restrictions and requirements relating to storage and disposal of psychoactive substances | An importer, manufacturer, or seller of a psychoactive substance to which a prescribed restriction or requirement relating to storage or disposal applies, stores or disposes of the substance in a way that does not comply with the restriction or requirement | Individual – fine not exceeding $5,000  
Body corporate – fine not exceeding $10,000 |
| Restrictions and requirements relating to storage and display of approved products | A person who sells or supplies an approved product to which a prescribed restriction or prescribed requirement relating to storage or display applies, stores or displays the product in a way that does not comply with the restriction or requirement. | Individual – fine not exceeding $5,000  
Body corporate – fine not exceeding $10,000 |
| Requirement to keep records relating to approved products | Person does not keep in some place of security any records required to be kept by an regulation | Individual – fine not exceeding $5,000  
Body corporate – fine not exceeding $10,000 |
| Prohibition on certain persons selling approved products | Person sales or manufactures in contravention of an order in place with restrictions on sale / manufacture | Fine not exceeding $50,000 |
## Attachment one – additional offences

<table>
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<tr>
<th>Recall Orders</th>
<th>Manufacturer, importer or retailer fails to act on a recall order</th>
<th>Retailer fine not exceeding $100,000</th>
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<td>Manufacturer or importer fine not exceeding $500,000</td>
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<tr>
<td>Duty to notify Authority about adverse reactions</td>
<td>A person who applied for approval and the licence holder fails to notify the authority, as soon as is reasonably practicable, of a serious adverse effect arising from the use of an approved product in NZ or overseas</td>
<td>Term of imprisonment not exceeding 3 months; and/or</td>
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<td>Fine not exceeding $500,000</td>
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Health report

Hon Peter Dunne (Associate Minister of Health)
cc Hon Tony Ryall (Minister of Health)
Cabinet paper for the new regulatory regime for psychoactive substances

Advice

1. This paper provides you with a Cabinet Paper to take to Cabinet Social Policy Committee (SOC) on 27 June 2012. It seeks your agreement to lodge the attached papers with Cabinet Office by 12pm on 22 June.

2. The Cabinet Paper contains proposals for the development of the new regime for psychoactive substances. These are consistent with proposals you considered in Health Report 20120689.

3. The Ministry has prepared a Regulatory Impact Statement, which is attached. This provides a problem definition, and considers options for where the new regulator should be established, border control, and the approval criteria.

4. The recommendations in the Cabinet Paper include:
   a. The establishment of a new regulator in the Ministry of Health;
   b. Full cost recovery through fees for licences and approval assessments, which would cover the costs of the regulator;
   c. Approval will be considered for manufactured products and will be informed by toxicological and behavioural data;
   d. Importation of active ingredients and manufactured products will be consistent with the importation requirements for medicines;
   e. Unapproved substances should be prohibited imports under the Customs and Excise Act 1996;
   f. Transitional provisions should be developed to allow the restricted sale of psychoactive substances whilst they undergo assessment by the regulator.

5. The Cabinet Paper recommends separate report backs to SOC by 1 October 2012 for the following areas:
   a. A detailed framework for all the offences and penalties required for both criminal activity and regulatory non-compliance;
   b. The options and recommendations for regulations for retail restrictions, including price control measures (excise or minimum price);
   c. The Ministry will provide you and the Minister of Finance with details of costs and fee-setting by 1 October, to include in the paper to SOC due the same date.

6. The Cabinet paper seeks authorisation for you to issue drafting instructions to the Parliamentary Counsel Office to give effect to the recommendations. The Ministry intends to start this process immediately. The issues due to be considered in separate report backs by 1 October will be incorporated into drafting following Cabinet's decisions. It is expected that the Bill will be ready for introduction by the end of 2012.

7. During the passage of the Bill, the Ministry will develop regulations to be made under the Bill, and undertake preparatory work to establish the regulator to ensure rapid implementation following enactment.
The Ministry recommends that you:

a) **Agree:** to lodge the attached Cabinet Paper and Regulatory Impact Statement with Cabinet Office by 12pm 22 June 2012.

---

**Ministry of Health contacts**

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<tr>
<th>Name</th>
<th>Position</th>
<th>Phone</th>
<th>Cellphone</th>
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<tr>
<td>Oliver Poppelwell</td>
<td>Manager, Sector and Services Policy</td>
<td>04 496 2158</td>
<td>Cellphone</td>
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<tr>
<td>Sara McFall</td>
<td>Senior Policy Analyst, Sector and Services Policy</td>
<td>04 816 4363</td>
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**Minister's feedback on quality of report**

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**END.**
Consultation on Cabinet and Cabinet Committee Submissions

Certification by Department:

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- The Ministry of Justice, New Zealand Customs Service, New Zealand Police, the Ministry for the Environment, the Environmental Protection Authority, the Ministry for Primary Industries, the Ministry of Consumer Affairs, Treasury, the Ministry of Economic Development

**Departments/agencies informed:** In addition to those listed above, the following departments/agencies have an interest in the submission and have been informed:
- The Department of Prime Minister and Cabinet

**Others consulted:** Other interested groups have been consulted as follows:
- Affected industry has been consulted at different stages of policy development

**Name, Title, Department:** Don Gray, Deputy Director-General, Ministry of Health

**Date:** 21/06/2012

Certification by Minister:

Ministers should be prepared to update and amplify the advice below when the submission is discussed at Cabinet/Cabinet committee.

**The attached proposal:**

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**Portfolio** | **Date** | **Signature**
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/ | / | /
In Confidence

Office of the Associate Minister of Health
Cabinet Social Policy Committee

REGULATION OF PSYCHOACTIVE SUBSTANCES

Proposal

1. I am asking Cabinet to agree to policy proposals for a new regulatory regime to control psychoactive substances such as party pills and legal cannabis-like products. Currently distributors of psychoactive substances are not required to establish the safety of their products before they may be legally sold. The new regime would reverse this and require pre-market safety testing before any substance could be imported or sold.

Executive Summary

2. On 29 August 2011, Cabinet Business Committee agreed in principle to the development of separate legislation for low-risk psychoactive substances (CBC (11)8/19 refers). I was invited to report back with policy proposals for this new regime by 30 June 2012. These proposals, if agreed to by Cabinet, will form the policy basis for new legislation for low-risk psychoactive substances and allow officials to work with the Parliamentary Counsel Office on the details of the new regime. I intend for the Bill to proceed to Select Committee in 2012.

3. Cabinet's decision formed part of the Government Response to the Law Commission report Controlling and Regulating Drugs: A review of the Misuse of Drugs Act 1975. The Law Commission conducted a first principles review of the Misuse of Drugs Act 1975 (MoDA) in response to concerns that sponsors of new psychoactive substances were not required to establish the safety of their products before they could be legally sold. The Law Commission recommended that "there should be a new regime with its own criteria and approval process for regulating new psychoactive substances." Cabinet considered the Law Commission's report and recommendations in August 2011 (CBC (11)8/19).

4. Drug legislation in New Zealand, and in other countries such as the UK, Australia and the USA, has proven to be ineffective in dealing with the rapid growth in synthetic psychoactive substances. Party pills and cannabis-like substances such as "Kronic" can be synthesised to be one step ahead of legislative controls. Each time the Government restricts one or more of these products, several more become available.

5. New Zealand and other jurisdictions have looked for a solution to this problem and found that bans, even the temporary class drug notices that provide for emergency restrictions, cannot keep up with the emergence of new psychoactive substances. Temporary class drug notices have given New Zealand a useful mechanism to deal with emerging substances, but the Government is still required to react to substances being marketed rather than stopping them being marketed in the first place.

6. I propose to address the problem by introducing new legislation to remove all psychoactive substances from the legal market and only allow the sale of those that have met testing requirements broadly similar to those required for new medicines. The sponsor of a psychoactive product would need to apply to a new regulator for approval
with credible scientific data showing that their product meets criteria of "low risk" before they may legally sell it. The sale of approved products would be subject to restrictions on matters such as purchase age, place of sale, advertising, labelling and packaging.

7. I am asking Cabinet to authorise drafting to begin for new legislation for a new regime including:
   a. the purpose and definition of the new regime
   b. the establishment of a new regulator within the Ministry of Health with provisions for cost recovery
   c. retail restrictions on approved products
   d. that pre-market safety testing be required for all psychoactive products
   e. importation, exportation and trade implications
   f. offences and penalties
   g. consequential amendments to the Misuse of Drugs Act
   h. transitional arrangements

Background

8. Currently, there is no mechanism to stop new psychoactive substances coming to market unless they are already scheduled in the MoDA as controlled drugs, or have a substantially similar chemical structure to a controlled drug. This problem first came to public attention with party pills containing benzylpiperazine (BZP) in the early 2000s. A 2007/8 survey found that 13.5% of New Zealanders aged 16 to 64 had tried BZP at least once whilst it was legally available. This compares to 46.4% and 6.2% for the illegal substances cannabis and ecstasy respectively. BZP was scheduled in the MoDA in 2008 but was immediately replaced by another unregulated substance.

9. These substances pose a risk to consumers because they have unknown short or longer term harms to health. The substances are marketed without any control over their ingredients, potency, or quality, and without a minimum purchase age.

10. There is demand for psychoactive substances. The annual turnover of the industry is estimated to be NZ $25 – NZ $35 million, depending on the type of products legally available at a given time.

11. The Government introduced temporary class drug notices in 2011 in response to legal cannabis-like products such as "Kronic" that were being widely sold in New Zealand. This provided a temporary emergency power to restrict psychoactive substances of concern. Twenty-four substances have been controlled by this power since August 2011. This approach still requires the Government to continually react to a fast changing market. Moreover, there is still a window of around two months where potentially harmful substances can be legally sold to the public while they are tested, and then potentially restricted. These bans were introduced as a temporary measure and the first notices will only be in effect until August 2013, at the latest.

12. To permanently schedule a drug in the MoDA, evidence of harm must be assessed by the Expert Advisory Committee on Drugs (EACD). However, most new substances do not have this evidence which means that research often needs to be commissioned before an accurate level of harm can be determined. In the case of BZP, this took six years.

13. These problems are not unique to New Zealand. Other countries such as the UK and Australia are looking for solutions to the same issues. No jurisdiction has found an
effective long-term solution and many are looking to New Zealand for a model for future legislation.

14. The Law Commission published an issues paper in February 2010 on options to address these problems and other issues arising from its review of the MoDA. The Law Commission consulted widely and received 3,800 submissions. Submitters were strongly in favour of a scheme that required those wishing to distribute psychoactive products to prove they were safe before they could be legally sold. In its final report, the Law Commission made 45 recommendations in relation to this new regulatory regime. I have taken these recommendations into account in the development of this paper.

Comment

15. A detailed problem definition and option analysis for the new legislation is considered in the attached Regulatory Impact Statement (RIS).

Purpose and definition

16. I propose new legislation to address the rapidly evolving market for legal psychoactive substances. The purpose of the legislation is to reduce risks to consumers by removing untested and potentially harmful products from legal sale. The legislation will introduce a pre-market approval scheme with testing requirements and retail restrictions for low risk psychoactive products.

17. Low risk will be determined through an assessment of toxicological and behavioural data by an expert technical committee. The assessment will take into account matters such as the likely harms to physical and mental health, the potential for dependence and withdrawal and societal implications, whether using the product might cause aggression.

18. This regime is does not consider or change the illegal status of controlled drugs under MoDA. Products which do not meet the low risk criteria will continue to be assessed by the EACD and scheduled in the MoDA as controlled drugs.

19. I propose that the definition of a psychoactive substance should be a substance which has the primary purpose of being administered or taken in order to induce a psychoactive effect. This would include all party pills and other legal highs. Psychoactive substances already controlled by existing legislation, such as alcohol and tobacco, would not be covered by this regime. The Ministry of Health will continue to work with other agencies to manage the interface between the new regime and other regulatory regimes around products containing substances such as caffeine and kava.

20. This definition should be broad enough to cover any substance imported, manufactured, or supplied for psychoactive effect, both natural and synthetic. However, it will be important to ensure that those substances which have psychoactive properties but are not generally used to induce a psychoactive effect are not captured by this legislation. Examples include some garden plants and industrial chemicals. The new regulator established by this regime should have the power to declare a substance to be a psychoactive substance for the purposes of the legislation in the event of a dispute about regulatory boundary issues. This is consistent with the approach taken in the Medicines Amendment Bill and the Natural Health Products Bill, and would prevent attempts to market a product in a way that avoids control. For example, psychoactive products have previously been marketed as incense and plant food.

21. I propose that each finished product will need an approval under the new regime, rather than the constituent active ingredients. This ensures that each combination of
ingredients and dose is assessed and allows for consideration of harms from the manner in which the product is taken, for example, harms associated with smoking plant material. This is in accordance with the Law Commission’s recommendations.

The regulator

22. I propose that a regulator is established within the Ministry of Health as the Law Commission recommended. On balance I consider that the Ministry of Health is the most appropriate agency given the proposed purpose of the legislation is to minimise harms to health. In the RIS, the Ministry of Health considered other options for the regulator, including the Ministry for Primary Industries and the Environmental Protection Authority. I consider that a regulator in the Ministry of Health is the most cost-effective and practical option.

23. The regulator would be responsible for managing the assessment process for new psychoactive products, issuing licences to import and manufacture, surveillance, auditing, and enforcement. There is opportunity for cost saving by sharing back office functions, such as administration and IT support, with the new natural health products regulator, while maintaining separate front office objectives and functions.

24. The Ministry, on current information, estimates that the regulator would cost a minimum of $1 million per annum. This is based on a staff of three full time equivalent employees (FTE), and overheads including a dedicated database. I propose that this be met through cost recovery. Fees need to cover the cost of all aspects of the regulatory process necessary to assess safety and quality before the product enters the market and safety monitoring after it is on the market. There are two options for cost recovery:

   a. Option 1: Full cost recovery (including set-up costs, which may need to be met up front by the Crown and recouped through fees), including enforcement activities.

   b. Option 2: Partial cost recovery (including set-up costs) but not charging industry for enforcement activity. Post-market safety activities including compliance, audit, and monitoring should be recovered, which is consistent with medicines regulation.

25. The Ministry recommends Option 1. Given the current tight fiscal constraints along with the fact that there is little public good, I agree that full cost recovery is the most appropriate approach. There are other areas of Government that are already fully cost recovered, particularly in the Ministry of Economic Development. These include the Companies Office, the Patents Office, and it is proposed Financial Markets Authority will be fully cost recovered. I propose that the Ministry of Health report to me and the Minister of Finance by 1 October 2012 with detailed proposals for costs and fee-setting.

26. It is proposed that the new legislation provides for the establishment of an expert technical committee to assist the regulator in decisions regarding approvals. The cost of this technical committee would be met through fees.

Approval of psychoactive products

27. I propose that a standardised process involving toxicological and behavioural data be required for all applications for approval of a product. My preference is not to have detailed requirements in primary legislation as it is important to have flexibility to update the required tests in response to scientific developments in this area. I propose that officials work with the Parliamentary Counsel Office to identify the best mechanism to establish these requirements.
28. It is my view that the minimum pre-clinical data required is acute toxicity, repeat dose toxicity, pharmacokinetics and genotoxicity. Where applicable, this data should be obtained using the route of administration that is intended for each product. This will account for the damage caused by more harmful routes of administration such as smoking. These tests are undertaken on small animals, such as rats and will take between 6 – 12 months to complete and report.

29. An expert technical committee would then assess the pre-clinical data to determine whether the product is of low enough risk for human clinical trials. These trials would look for harms to physical and mental health and signs of dependence, withdrawal or aggression in users. These trials would take around six months to complete and report.

30. The regulator would then be able to make a decision about a product based on data that documents its common short and longer term reactions. It will not be possible to screen for all adverse reactions to a product. This is because different people have different reactions to pharmacologically active substances. Individuals will therefore continue to assume some level of risk from the use of these products, but it will be a significant improvement on the status quo whereby products can be sold with no consideration of their potential harms.

31. The Ministry of Health consulted with experts in the field of pharmacology, toxicology, psychiatry, and emergency medicine on the proposed testing regime. The Ministry also consulted with members of industry. Feedback has been positive and both technical experts and industry representatives support this approach. Based on initial proposals, the Ministry estimates that the cost of this testing to the sponsor will be in the range of NZ $1 to $2 million per product and will take between one - two years.

32. It is difficult to predict the future size of this industry. However, I expect the initial number of applications for approval to be very low. Applications that contain a complete data package will likely take between one to two months to process.

*Import*

33. I propose that the requirements for the importation of active ingredients and finished products be consistent with the requirements for importing medicines. The importation of pharmaceutical active ingredients and bulk medicines is managed under the provisions of the Hazardous Substances and New Organisms Act 1996 (HSNO). There is an exemption under the Medicines Act 1981 for products in dose form. This means that medicines are controlled by the Medicines Act once they are in their finished form allowing for targeted provisions around retail and use.

34. I propose that the risks posed by bulk psychoactive products and their active ingredients used in the domestic manufacture of psychoactive products will continue to be managed under the provisions of the HSNO. This avoids the need for additional regulations and HSNO is fit for purpose to manage the risks associated with the importation, storage and transportation of bulk hazardous substances. Unapproved active ingredients would continue to be prohibited imports under HSNO and the Customs and Excise Act 1966. They may be seized at the border by New Zealand Customs Service. To prevent the misuse of active ingredients, importers will also be required to be licensed under the new legislation.

35. As with medicines, the importation of products in finished dose form would be regulated by dedicated legislation and exempted in the new legislation from the HSNO. Any risks associated with the finished products would be managed by the new regime. As with
medicines, the HSN0 life-cycle will end when the active ingredient is manufactured into a finished dose product, at which point the new regime will commence. In general, a finished product would only be cleared for import once it had successfully completed the assessment process and the new legislation would be the appropriate mechanism to manage this.

36. I propose that a licence be required to import small quantities of an unapproved finished product. These licenses should be issued for authorised testing purposes only. This requirement will prevent individuals from importing small quantities of psychoactive products for personal use. Individuals will not be able to circumvent the proposed safety tests by importing products from other jurisdictions they have purchased on the internet.

37. I propose that all unapproved substances be prohibited imports under the new legislation and the Customs and Excise Act. This gives Customs the power to seize any product which does not have evidence of approval under the new regime.

Trade issues

38. The Ministry is working through trade issues and implications for New Zealand, for instance export requirements and implications under the Trans-Tasman Mutual Recognition Act 1997 (TTMRA). The TTMRA establishes the obligation that a product that can legally be sold in one Australian State or Territory can be sold in New Zealand and vice versa, without requirements to meet any further standards or testing. This has implications in relation to New Zealand's proposal to regulate and approve psychoactive substances which are not currently regulated in either jurisdiction. There is provision under the TTMRA to prohibit imports under the Customs and Excise Act. If Cabinet agrees that unapproved substances should be prohibited imports under the Act, then no Australian products could be imported or sold unless approved by the New Zealand regulator. New Zealand approved products, however, could enter Australia under the TTMRA provisions. Australia may, in due course, establish similar regulatory scheme at which point it may be possible to apply trans-Tasman mutual recognition again.

39. The Ministry of Health has initiated discussions with officials in Australia to inform them of the New Zealand Government’s proposals. The Ministry will continue to work through these issues with Australian officials.

40. The World Trade Organization Agreement on Technical Barriers to Trade (TBT) aims to ensure that regulations do not create unnecessary obstacles whilst providing members with the right to implement measures to protect human health. In accordance with New Zealand’s obligations under the TBT, the Ministry of Health will notify the World Trade Organization of the pending regulations should Cabinet agreed to the proposals in this paper.

Retail restrictions including price controls

41. The Law Commission recommended regulation-making provisions for retail restrictions consistent with existing restrictions made by the Misuse of Drugs (Restricted Substances) Regulations 2008. These include:

a. minimum purchase age
b. advertising restrictions
c. restrictions on the type of outlets that are not permitted to sell approved products
d. display restrictions
e. labelling restriction such as requirements to list ingredients, health warnings, and the poison centre contact number
f. packaging, such as tamper-proof and child-proof packaging.

42. The Law Commission also proposed the investigation of price controls, including a possible excise, to regulate the retail price. This is consistent with New Zealand’s approach to the sale of tobacco and alcohol. The Ministry of Health is working with Customs, the Ministry of Economic Development, and Treasury on options for control, including a possible excise or a minimum price.

43. I propose that an analysis of options and recommendations for all retail restrictions, including price control measures, be reported back to SOC by 1 October 2012.

Offences and penalties

44. It is important to ensure that Police and Customs have adequate powers to address the illegal import, manufacturing, dealing, supply of, and intention to supply, unapproved substances, and any offending related to approved products. My intention is that offences and penalties are designed to prevent legislative loopholes and ensure a sufficient level of deterrence against offending. It will also be necessary to ensure compatibility with the powers under the Search and Surveillance Act 2012.

45. Agencies will continue to work together to develop an appropriate offence and penalty framework, and consider any consequential amendments required to provisions in other legislation such as the MoDA. The full details of all the necessary offences, penalties and enforcement powers for criminal offences and for regulatory non-compliance will be reported back to SOC by 1 October 2012. These will also be assessed for consistency with the New Zealand Bill of Rights Act 1990.

Transitional periods

46. I propose a transition period, including an amnesty, following enactment of the new legislation. During the transition period, a sponsor could only sell those products with an application pending approval by the regulator. This would only apply to those substances that had been legally sold six months prior to enactment provided there were no health concerns associated with these products. The regulator would have the power to recall any product of concern during the transition period. This arrangement would allow continuing but restricted access to some products, which I believe would be fair to legitimate industry.

47. The amnesty period would prevent industry and retailers being prosecuted whilst they adapted to the new regime. Following the transition period, only products which have been approved by the Regulator could be legally marketed and sold.

Consultation

48. The proposals in this paper have been developed in collaboration with the Ministry of Justice, the New Zealand Customs Service, and New Zealand Police and reflects their comments.

49. The Ministry for the Environment and the Environmental Protection Authority, the Ministry for Primary Industries, the Ministry of Consumer Affairs, the Treasury, and the Ministry of Economic Development have been consulted at different stages of policy development. This Cabinet paper incorporates their feedback.

50. The Department for Prime Minister and Cabinet has been informed.
Financial Implications

51. As noted above, the Ministry of Health estimates that the new regulator could cost a minimum of $1 million per annum. If you agree to full cost recovery there will be no implications for Vote: Health. If the preference is for partial cost recovery the difference will be met from within existing Health baselines. Any costs that are incurred in Health above the cost recovery will be met within the Departmental Output Class – Regulatory and Enforcement Services (M36).

52. It is anticipated that three FTE and a support IT system will be required. Health will meet the capital costs of the system and the operating costs will be recovered through the assessment applications and licences fees. The operating of the regime will be integrated with other like services where possible. It is likely that the number of applications will not be large, the Ministry will consider establishing a memorandum account to manage costs over time, and this will be addressed in the report back.

53. The Government will meet the costs of strategic policy development including the development of regulations. All other costs, including post market activities and enforcement will be met by way of fees imposed on industry. This will include set-up costs to be covered over time through a memorandum account.

54. At the time of this paper, detailed costs of both the establishment of the regulator and the required resources, and subsequent fee levels on industry are still to be determined. The Ministry will report back on these details to joint Ministers of Health and Finance by 1 October 2012, and this report back will be included in the paper due with SOC by the same date.

55. A number of affected industry members have been consulted on these proposals. In general, industry has signalled its support for this new regime as it will mandate all industry to meet consistent quality requirements and will provide a degree of market certainty. Most industry submitters are willing to pay the fees charged by the regulator and to fund the estimated $1 to $2 million of testing that will be required to establish the risk for each product. Some industry members caution that if the barriers to bringing a product to market are set too high, some producers may choose to distribute products outside of the proposed regime. If this happened it would be an offence and we could expect enforcement agencies to take action.

56. The final proposals are likely to result in costs and savings across the criminal justice sector. The magnitude of any impacts cannot be assessed until the proposals relating to offences, penalties and enforcement powers have been determined. This information will be provided in the report back to SOC by 1 October 2012. Other impacts, including to the court system, legal aid, and the Department for Corrections will also be determined once the offences, penalties, and enforcement powers have been finalised.

57. For Customs, there may be some savings as the new regime will ensure that all imports of psychoactive substances are accurately labelled and have the appropriate certification for legal entry into New Zealand. However, Customs considers that these are likely to be marginal. The potential scale and volume of illegal and legal imports is currently unknown. Customs would continue to investigate and act upon suspicious activity as part of their core business under the Customs and Excise Act. Customs will continue to enforce the controls on the importation of active ingredients under HSNO within its baseline. There may be future financial implications for Customs in the enforcement of import and export of finished manufactured products. Customs will monitor the costs of these activities and apply for additional funding to enforce these controls if necessary.
58. Police will be in a position to estimate the likely financial impact of enforcing the new regime once the details of the offences, penalties, and enforcement powers are finalised.

59. For the EPA, there will be minimal additional work over the long term. The EPA will be required to approve the activities and there may also be a need to ensure consistent toxicological data requirements and scientific assessment between HSNO and the new regime.

Human Rights

60. The proposals in this paper, which relate to the psychoactive substances approval regime (and not the offences and penalties framework), appear to be consistent with the New Zealand Bill of Rights Act 1990 (NZBORA) and the Human Rights Act 1993. The regime will not be retrospective.

61. Whether proposals relating to offences, penalties, and enforcement powers are consistent with the NZBORA will be assessed during the development stage and will be provided in the report back to SOC by 1 October 2012.

Legislative Implications

62. It is proposed that new legislation is drafted to give effect to the policy proposals in this paper. As part of the 2012 Legislation Programme, this Bill has been given a category four priority. This means it would be referred to Select Committee during 2012.

63. Twenty-four substances are currently controlled by temporary class drug notices. These last for 12 months and may only be renewed once. Some will need to be renewed in August 2012 and will then permanently expire in August 2013. New legislation will therefore need to be enacted prior to August 2013 to prevent these substances returning to the legal market.

64. If Cabinet agrees to the proposals, drafting will begin immediately on those recommendations agreed to. Once Cabinet has considered recommendations in the separate report back papers due by 1 October 2012, drafting will commence on these matters. I expect a Bill to be introduced by the end of 2012.

Regulatory Impact Analysis

Regulatory impact analysis requirements

65. The Regulatory Impact Analysis (RIA) requirements apply to the proposals in this paper and a Regulatory Impact Statement (RIS) has been prepared and is attached.

Quality of impact analysis

66. The Regulatory Impact Analysis Team at the Treasury has reviewed the RIS prepared by the Ministry of Health and considers that the information and analysis summarised in the RIS meets the quality assurance criteria.

Consistency with Government Statement on Regulation

67. I have considered the analysis and advice of my officials, as summarised in the attached RIS and I am satisfied that, aside from the risks, uncertainties, and caveats already noted in this Cabinet Paper, the regulatory proposals recommended in this paper:
a. are required in the public interest,
b. will deliver the highest net benefits of the practical options available, and
c. are consistent with our commitments in the Government statement "Better Regulation, Less Regulation".

Gender Implications

68. The proposals for a new regime have no specific gender implications.

Disability Perspective

69. The proposals have no implications for the New Zealand disability sector.

Publicity

70. This issue is likely to generate some media attention, although the public has been made aware of the need for this legislation. The Ministry of Health has developed a communication plan with my office to respond to any media queries or other publicity.

Recommendations

71. I recommend that the Committee:

1. **Note:** that on 29 August 2011, the Cabinet Business Committee agreed to consider the development of new legislation for low-risk psychoactive substances that would require approval by a regulator before any substance could be legally sold (CBC Min(11)8/19)

2. **Note:** that this legislation is required to address the problem of potentially harmful untested psychoactive substances being sold without controls over ingredients, purchase age, or place of sale

Policy recommendations

3. **Agree:** to establish a pre-market approval regulatory regime for new psychoactive substances, which are substances with the primary purpose of being administered or taken to induce a psychoactive effect

4. **Agree:** that approval will be considered for manufactured products rather than individual active ingredients and that approval of products will be informed by consistent toxicological and behavioural data

5. **Agree:** to the development of transition provisions following enactment to allow the sale of some psychoactive products whilst they undergo assessment by the regulator
Regulator

6. **Agree:** to establish a new regulator within the Ministry of Health to manage the assessments, approvals, licensing, and post-market surveillance of low-risk psychoactive products

7. **Agree:** that the regulator is funded through full cost recovery

8. **Note:** that the regime is expected to cost operating expenses of $1 million per annum, in Departmental Output class- Regulatory and Enforcement Services, which will be fully or partially met through an increase in third party revenue, and that the Ministry will report back on actual costs and recoveries to the Ministers of Health and Finance by 1 October 2012

9. **Delegate:** to joint Ministers of Health and Finance, to approve changes to Output classes bases based on the final decisions on recovery and licences/ application fees.

Importation and trade

10. **Agree:** that the importation of active ingredients and finished products should be consistent with the requirements for medicines and pharmaceutical active ingredients: active ingredients will be imported under the Hazardous Substances and New Organisms Act 1996, and finished products will be regulated under the new legislation

11. **Agree:** that the importation of unapproved ingredients and finished products will be prohibited without a licence issued by the new regulator and that all unapproved substances should be prohibited imports under the Customs and Excise Act 1996

12. **Note:** that the Ministry of Health is considering trade and export issues and has initiated discussion with Australian officials and will continue to work with them regarding Trans-Tasman Mutual Recognition Act implications and the intention to make unapproved substances prohibited imports under the Customs and Excise Act

Report backs

13. **Agree:** that the Ministry will report back to the Ministers of Health and Finance on detailed costs and fee-setting by 1 October 2012, and I will report back to SOC by this date

14. **Agree:** that I will report back to SOC with the offences, penalties, enforcement powers, and any required consequential amendments by 1 October 2012.

15. **Agree:** that I will report back to SOC by 1 October 2012 with options and recommendations for retail restrictions including price control measures

Legislative implementation

16. **Agree:** that, as part of good regulatory practice, there will be a policy review of the regulatory scheme five years after commencement

17. **Note:** that, as part of the 2012 Legislation Programme, Cabinet has previously agreed to a Misuse of Drugs Amendment Bill to implement the new psychoactive substances regime, with a priority four (to be referred to Select Committee in 2012)
18. **Authorise:** the Associate Minister of Health to issue drafting instructions to the Parliamentary Counsel Office to give effect to the recommendations.
Regulatory Impact Statement

New regulatory regime for psychoactive substances

Agency Disclosure Statement

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

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

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

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

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

Don Gray
Deputy Director-General
Policy Business Unit
Introduction – the Law Commission Review and Government Response

1. In July 2007, the Government invited the Law Commission to review the Misuse of Drugs Act 1975 (the Act) in response to concerns that sponsors of new psychoactive substances were not required to establish the safety of such products before they could be legally sold.

2. The Law Commission carried out a first principles review with a mandate to make proposals for a new legislative regime consistent with New Zealand's international obligations under the United Nations drug conventions and taking account of a range of issues and concerns about the Act. In February 2010, the Law Commission published an Issues Paper providing a detailed discussion of the problems with the current legislation and proposing options to address these problems. The Law Commission conducted targeted and public consultation and received 3,800 submissions on the Issues Paper. On 3 May 2011, the final report of the Law Commission was tabled in the House.

3. In relation to the issue of the sale of new psychoactive substances, the Law Commission identified two inter-related problems with the status quo. Firstly, potentially harmful psychoactive substances are available with little or no control over their ingredients, dose, place of sale, and purchase age. Secondly, the onus is on the Government to identify that these substances are available, and then to determine whether they are harmful before placing restrictions upon them.

4. In its final report, the Law Commission recommended a regime that would require sponsors of psychoactive products to demonstrate that products do not pose an undue risk of harm before they are marketed. This recommendation and alternative options for addressing the problems identified by the Law Commission were analysed in the RIS which accompanied the Government Response to the Law Commission recommendations.¹

5. On 8 September 2011, the Government Response to the Law Commission recommendations was tabled in the House. In the response, the Government agreed to consider the development of legislation for psychoactive substances posing a low risk of harm, which may require the supplier or manufacturer to apply to a regulator for approval or otherwise demonstrate that it meets required standards before substances can be manufactured, imported or distributed, subject to regulatory impact analysis (CAB Min CBC/ (11)59/CBC(11) 8/19).

Status quo

Prevalence of psychoactive substance use and population profile of users

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

7. The Ministry has collated data available on the use of "legal highs" in order to build a picture of the user, estimate the potential scale of use, and the potential impact on the health system associated with their use. There is no current prevalence data for party pills and other legal highs. The most complete information available relates to BZP which was legally-available until October 2008. BZP is a stimulant and information about its use may not be comparable with other products, such as legally-available synthetic cannabinomimetic products.

8. National survey data is available from the New Zealand Drug Use Survey 2007/08, which reports on the prevalence of use of illegal and other drugs for 16-64 year olds. Lifetime use of BZP, which was still legally available at the time of the survey, was reported at 13.5%, and past year use at 5.6%. This compares to illegal stimulant use: 7.2% lifetime use of amphetamines and 2.1% past year use, and 3.6% lifetime use of cocaine and 0.6% past year use. BZP users were significantly more likely to be male than female and were predominantly aged between 18-34. Users were more likely to be Māori.

9. The Ministry has also reviewed publicly funded hospital discharge data from the National Minimum Dataset (NMDS) from 1 July 2008 until 30 June 2011 (prior to the first TCDDN). This includes information on BZP while it was legal, and synthetic cannabinomimetic substances. Although there are no specific diagnosis codes for legal highs or BZP, it is possible to extract free text diagnosis descriptions from discharge data. Using the encrypted form of National Health Index (NHI) identifier, the Ministry linked this discharge data with demographic data (age, gender, ethnicity, NZDep 2006 quintile), emergency department attendance data, and information on secondary mental health and addiction service use. This resulting linked dataset allows the Ministry to build a profile of the people most at risk of harm from drug use – in effect using hospitalisation as a proxy for a certain level of severity.

10. The introduction of a district health board performance measure in the 2008/09 year encouraged greater use of free text for discharge diagnosis and procedure descriptions in the NMDS. This means that the data for the period July 2009-June 2011 is more detailed for the purposes of comparison. During this period, there were 37 people with hospital discharges involving legal highs, compared to 3161 for cannabis, and 808 for stimulants. Compared to people with hospital discharges involving cannabis use, legal high users were younger (median age 23, compared to 30 for cannabis users), were less likely to be Māori (41% compared to 51% of cannabis users) and less likely to be living in an area of high deprivation (NZDep 2006 quintile 5) (27% compared to 40% for cannabis users).

11. Health service use data from the linked dataset gives some indication of the general health status of legal high users. Caution is required with the interpretation of these data as there may be no direct relationship between health service use and a person's drug use. It would appear that legal high users have similar numbers of visits to emergency departments (the reason for the visit is not recorded) to cannabis users, and a similar percentage of people have had contact with secondary alcohol and drug teams. A greater percentage of users of stimulants and opioids have had contact with secondary alcohol and drug teams and these users had a higher number of visits to emergency departments than users of legal highs.
12. Out of the 37 people with hospital discharges involving legal highs in the two-year period examined, eight had no indication of any other drug use in the hospital discharge data for this period (22 percent). The remaining 29 people did have indications of cannabis or other drug use in the same period.

Nature of the market

13. There is no comprehensive information on the size of the market in New Zealand. With the introduction of the TCDN in August 2011, the legal market changed as a number of products were removed from it. The Ministry has made some estimations based on the BZP market prior to its scheduling in the MoDA in 2008 and on the height of the market prior to the TCDN.

14. It is estimated that 20 million pills containing BZP were sold in New Zealand in the period between 2001 and 2006. This resulted in turnover of around NZS$25-$35 million per year at the height of their popularity. Comparable data on the size of the market for legal cannabis-like products in New Zealand is not available. However, the Ministry considers that the market for these two types of product in New Zealand is broadly comparable.

15. The Ministry estimates that at the height of each of these substance’s availability there would have been between 80 and 120 products available. The types of products that have been sold include capsules/pills, bags of pure chemical powders, bags of powders containing chemicals mixed with excipients, and both natural and synthetic smoking products.

16. There are approximately 10 major importers and/or manufacturers of these products in New Zealand and potentially a further 10 smaller businesses supplying their local markets. Domestic manufacturing capability exists in New Zealand and a large proportion of the tablets, capsules, and smoking products on the market in New Zealand would have been locally manufactured using imported active ingredients.

17. We estimate that at least 1000 retailers traded in legal cannabis-like products at the height of their availability in 2011. This is greater than the number of retailers that traded in BZP products at the height of their legal availability in 2008. This may be as a result of the different type of product, or it may demonstrate a shift towards more aggressive marketing practices by industry.

18. The types of retailers that have traded in these products include specialist stores, adult stores, on-line suppliers, clothing stores, and smaller community-based businesses such as dairies. The Ministry understands that the greatest volume of these products was sold through specialty stores but that this type of store made up only a small proportion of retailers in New Zealand. The Ministry estimates that the market consisted of roughly 20 specialty shops, 30 adult stores, 5 major internet based retailers, and as many as 1000 dairies.

Current Regulatory environment

19. The current mechanisms for dealing with psychoactive substances are:

   a) New Zealand has ratified three United Nations (UN) drug conventions that require New Zealand to make the cultivation, distribution, and possession of drugs listed in the conventions’ schedules a criminal offence. New Zealand meets its international obligations by scheduling drugs in the Act.
The Act prohibits the importation, manufacture, cultivation, possession and supply of substances listed in the Act's schedules. Exemptions are in place to allow the medical use of certain controlled drugs. The Act classifies controlled drugs in three schedules according to the risk of harm from each substance: Class A substances are considered to pose a very high risk of harm, Class B a high risk of harm and Class C a moderate risk of harm. The schedules determine the maximum penalties for offences against the Act and determine certain enforcement powers and provisions such as prescribing rights.

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

b) The analogue provisions of the Act state that substances with molecules structurally similar to those of controlled drugs are analogues of these drugs and automatically considered Class C controlled drugs.

c) The EACD can advise the Minister to classify substances assessed as posing less than a moderate risk of harm, under the restricted substances schedule of the Misuse of Drugs Amendment Act 2005 (MODAA 2005). The MODAA 2005 makes provision for the regulated sale of psychoactive substances. There are currently no restricted substances listed in the MODAA 2005.

d) The Smoke-free Environments Act 1990 prohibits the sale of herbal smoking products, such as synthetic cannabimimetic substances, to people under the age of 18.

e) The Temporary Class Drug Notices (TCDN) introduced by the Misuse of Drugs Amendment Act 2011 provide an emergency mechanism to prohibit for a twelve month period the importation, manufacture, sale and supply of substances listed by a notice in the Gazette. These may be extended once for an additional twelve months.

20. In August 2012, the Government agreed to the development of proposals for new legislation which would require that low-risk psychoactive products be approved by a regulator before they can be sold.

Problem definition

21. There is no mechanism to prevent psychoactive substances not already scheduled in the Act as controlled drugs or structurally similar analogues from being sold. The current system relies upon Government identifying that a substance is being sold and then reacting accordingly.

22. The EACD is tasked with providing evidence-based assessments and recommendations to the Minister. However, for many of the emerging substances such as legally-available party pills, there are delays while evidence is collated or research is commissioned before the appropriate level
of harm can be determined and recommendations made to the Minister. This means that substances which could eventually be found to cause moderate or even high levels of harm could remain uncontrolled until such time as adequate evidence is available.

23. GHB (fantasy) was identified as a popular party drug in 2000. Between 2000, when it was assessed by the EACD and its eventual scheduling in the Act in 2002, Auckland Hospital reported over thirty admissions and one death associated with GHB misuse.

24. This system differs from the system in place for food, alcohol, medicines, and hazardous substances. In the case of medicines, there are significant requirements on the pharmaceutical industry to demonstrate the safety of their products before they are approved for use. In the case of alcohol, no alcoholic products can be sold without a licence and there are a number of restrictions around purchase age, advertising, pricing controls, and manufacturing standards.

25. There is no requirement for manufacturers or distributors of psychoactive products to provide any consumer information about contents, dose, or potency. There are no manufacturing standards or safety requirements for products. Unlike medicines, there are no requirements around labelling, ingredients, dose, potential side-effects and/or drug interactions. Unlike tobacco, there are no requirements for health warnings.

26. The legal status of psychoactive substances is ambiguous and can change rapidly. This affects users, retailers, manufacturers, and importers and gives industry no market certainty and little incentive to invest in safety testing and labelling. There is ambiguity at the New Zealand border with some shipments being held by Customs for testing and importers not using existing provisions of the Hazardous Substances and New Organisms Act 1996.

27. To address these problems, the Government has agreed to the development of proposals for a regime that requires low-risk psychoactive products must be approved by a regulator before they can be sold. Currently, there is no accepted definition of low-risk that can be used to set the bar for approvals. The criteria for classifications in the Misuse of Drugs Act are intended to determine moderate, high, and very high risk of harm to individuals and society. The criteria are very broad and rely on the EACD’s technical judgement which cannot always be informed by scientific data given the novel nature of the substances being considered. The Ministry therefore does not consider the criteria in the Misuse of Drugs Act to be suitable for this approval process.

28. There is also no accepted definition of a psychoactive substance. Psychoactive is a broad term which applies to a substance that “affects the mind” and could therefore include many common products, including a number of foods and plants. Certain psychoactive substances are already regulated under existing legislation, such as some caffeine products, alcohol, and tobacco. The interface between the new regime and existing regulatory regimes will require the development of a clear definition of psychoactive substance.
Objectives

29. The primary objective of the proposed legislation is to develop a regime capable of dealing with the rapidly evolving market in psychoactive substances, balancing the risk of harm to individuals and society with the demand for access to such substances.

30. The regime should:

- provide a mechanism for effectively regulating psychoactive substances before they reach the market,
- provide public confidence about the risk profile of the psychoactive products legally available for sale,
- place controls on the availability of psychoactive products, including purchase age and place of sale,
- provide information for consumers on product contents, dose and potency,
- provide certainty on the status of psychoactive substances, reducing the risk that people will seek them through the black market, and giving the industry long-term financial confidence,
- provide an equitable process that does not disadvantage one segment of the market over another by imposing onerous requirements on either import or domestic manufacture
- establish an enduring regime to replace interim measures, analogue and restricted substances provisions.

Regulatory Impact Analysis

31. The Regulatory Impact Statement prepared for the Cabinet Paper to agree the Government Response considered four options for addressing the two problems identified by the Law Commission. The option agreed to by the Government was to introduce a regime that would require sponsors of psychoactive substances (importers or manufacturers) to demonstrate that products they wish to market do not pose an undue risk of harm and apply for a pre-market approval from a regulator.

32. As recommended by the Law Commission, the definition of psychoactive substance should be those substances taken for the primary purpose of inducing a psychoactive effect. The Ministry does not think this should be limited to synthetic products as this could create a loophole and distort the market leading to the sale of potentially harmful psychoactive plants. Psychoactive substances already controlled by existing legislation, such as alcohol and tobacco, should be excluded from this regime. Other substances that have a psychoactive effect, but are not used primarily to induce this effect, such as industrial chemicals, garden plants, and some foods should be excluded through the definition. There may still be some interface issues at the boundary between legislative provisions, and we consider there should be a declaring power for the regulator to declare something to be a psychoactive substance for the purposes of the new regime. This is consistent with the Natural Health Products Bill and the Medicines Amendment Bill which contain a regulatory power to declare. This would address an attempt to market a product with psychoactive properties in such a way as to avoid control. For example, products have previously been marketed as incense or plant food.
33. This Regulatory Impact Analysis considers the proposed model and other options for how the regime might work. It covers the following issues:

- What the criteria for approval should be and what evidence would be required to meet approval standards (Part A)
- What the appropriate regulatory vehicle should be (Part B)
- What the process should be for the importation of psychoactive substances (Part C)

34. This paper also describes issues which the Ministry is still working on, namely:

- Offences and penalties (Part D)
- What the retail restrictions should be for approved products (Part E)
- Trade issues (Part F)
Part A - Approval criteria

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

The Law Commission recommendations

35. In its final report on the Misuse of Drugs Act, the Law Commission recommended criteria against which psychoactive substances could be assessed. These are:

1. the nature of the harms and benefits of the product,
2. whether the harms can be effectively managed through regulation,
3. likely consequences of regulation compared to prohibition,
4. potential displacement issues.

36. The first criterion is intended to encompass an assessment of the composition, pharmacology, and toxicology of the product. The other criteria relate to the potential impacts of regulation. The Law Commission did not make any recommendations on the types of evidence and data required to adequately assess products submitted to the regulator.

37. There are options for the stage at which an approval would take place. Firstly, the regulator could approve each active ingredient. Secondly, the regulator could approve the finished manufactured product which may contain more than one active ingredient.

38. The Law Commission recommended that it should be the final manufactured products that are given approval. The Ministry agrees with this approach as it will ensure that each combination of active ingredients is assessed for drug interactions, that a final approved dose per product can be set, and that the manner in which the product is meant to be administered can be considered. This approach will also provide industry with some protection over intellectual property as each product would have trade mark protection, whereas approval based on the active ingredient would result in that substance being available for sale by any manufacturer or retailer.

39. We think there is a strong enough argument to proceed on the basis that applications should be made for finished products and not substances. We have structured our analysis below accordingly.

Objectives:

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

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

Options

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

<table>
<thead>
<tr>
<th>CRITERIA</th>
<th>Self-certification</th>
<th>Assessment by the regulator of toxicological and behavioural data</th>
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<tbody>
<tr>
<td>Valid</td>
<td>×</td>
<td>✓</td>
</tr>
<tr>
<td>Transparent/objective</td>
<td>partial</td>
<td>✓</td>
</tr>
<tr>
<td>Minimise unintended consequences</td>
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<td>partial</td>
</tr>
<tr>
<td>Minimise harms</td>
<td>×</td>
<td>✓</td>
</tr>
<tr>
<td>Efficient</td>
<td>✓</td>
<td>partial</td>
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</table>

Self-certification

41. A self-certification system would operate in a similar way to the proposed system for registering natural health products, such as vitamins and health supplements. This requires sponsors to self-certify on an on-line database before marketing a product. The database has a list of permitted ingredients and a list of prohibited ingredients.

42. If a sponsor wishes to use a new ingredient, not on the permitted list, they would notify the regulator who would have the option to assess the ingredient for its safety.

Impact on industry

43. A system similar to this approach would have low compliance costs for industry as sponsors would complete an on-line form and be expected to provide evidence regarding the products if required. Requirements could include that all active ingredients are listed, in addition to the likely effects and side-effects. This would be quick, straightforward, and cheap. The cost estimates for notifications of natural health products are around $100 per product.

44. However, unlike natural health products, most of which have a long history of use with little evidence of adverse health effects, the new regime will apply to new substances with little or no history of use. This option would be efficient but would not give the public confidence that approved products had been robustly assessed for toxicity. Accordingly, we do not believe that self-
certification can meet the primary objective of effectiveness and the Ministry does not support this option.

Assessment by the regulator of toxicological and behavioural data

45. This option would require consistent toxicological and human clinical trial data for each product submitted for approval. The regulator would then examine the dataset for each product and make a determination as to whether it meets the criteria of low risk. This is broadly similar to the approval process for new medicines but without the requirement for a product’s sponsor to establish the product’s efficacy.

46. A separate application would be required for each product (that is any variation in name, dose, or identifier such as flavour would require a new application), although an application would be able to specify that a product is “based on a parent product”.

47. At the minimum we think that data should be required on acute toxicity, repeat dose toxicity, genotoxicity, and observations from human clinical trials. We are also considering whether requirements for carcinogenicity and developmental toxicity testing will deliver enough additional benefit to be justified. These extra tests would provide greater clarity about the risks of a substance, but would significantly increase the costs to industry and the time required to bring a product to market.

48. Industry and scientific experts have been consulted on the testing requirements that we propose. Both of these groups support the validity of this approach as a way of measuring the harm of a psychoactive product.

Impact on industry

49. The option of self-certification would have a significantly smaller impact on the industry than requiring toxicological and behavioural data. However, we do not believe that self-certification will be able to protect the public from harmful products.

50. For this reason, we propose a requirement that the industry obtain toxicological and behavioural data for each product seeking approval. The cost of this is difficult to quantify until the nature of the testing requirements has been confirmed. However, based on our initial proposals we estimate that this testing could cost in the range of NZ $1 million to NZ $2 million per product. This does not include the cost of product discovery, manufacturing or protection of intellectual property. We have consulted with the industry on this and almost all manufacturers that responded to our discussion document support this approach and are willing to fund this testing.

51. The Ministry also understands that one company is considering initiating testing now with the knowledge that the regime is still only at the stage of policy development.
Impact on the public

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

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

Objectives:

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

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

<table>
<thead>
<tr>
<th>CRITERIA</th>
<th>Stand-alone regulator</th>
<th>MPI²</th>
<th>EPA³</th>
<th>Medsafe</th>
<th>MOH⁴</th>
<th>Minister of Health</th>
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<tr>
<td>Independence</td>
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<td>✓</td>
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<tr>
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<tr>
<td>Suitability</td>
<td>✓</td>
<td>✗</td>
<td>✗</td>
<td>✗</td>
<td>✓</td>
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Option one - a new stand-alone agency

53. A new stand-alone agency could be established to act as the regulator with administrative functions and scientific expertise for the assessment of products submitted to the regulator.

54. A stand-alone regulator would provide a clear point of contact for queries from the industry and the public. In addition, this option would also be considered the most independent by public and industry. As it would be purpose-built, it would meet the suitability objective.

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² The Ministry for Primary Industries  
³ The Environmental Protection Authority  
⁴ The Ministry of Health
55. The Ministry does not consider a new stand-alone agency would be justified in light of the estimated annual number of applications for approval. The Ministry estimates that in the first two years at least, the regulator would be considering fewer than 10 products. It would also not be consistent with the government commitment to provide value for money and minimise unnecessary administration.

Option two - Ministry for Primary Industries

56. Establishing a regulator for psychoactive substances within the Ministry for Primary Industries (MPI), which administers food legislation and standards, was not an option that was considered by the Law Commission. However, MPI regulates some products which have psychoactive effects, most notably food containing caffeine, and so the Ministry has considered it as an option for the regulator.

57. There are already provisions in place in the Australia New Zealand Food Standards Code for the assessment of novel foods which could have psychoactive properties. Food Standards Australia New Zealand (FSANZ) is the trans-Tasman agency responsible for the development of food labelling and composition standards, including the assessment of ‘novel foods’ (foods without a history safe use in Australia or New Zealand). MPI participates in the FSANZ assessment and provides advice on New Zealand’s position in relation to food safety issues. Decision-making on approvals for novel foods is carried out by Ministers from New Zealand and the Australian States and Territories.

58. The Ministry considers there are more appropriate options than the MPI for the new regulator. The approval process for psychoactive products is likely to be closer to medicines than novel foods. Moreover, FSANZ which carries out the novel food pre-market assessments is an Australia public service agency (though jointly funded by Australia and New Zealand) and may not be a suitable to regulate New Zealand’s regime for psychoactive substances.

Option three - Environmental Protection Authority

59. The Law Commission considered whether the regulator for the new regime should be the Environmental Protection Authority (EPA) which implements the Hazardous Substances and New Organisms Act 1996 (HSNO), and other environmental legislation.

60. The EPA operates a pre-approval regime under the HSNO to manage the safe importation, manufacture, transportation, and use of hazardous substances. These are substances that meet defined minimum degrees of hazard criteria, including toxicity and corrosivity. All hazardous substances require an approval under the HSNO unless otherwise exempt such as finished dose medicines.

61. The raw materials meeting minimum degrees of hazard used in the manufacture of psychoactive products, including the active ingredients and the incipients, will require HSNO approval. The excipients which are the binders and bulking agents used to flavour, colour or for consistency, are likely to be used in the manufacture of other substances and may already have HSNO approval. Consequently, and irrespective of the option agreed to, the EPA will have a role in the regulatory process for psychoactive substances.
62. The EPA's role could be extended to administer the whole process for approving and managing psychoactive substances, including active ingredients and the finished product. Enforcement would probably need to be carried out by other agencies, including the Ministry of Health, Customs, and Department of Labour, as is currently the case for hazardous substances enforcement.

63. The Ministry does not consider the EPA to be the best fit for the new regulator. The mandate of the EPA is environmental protection, and psychoactive substances would have no environmental impact. When assessing the risks to people from hazardous substances, the EPA generally only assesses unintentional or inadvertent exposure, rather than intentional consumption (cosmetic products and tattoo inks are the exception). Drugs, principally medicines, are only regulated by the EPA when they are bulk pharmaceutical active ingredients and not in a manufactured dose form. From the point of manufacture to retail and end-use, regulation is managed by Medsafe.

Option four - the Ministry of Health

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

65. The new regulator for psychoactive products could either be part of Medsafe which is a business unit of the Ministry of Health responsible for the regulation of therapeutic products, or within another unit of the Ministry.

Medsafe

66. The benefit of Medsafe being the regulator is that it already operates a pre-approval regime for new medicines and post-market surveillance for approved medicines. There would be potential savings in sharing administrative functions. Staff are familiar with toxicology data packages, licensing, and retail restrictions.

67. The limitation with Medsafe being the new regulator is the lack of fit as the focus of the new regime is to regulate recreational substances with no therapeutic purpose. Furthermore, the development of the trans-Tasman regulator, Australia New Zealand Therapeutic Products Authority (ANZTPA), would have implications for Medsafe's capacity to regulate psychoactive products which would be outside the scope of ANZTPA.

Ministry of Health

68. There are other areas of the Ministry where the new regulator might more comfortably sit. For instance, the Natural Health Products Bill establishes a new regulator, to be administered by the Ministry of Health. The regulator would operate a pre-market notification database for natural health products, administer lists of permitted and prohibited ingredients, and conduct safety assessments as required for new ingredients. There will be auditing and
surveillance, in addition to enforcement activities. There is potential for back-office administrative functions for the psychoactive substances regime to be shared with the proposed regulator for natural health products.

69. The Ministry funds and manages Public Health Units in each District Health Board area. These units have enforcement responsibilities through the Health Protection Officers which carry out controlled purchase operations around the retail of alcohol and tobacco. There are also monitoring and compliance investigators employed within the Ministry. The Ministry of Health is also an enforcement agency for the HSNO.

70. The advantage of the regulator being in the Ministry of Health would be to provide a link between the approval of products and monitoring and enforcement. The Ministry administers the MoDA which schedules drugs considered to pose a moderate to very high risk of harm, and is secretariat for the expert committee which assesses them. This would provide an easy conduit to refer unapproved substances which are found to pose more than a low risk of harm to the Expert Advisory Committee on Drugs for assessment.

Option 5 – the Minister of Health

71. In the case of medicines, the final decision regarding the approval of new medicines lies with the Minister of Health. There is a precedent for Ministers to issue approvals on matters relating to public safety. The Minister of Health is also empowered to issue Temporary Class Drug Notices to prohibit psychoactive substances for a period of up to 12 months.

72. The Law Commission considered that decision-making around drugs has the tendency to become highly politicised and that the Minister of Health might not be seen as independent or objective in the approval process. The Minister may also wish to keep a certain distance from the process to avoid any sense that a product has ministerial endorsement.

Impact analysis

Costs of the regulator

73. At this stage, it is not possible to be clear about the cost of establishing and running the regulator, as there is no information on the likely demand for the regulatory activities. The Ministry of Health’s preliminary estimate is that it could cost $1.00 million at a minimum per annum. This is based on an estimated three FTE and overheads, such as a dedicated database. However the Ministry has identified a number of cost saving or funding measures that could be used in the first two years until we know the scale of the market.

74. The regulator will need to be funded for the following outputs:
   a. regulatory advice,
   b. standards setting,
   c. import/export licences,
   d. compliance, audit, licensing manufacturers, and monitoring,
   e. enforcement.
Fee setting

75. Marketing psychoactive products is a commercial activity and the Ministry considers it appropriate that fees are charged to fund the activities of the regulator.

76. Fees need to cover the cost of all aspects of regulatory process necessary to assess safety and quality before the product enters the market and safety monitoring after it is on the market.

77. Option 1: Full cost recovery (including set up costs, which may need to be met up front by the Crown and recouped through fees), including regulatory advice and enforcement activities.

78. Option 2: Cost recovery (including set up costs) but not charging industry for enforcement activity. However, it must cover the cost of post-market safety activities including compliance, audit, and monitoring.

79. Each element of the regulatory function can be met by companies via a fee for service. Because we currently do not know exactly what, and how many products are likely to apply for approval to sell, the fee should be based on a conservative estimate of the number of approvals. A funding review would be undertaken after three years to determine whether the fees charged matched the actual costs of providing the regulatory services.

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

Examples of similar regulatory functions:

<table>
<thead>
<tr>
<th></th>
<th>EPA</th>
<th>Medsafe</th>
<th>New Regulator</th>
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<tbody>
<tr>
<td>Functions required</td>
<td>Admin, Toxicology, risk assessment and decision making</td>
<td>Admin, Toxicology Secretariat for technical committees</td>
<td>Admin, Toxicology Secretariat for technical committee (initially piggy back off Natural Health Products and or expertise at Medsafe)</td>
</tr>
<tr>
<td>IT requirements</td>
<td>Database/Word/CRM/EDRMS</td>
<td>Database</td>
<td>Clone Medsafe database</td>
</tr>
<tr>
<td>Approvals received per annum</td>
<td>130 – 170. In 2010/11 EPA carried out six full assessments which each took on average 220 hours to complete</td>
<td>200 of which 40 brand new medicines which require pre-clinical data</td>
<td>Unknown but expected to be fewer than 10</td>
</tr>
<tr>
<td>Approval Fees</td>
<td>$17,250 per substance – hourly rate of $115 can be charged for new high risk substances that require</td>
<td>$88 000 (high risk medicine containing new active</td>
<td>Unknown and to be reviewed after three years. Expected to be in</td>
</tr>
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</table>
80. Because we currently do not know exactly how many products are likely to request approval, it is intended that in the first three years of the scheme, the approval fee be based on a new medicines approval of $88,000. The Crown would initially meet any shortfall, which would subsequently be recovered from industry. We expect that at most there will be 10 approval applications in the first year or two. In reality there may only be one or two approvals in the first year and hence the need to cost recover in out years. If the regulator is placed within the Ministry of Health we believe there are ways we could attempt to keep costs to a minimum by integrating some of the regulator’s functions with similar functions already in place.

81. The Ministry will still be required to work within the FTE cap. Staffing the regulator will have implications for servicing other Ministry priorities. There are opportunities for sharing back office functionality with other regulators including the proposed natural health products regulator.

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

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

Objectives:

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

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

<table>
<thead>
<tr>
<th>CRITERIA</th>
<th>New regime</th>
<th>New regime + HSNO 6</th>
<th>HSNO</th>
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<td>Certainty for industry</td>
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<td>Adequate coverage</td>
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<td>partial</td>
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<td>Safety</td>
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<td>✓</td>
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</tr>
<tr>
<td>Efficient</td>
<td>x</td>
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<td>x</td>
</tr>
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</table>

87. Psychoactive substances are hazardous substances as defined by the Hazardous Substances and New Organisms Act 1996 (HSNO) as they are target organ toxicants. The HSNO places controls on the importation of hazardous substances. HSNO controls could be used to regulate the importation of both active ingredients used in the manufacture of psychoactive products, and the importation of finished manufactured products.

88. Alternatively, the Ministry has considered whether it would be possible or practical to use the new regime to control the importation of active ingredients and finished products.

89. A third option would be to use HSNO controls to regulate the importation of just the active ingredients, but the importation of finished manufactured products would be controlled under the new legislation. This split approach is consistent with the legislative mechanisms for controlling the importation of medicines.

6 Hazardous Substances and New Organisms Act 1996
Option one - Hazardous Substances and New Organisms Act 1996

90. The purpose of the HSNO is to protect the environment, and the health and safety of communities, by preventing or managing the adverse effects of hazardous substances and new organisms. Under the HSNO, the EPA is empowered to assess and decide on applications to introduce hazardous substances or new organisms into New Zealand.

91. Approvals by the EPA are granted with controls to regulate the whole life-cycle of the hazardous substance, from import and manufacture through to use and disposal. In a few cases, the HSNO only regulates part of the life-cycle of a substance. One such case is human medicines, where the life-cycle ends at the point at which the pharmaceutical active ingredient is manufactured into a finished dose product. There is an exemption under the HSNO regulations, and Medsafe regulates medicines from this point to retail and end use under the Medicines Act 1981.

92. It would be possible for the HSNO to regulate the importation of both the active ingredients used to manufacture psychoactive products and the manufactured products. One potential benefit of this is the signal it would give about products being hazardous. It would be straightforward for industry as a single piece of legislation would regulate the whole life-cycle of the products.

93. The disadvantage is that, if the EPA was assessing the manufactured product for importation, it would mean that the EPA would be required to consider the end-use and retail of the products. This would essentially make the EPA the regulator for the new regime. Part B of this analysis has discussed why, on balance, the Ministry does not consider the EPA to be the best option for the regulator. The Law Commission also considered that dedicated legislation for psychoactive substances was preferable to using the HSNO. This is principally because the HSNO controls a large number of highly varied substances, and the monitoring and evaluation of controls on psychoactive substances may be better targeted with specific legislation.

94. The Ministry also considers that HSNO would not provide the desired amount of control over importers of psychoactive substances. Once an active ingredient or product has a HSNO approval, anyone can import it. The EPA does have discretion to set additional controls and, were this option preferred, it may be appropriate to include controls over importers. The Ministry for the Environment (MFE) administers the HSNO and does not support this option.

Option two - new regime

95. The new regime could include provisions to control the importation of both the active ingredients used in the domestic manufacture of psychoactive products, and finished products.

96. In the case of active ingredients, any risks associated with their importation and transportation would need to be managed, including requirements for packaging and labelling. Active ingredients would be registered with the new regime’s regulator before they entered New Zealand, and importers would be required to provide sufficient safety information to demonstrate that any toxicity or other factors such as volatility could be adequately managed. There would need to be an exemption from control under the HSNO.
97. In the case of manufactured products, approval by the regulator would be required prior to importation, and the approved product would come in to New Zealand ready for retail. If products were allowed into New Zealand before approval had been granted by the regulator, products would need to be held by Customs pending approval. This is not practical. However it would be appropriate to provide for a licence to import small amounts for testing and research purposes.

98. The benefit of using the new regime to manage the importation of both active ingredients and manufactured products would be that the whole life-cycle of products, from ingredient to end product and disposal, could be covered by a single piece of dedicated legislation.

99. The disadvantage of this option may be some lack of certainty for industry as some of the active ingredients may be used in other areas of manufacturing. Some ingredients may already have HSNO approval and this may create confusion.

100. This option creates unnecessary regulatory duplication as the importation of chemicals is already regulated by the HSNO. It would require the new regulator to establish systems and expertise for managing the safe importation of chemicals which would entail both set-up and on-going costs. This option is not supported by MFE, Customs, or the EPA.

Option three - HSNO and the New Regime

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

102. This option would minimise duplication by using the existing provisions in the HSNO to import active ingredients for manufacture of psychoactive products. It would use dedicated legislation to manage the approval and importation of the manufactured product, in addition to retail and accompanying offences and enforcement powers.

Impact analysis

Costs to industry

Active ingredients

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

104. Each hazardous substance must go through an assessment and meet data requirements regarding toxicity, and other risk factors. Once a substance has a HSNO approval, anyone can import or manufacture it in accordance with the controls imposed on that approval.

105. Requirements for individual approval include: full chemical identification, chemical properties of the substance such as boiling point and solubility, and the life-cycle of the substance including manufacture, use, and disposal. A sponsor must provide information about potential risks and benefits of approving the release of a hazardous substance. Information on the hazardous properties of the substance must be provided including whether it is corrosive, explosive, toxic, flammable, or ecotoxic.

106. The EPA charges fees for an individual approval. For instance the fee is $17,250 for a new active ingredient requiring a comprehensive information package, or a reduced risk rate of $5,750 applied to substances for which there is a reference substance already in active use in New Zealand. This does not include the costs to industry of conducting testing required for a HSNO data package.

Group standard approval

107. Group standards under the HSNO apply to groups of hazardous substances of a similar nature, type, or use. Group standards are in place for many different types of hazardous substance including: laboratory chemicals, pharmaceutical active ingredients, as well as for additives, process chemicals and raw materials.

108. Generally group standard approvals expect industry to certify that a substance comes under one of the group standards. Importers would be expected to have relevant data available but a substance would not go through HSNO assessment process for individual approval. Group standards are often developed by the relevant industry.

109. The exact cost of issuing a new group standard is arranged by negotiation between industry and the EPA but is usually around $15,000 (ex. GST) excluding hearing costs. The process for issuing a group standard generally includes public notification and opportunity for submissions to be made. Once established, importers generally self-certify that substances are covered by a group standard. There is no cost for self-certification to import substances covered by a group standard.

Discussion

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

112. The Ministry proposes using the HSN group standard approval mechanism to import active ingredients and then both products manufactured domestically and those manufactured overseas would go through the same approval process with the new regulator. The EPA agrees with this approach.

113. The onus would be on industry to initiate this process and there would be some initial cost shared across industry in establishing a group standard. Once the group standard is in place, there would be minimal additional costs.

114. There would be a small additional cost to importers of active ingredients in the form of licences granted by the new regulator. The licence would provide some additional controls over who can import active ingredients which are not generally provided for under a HSN group standard.

Finished products

115. The cost of importing finished products would by the cost of an approval by the new regulator, set out in Parts A and B.

116. There would be some small additional cost to importers in the form of a licence to import a small quantity of unapproved finished product for testing purposes.

Impact on agencies

117. Customs has indicated there may be some savings associated with the new regime if active ingredients and products are accurately labelled and managed appropriately through the HSN and the new regime. However, Customs considers that this is likely to be marginal.

118. The enforcement of the controls on the importation of active ingredients under the HSN is part of Customs’ core business and is expected to be met within baselines. However, the import and export of approved products under the new regime may have financial implications. As yet, there is insufficient information on which to assess this impact. Customs intends to monitor this situation.
Part D - Offences and penalties

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

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

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

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

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

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

121. With other psychoactive substances, particularly alcohol and tobacco, the Government restricts the access of young people, and minimises the visibility through controls on advertising and display. There are also restrictions on products such as medicines to provide consumer information on ingredients and dose, and emergency information in case of concern.

122. It is intended that regulation-making provisions are included in the new regime to allow for controls to reduce the demand for approved products, control availability, and to require the industry to provide accurate consumer information.

123. Controls will be based on the Misuse of Drugs (Restricted Substances) Regulations 2008, together with the recommendations of the Law Commission. In May 2012 the Ministry undertook a targeted consultation with industry on a proposed set of retail restrictions. Industry members were generally supportive of the proposed controls. However, some in the industry argued for a more restrictive model of distribution that would allow them additional controls over who may access their products.

124. We have been unable to give due consideration to this proposal in the time available. We intend to report back to Cabinet Social Policy Committee by 1 October 2012 with a detailed rationale and impact analysis for a set of retail restrictions for approved products. The retail restrictions we will propose in this report back will have the primary objective of mitigating harms from the legal availability of psychoactive products and will take into account the views expressed by industry in the targeted consultation we undertook in May 2012.
Part F – Trade issues

125. Consideration will need to be given to trade and the export of approved products. The Ministry is still considering possible implications under the Trans-Tasman Mutual Recognition Act 1997 (TTMRA) and the World Trade Organization (WTO) Technical Barriers to Trade.

126. Whilst some psychoactive products may be approved for sale in New Zealand, their legal status may be more ambiguous in other countries. Other jurisdictions are taking different approaches to addressing the issue of emerging uncontrolled substances, such as emergency measures including temporary bans. This means the legal status of substances can change quickly and exporters may find products in a legal limbo.

Trans-Tasman Mutual Recognition Act 1997

127. The TTMRA establishes the obligation that a product which is legally able to be sold in New Zealand can be legally sold in all Australian states and territories, and vice versa.

128. This is overarching legislation so it overrides any other goods-specific legislation, unless there is a standing exclusion (such as prohibited imports in the Customs and Excise Act 1996) or if there is a permanent exemption as there currently is for therapeutic goods.

129. It is proposed that all unapproved substances would be prohibited imports under the Customs and Excise Act. This means that products legally available in Australia could not be imported into or sold in New Zealand unless approved by the New Zealand regulator. New Zealand approved products, however, could enter Australia under the TTMRA provisions. Australia may, in due course, establish similar regulatory scheme at which point it may be possible to apply trans-Tasman mutual recognition again.

130. The Ministry has initiated discussions with officials in the Australian States and Territories about New Zealand’s proposals for new regulation. The Ministry will continue to work through these issues with Australian officials.

Technical Barriers to Trade

131. The World Trade Organization (WTO) Technical Barriers to Trade aims to ensure that regulations, standards, testing and certification procedures do not create unnecessary obstacles, while also providing members with the right to implement measures to achieve legitimate policy objectives, such as the protection of human health and safety.

132. New Zealand will need to balance its WTO obligations, obligations to domestic industry to allow legitimate export trade, and its relationship with other countries that might be concerned about New Zealand exporting psychoactive substances.

133. The Ministry plans to notify the WTO of this proposed new regulatory scheme once Cabinet has agreed to a policy direction.
Consultation

134. The Law Commission published an issues paper in February 2010 which set out options for a new regime for psychoactive substances. The Law Commission carried out targeted and public consultation and received 3,800 submissions on the paper. On the basis of the feedback received the Law Commission made 45 recommendations for a new regime. The Ministry has taken these into account in the development of policy proposals.

135. The Ministry has also collaborated with other government agencies on the proposals, namely: the Ministry of Justice, New Zealand Police, and the New Zealand Customs Service. The Ministry has consulted with the Ministry for Primary Industries, the Ministry for the Environment, the Environmental Protection Authority, the Ministry for Consumer Affairs, the Treasury, and the Ministry for Economic Development.

136. A number of scientific experts, including toxicologists, psychiatrists, and emergency department specialists, have been consulted on proposals for the approval criteria and retail restrictions.

137. The Ministry has met with key industry members and ran a targeted consultation in May 2012 on some proposals such as on the approval criteria and retail restrictions. The Ministry has requested market information from industry to ascertain the current scale and the potential scale of market activity under the new regime but has received little information in this regard.

Implementation

138. If Cabinet agrees to the policy approach proposed, the next stage will be for the Parliamentary Counsel Office to draft a Bill for First Reading in the House. There are a number of details that will be worked through during the drafting stage, including the offences and penalties, and any necessary consequential amendments to other legislation.

139. There would be a number of impacts following enactment. Following enactment, the importation and supply of any unapproved substance would be illegal. There will also be regulations restricting which retail outlets are permitted to supply approved products. The Ministry has considered options for transitional and amnesty arrangements to allow those affected by the change make the necessary changes.

140. There are three options. The first option is that there is no transition or amnesty, which means that industry and retail outlets would need to be compliant with the legal changes immediately following enactment. This would mean that all substances being legally sold at the time of enactment would need to be removed from sale pending approval. This would have a cost to industry from lost revenue while applications are made to the new regulator for assessment. There would also be a loss of revenue to retail outlets. During the period between enactment and the approval of products, there would be no psychoactive products legally available, which would affect the public. The Ministry considers it likely that the continuing demand for psychoactive substances would be met during this period through the black market.

141. The second option would allow for an amnesty during which, industry and retail outlets could adjust to the legislative change without being prosecuted. This
still has many of the negative impacts of the first option and there would still be
a vacuum leading to consumers satisfying demand through the black market.

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

Monitoring, evaluation and review

143. Although consistent with the way New Zealand controls medicines, food, and
hazardous substances, a pre-market approval regime is a novel approach for
drug control. The Ministry therefore considers it appropriate that there is a
review of the legislation five years following enactment. There will also need to
be a review of the fee structure sooner than this.

144. In order to monitor the health effects of the new legislation, there are a number
of data sources the Ministry can draw upon. New hospital codes will be
created for each approved product and better coding for unapproved
substances. The Ministry will also continue to monitor the free text used for
hospital discharges. Data from the Poisons Centre and the Centre for Adverse
Reactions Monitoring will also be reviewed for self-reported adverse events.

145. Supply of both approved and unapproved substances can be monitored from
Police and Customs data. It is proposed that Customs provide the new
regulator with a monthly report of all imports which meet the import
requirements for tracking. The different stages of importation and manufacture
will be licensed by the regulator and will be audited as part of surveillance.

146. Police data will provide information on activity around unapproved substances
and illegal drugs and would help indicate displacement issues if there is a spike
or decline in supply of these substances.

147. Demand and prevalence will be measured through existing surveys managed
by the Ministry. This will provide information on both the use of legally
available psychoactive substances and illegal drugs.
Health report

Hon Peter Dunne (Associate Minister of Health)
cc Hon Tony Ryall (Minister of Health)

Summary of proposals for the new regime to control low-risk psychoactive substances

Executive summary

i. The Ministry is preparing a Cabinet Paper for you to take to Cabinet Social Policy Committee on 27 June 2012 with proposals for the new regime for psychoactive substances. This health report provides you with an overview of how the Ministry envisions the regime would work, and seeks your agreement to the direction we are proposing.

ii. We propose that:

   a. A new regulator for low-risk psychoactive substances be established within the Ministry of Health;

   b. The regulator will be responsible for issuing licences, assessing and approving new products, post-market monitoring and audit, recall, and other enforcement functions;

   c. Approvals will be for a manufactured product rather than the individual active ingredients to account for potential drug interactions;

   d. Toxicological and behavioural data will be required to inform the approval of new products. These requirements will be broadly similar to those used in the assessment of new medicines but without consideration of the product’s efficacy;

   e. Requirements around the importation of active ingredients and finished products will be consistent with that for medicines. Active ingredients will be imported under the Hazardous Substances and New Organisms Act 1996. Finished products will be imported under the new regime;

   f. Retail restrictions will be similar to those made under the Misuse of Drugs (Restricted Substances) Regulations 2008, in line with the Law Commission’s recommendations;

   g. Export of approved products will only be allowed with an export licence granted by the regulator;

   h. There will be a suite of offences and penalties consistent with other similar legislation;

   i. There will be price control measures to prevent discounting;

   j. There will be transitional provisions following enactment;

   k. The new legislation will revoke the following provisions of the Misuse of Drugs Act 1975 (MoDA): the restricted substances provisions, the controlled drug analogue provisions, and the provisions for temporary class drug Notices (TCDN).

iv. You may wish to discuss aspects of the proposed direction in greater detail with Ministry officials.
The Ministry recommends that you:

a) **Agree** to the Ministry's proposed direction (proposals a – k above) for the new regime  
   Yes / No

b) **Signal** areas where you would like further briefing in advance of receiving the draft Cabinet Paper  
   Yes / No

Don Gray  
Deputy Director-General  
Policy Business Unit

Minister's signature  
Date 5-06-12

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Minister's feedback on quality of report

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Advice

1. On 29 August 2011, Cabinet agreed to consider the development of new legislation for low-risk psychoactive substances requiring (CBC Min(11)8/19 refers). The reverse onus regulatory regime would make the importation and supply of all psychoactive substances illegal unless they have been assessed for risk and granted approval.

2. You were invited to report back to Cabinet with policy proposals for the new regime by 30 June 2012. You will be provided with a paper on 20 June to take to Cabinet Social Policy Committee on 27 June 2012.

3. The new regime responds to two inter-related problems. Firstly, potentially harmful untested substances are on the market without any controls over ingredients, quality, potency, purchase age, or place of sale. Secondly, the Government has to play catch-up, identify that these products are being sold, and then place restrictions on them as appropriate.

4. In developing proposals for the new regime, we have been working with Police, Customs, and the Ministry of Justice, and consulting with the Ministry for the Environment, the Environmental Protection Authority (EPA), the Ministry for Primary Industries, and the Ministry for Economic Development. We have also received independent scientific advice on some elements of the proposed regime.

5. Attached is a diagram (diagram 1) of how we envisage the new regime operating from import to retail. There are two different paths depending on whether an active ingredient is being imported into New Zealand for domestic manufacture, or a finished product is being imported for retail.

Importation of active ingredients

6. In the case of active ingredients, we propose that their importation is largely managed under the Hazardous Substances and New Organisms Act (HSNO) which is implemented by the EPA. Active ingredients would need to comply with a HSNO group standard; any non-compliant active ingredient would be a prohibited import under the Customs and Excise Act 1996. The HSNO group standard would manage safety issues associated with importation, transport, and manufacture. Once the ingredient is manufactured into a formulated product, it would be controlled under the new regime. This is consistent with controls over the importation of active pharmaceutical ingredients and medicines.

7. In addition to the controls provided for by a HSNO Group Standard, we propose that an importer would be required to hold a licence granted by the new regulator to ensure that only approved importers can import active ingredients.

Importation of manufactured products

8. In the case of manufactured products, we propose that their importation is managed under the new regime and that importation is generally only allowed for approved products. The regulator would allow licences for the importation of small quantities of finished products for testing purposes.

Approval process

9. We agree with the Law Commission recommendation that each finished manufactured product should require approval from the regulator, rather than each active ingredient. This ensures that each combination of ingredients is assessed and taken into account the manner in which the substances are intended to be taken (for example, swallowing a tablet or smoking plant matter) as well as any potential drug interactions. Granting approval for products instead of individual substances will also allow more targeted controls to be made on the dose of active ingredients.
10. A product sponsor would be required to submit a data package to the regulator with full product details, results of animal toxicity and human trials, and evidence of manufacturing standards. The Ministry has consulted with industry, government agencies, and technical experts on the exact nature of this data package. Submitters have supported its validity and raised some minor technical amendments that will help ensure the framework is effective and reasonable.

The regulator

11. We have considered a number of options in relation to where the new regulator should be established. Based on criteria of independence, efficiency, proportionality and suitability, we propose that the regulator be in the Ministry of Health. This is consistent with the Law Commission’s recommendation.

12. The regulator would be responsible for issuing licences to manage the importation, manufacture, export, and retail of psychoactive products. The regulator would also carry out pre-market risk assessments for products, and post-market safety surveillance.

13. The cost of the regulator would be met primarily through cost recovery in the form of fees charged to industry for assessments and post-market monitoring. Options for the cost recovery model are being considered.

14. As it is not yet known how many products will be submitted to the regulator for assessment, or the size of the market, we propose that initially the new regulator shares back-office functions with the new regulator for natural health products.

15. The regulator would have the power to approve products, recall products and dispose of them. Appeals could be made to the District Court on decisions made by the regulator. This is consistent with HSNO provisions. Options are being considered for emergency recall powers for the Director-General of Health or the Minister of Health.

Retail restrictions

16. Once a product is approved, it is proposed that retail restrictions be placed around the product’s marketing, availability, and purchase age. The proposed restrictions were recommended by the Law Commission and in most cases already provided for under the Misuse of Drugs (Restricted Substances) Regulations 2008.

17. We have carried out a targeted consultation on the proposed restrictions. Feedback was generally supportive, but some submitters have asked for an older minimum purchase age and one submitter requested a different model of distribution. We are considering these responses and will provide you with further comment on these restrictions in due course.

Trade

18. We consider that exports of approved products should only be allowed with an export licence granted by the regulator. Any export without a licence would be a prohibited export under the Customs and Excise Act.

19. We have initiated discussions with counterparts in the Australian States and Territories about potential Trans-Tasman Mutual Recognition Act (TTMRA) implications of the new regime. In New Zealand, all unapproved products and substances would be prohibited imports under the Customs and Excise Act and so would be exempt from TTMRA requirements. Australia will need to consider whether an exemption would be required for products approved in New Zealand, to prevent their importation into Australia.

20. We have also initiated discussions on any implications to New Zealand’s obligations under the World Trade Organization regarding Technical Barriers to Trade.
Price control measures

21. We think that there should be price controls on the sale of approved products to prevent discounting. The options are setting a minimum price per dose of approved product, charging an excise on approved products, or both.

22. A minimum retail price would be administratively simpler than an excise but would not return revenue to Government. We intend to discuss these options in greater detail in the paper you will take to Cabinet in June.

Offences and penalties

23. The Ministry of Justice has considered the relevant offences for breaches under the new regime. The penalties Justice has proposed are consistent with the MoDA and the HSNO.

24. A decision will be required on the merits of having an offence for the possession of an unapproved substance. We are still discussing with Police and the Ministry of Justice on whether it is fair and practical to have a possession offence. An offence for possession would be consistent with the MoDA. Not having a possession offence would be consistent with the TCND, tobacco and alcohol legislation. There are costs and benefits associated with both approaches, which we are still discussing with Police and the Ministry of Justice. We will provide further information on the options in the Cabinet paper, and can discuss these with you further as appropriate.

Enactment implications

25. Diagram 2 (attached) which sets out implications following enactment of the new regime. Following enactment, the importation and supply of all unapproved psychoactive substances would be illegal. This has implications for importers, manufacturers, and distributors of psychoactive products.

26. We have been considering options for amnesty and transitional arrangements to allow importers, manufacturers, and retailers to adjust to the new legislation. The diagram includes three options: no transition, no transition but an amnesty, transition which includes an amnesty. During a transition period, products which had been legally sold six months prior to enactment could continue to be sold provided an application had been made to the regulator for approval. At the end of the transition period, only approved products could be legally sold. Retail restrictions would be enforced following the amnesty period and would apply during the transitional period. This would mean that dairies would not be permitted to sell psychoactive products three months following the date of enactment.

27. The new regime will revoke three existing provisions of the MoDA: the restricted substances regime, the analogue provisions, and the TCND. All three provisions will be redundant when the new legislation is enacted as the reverse onus regime makes all unapproved psychoactive substances and products illegal, which is more comprehensive than the current provisions. For instance, in the case of an analogue, currently testing is required to establish that a substance is structurally similar to a controlled drug. Under the new regime, this will be unnecessary, as anything without an approval would be controlled by default.

END.
Diagram 1 - New regime for psychoactive substances

- Overseas laboratory and manufacturing plant would require certification
- Importers of active ingredients would need to meet HSNO group standards and have licence to import from new psychoactive products regulator
- All unapproved products or active ingredients not complying with HSNO group standard would be prohibited imports under Customs and Excise Act
- NZNO controls over safety issues at point of manufacture. GMP licensing, audit, and enforcement by new regulator
- Approval criteria: Harm profile, toxicity, pharmacological effects
- Importers of finished products would need to meet requirements of new psychoactive products regulator
- Approval criteria: Harm profile, toxicity, pharmacological effects
- Approval: Outlet, purchase age, advertising
- Restrictions on type of outlet and retail licence
- Monitoring, surveillance, and enforcement by new regulator. Powers to audit, recall, remove etc.
- Psychactive products Regulator
- Approval
- NZ Border
- HSNO treatment conditions
- Product
- Approval
- Approval criteria: Harm profile, toxicity, pharmacological effects
- Product
- Approval criteria: Harm profile, toxicity, pharmacological effects
- Approval: Outlet, purchase age, advertising
- Restrictions on type of outlet and retail licence
- Monitoring, surveillance, and enforcement by new regulator. Powers to audit, recall, remove etc.
Diagram 2 - Implications following enactment of new regime for psychoactive substances

Enactment of new regime

- Revoke restricted substances regime
  - if there are offences for possession, then little impact

- Revoke analogue provisions
  - if no possession offence, then analogues considered by EACD

- Revoke TCDN
  - a. No transitional arrangement, everything off shelves from day of enactment
  - b. No transition but a three-month amnesty to adapt to new legislation
  - c. Transition period with three-month amnesty. After amnesty, only products which had a pending product approval with the regulatory could be sold during the transition. Retail restrictions would be enforced following amnesty period. After the transition period, only approved products could be sold

Import/supply of all psychoactive substances illegal

Transition options
Psychoactive Substances (Increasing Penalty for Supply and Distribution) Amendment Bill

Departmental Report

Prepared by the Ministry of Health

23 August 2018
Introduction

1. This report provides an overview of submissions on the Psychoactive Substances (Increasing Penalty for Supply and Distribution) Amendment Bill (the Bill).

2. The Parliamentary Counsel Office has been consulted in the development of this report.

3. This report provides advice on the proposed amendment to the Psychoactive Substances Act.

Submissions Received

4. The Committee received 78 written submissions on the Bill.

5. There were 18 submissions in support of the Bill and 53 submissions opposing the Bill. A further seven submissions are unclear.

6. The committee heard five oral submissions in Auckland on 18 June 2018, and two submissions in Wellington on 6 September 2018. X supplementary submissions were received during oral hearings.

7. There were 64 individual submissions and 14 submissions from organisations, including five health or treatment related organisations, three justice sector related organisations (including lobbyists), three local government or local business groups, two industry related organisations and one research organisation.

8. Some submissions appear to be form submissions. Of the individual submissions, 21 repeat similar statements including:
   - there is a lack of evidence that longer prison sentences contribute to reduced harm
   - that prohibition of drugs causes harm
   - that being tough on crime does not work
   - all drug use should be treated as a health issue rather than a criminal issue.

   Similar themes appear in other written submissions.

9. The submissions in support of the Bill generally argue that drug dealers should be punished, that penalties should be aligned with cannabis offences, and that this increase in penalties should be included along with a range of other interventions.

Comment

10. The Bill recommends that Section 70(3)(a) is amended to replace “2 years” with “8 years”. The intention of the Bill is to increase the penalty associated with the supply of non-approved products in line with the penalties for the supply of Class C drugs under section 6(2)(c) of the Misuse of Drugs Act 1975.

11. The Ministry of Health and the Ministry of Justice advise the following:

   Increases in penalties do not necessarily produce a corresponding deterrent effect:
   - In relation to “deterrence,” the international and domestic evidence does not support the contention that increased penalties results in reduced incidences of
offending. Instead the majority of the ‘deterrent effect’ is considered to be tied to the certainty of response to offending, rather than the severity of punishment which ensues. While there is strong evidence for the general deterrent power of a criminal justice system, increases in the severity of penalties do not produce a corresponding increase in deterrence.

12. Psychoactive substances may pose a greater or lesser risk of harm than Class C drugs, for which supply is punishable by 8 years’ imprisonment
   - Recent reports indicate the Coroner is currently investigating 40 – 45 deaths provisionally linked to synthetic cannabis, suggesting a higher risk of harm than Class C substances.
   - The Psychoactive Substances Act regulates substances that pose no more than a low risk of harm, and the Misuse of Drugs Act regulates drugs by classifying drugs according to the level of risk they pose.

13. Officials recommend that Parliament does not consider penalties in the Psychoactive Substances Act in isolation from other drug related legislation and a wider work programme.

Contact: Todd Krieble, Chief Strategy and Policy Officer, Strategy and Policy

Situation: The Ministry is advising the Justice Committee on Simeon Brown’s private member’s bill ‘Psychoactive Substances (Increasing Penalty for Supply and Distribution) Amendment’ Bill. The bill proposes to increase the penalty and offences provisions in the Psychoactive Substances Act 2013 (the Act).

The Ministry’s view is that while there may be a deterrent effect with increased penalties, there is insufficient evidence to show a direct link between increased penalties and reduced harm.

Next steps
We will provide the draft departmental report to you on 29 August 2018, seeking your final approval before it is sent to the Office of the Clerk. In the report we propose recommending that the offences and penalties in the Act should not be addressed in isolation from a wider work programme.

As the departmental report is due to the Committee on 4 September 2018, your approval is required by Friday 31 August 2018. The departmental report will be presented to the Committee on 6 September 2018.

Action: No action required. This information is for noting only.