A critical assessment of the new psychoactive substances regime in New Zealand

5th Addiction Research Research Symposium

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Overview

I. Recent NPS trends in New Zealand
II. The challenge of controlling NPS
III. Psychoactive Substances Act 2013
IV. A critical appraisal of the new NPS regulatory regime
I. Recent history of NPS in New Zealand
% noticed new drug for first time, 2009-2012

<table>
<thead>
<tr>
<th>Year</th>
<th>% of frequent drug users</th>
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<tbody>
<tr>
<td>2008</td>
<td>9%</td>
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<tr>
<td>2009</td>
<td>13%</td>
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<td>2010</td>
<td>24%</td>
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<td>2011</td>
<td>34%</td>
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<td>2012</td>
<td>27%</td>
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Drug types tried by the frequent ecstasy users for the first time, 2009-2012

- Synthetic cannabis: 30% (2009), 11% (2010), 16% (2011), 5% (2012)
- Ecstasy: 9% (2009), 5% (2010), 17% (2011), 16% (2012)
- LSD: 25% (2009)
- Any 2C drug: 10% (2009), 7% (2010), 0% (2011), 8% (2012)
- Ketamine: 11% (2009), 11% (2010), 6% (2011), 11% (2012)
- Salvia Divinorum: 9% (2009), 5% (2010), 5% (2011), 1% (2012)
NPS by ecstasy users, 2006-2012
II. The challenge of controlling NPS
Emergence of the NPS problem

- Number new NPS in Europe increased from 13 in 2008 to 73 in 2012
- New or obscure compounds with little scientific data on harm
- A range of compound classes (e.g. piperazines, cathinones, cannabimimetics)
- Marketed as ‘legal’ substitutes for existing illegal drugs
- Number websites selling in Europe increased from 170 in 2010 to 693 in 2012
Difficulties with prohibiting NPS

- Large number of individual compounds available
- Cost of identifying and testing active ingredients
- Slowness of legislative process to ban
- Capacity to rapidly replace newly controlled compound with uncontrolled compound
- Ability of manufacturers to sell products directly to users via internet websites
- The harm of existing legal drugs sometimes higher than legal high products
III. Psychoactive Substances
Act 2013
Pre-market approval regulatory approach

• NPS that can be shown to be ‘low risk’ with ‘toxicology and clinical testing’ will be approved for legal manufacture and sale
• Pre-market approval regime (e.g. medicines, novel foods, hazardous substances)
• Sale NPS subject to range of retail restrictions and regulatory standards
• NPS regulatory authority within Ministry of Health
• Independent expert technical committee (provide advice)
Psychoactive Substances Act 2013

- Approval for NPS *products* not compounds
- ‘Low risk’ products approved for legal sale
- Industry pays for & carries out product testing
- MOH ‘estimates’ testing products cost $1-2 million
- Application fee of $180,000 per product
- Advertising at ‘point of sale’ only
- No sale from convenience stores
- License required for import, manufacture and retail sale
Advantages of regulated approach

- ‘Reverse the onus of proof’ to manufacturers having to prove product ‘low risk’
- Govt no longer has to chase and assess products
- Manufacturers reduced incentives to continually introduce new obscure compounds
- Removal of high risk products from legal market
- Industry pays (‘cost recovery’)
- Manufacturers/sellers licenced and made known
- Possibility of a more nuanced response
Advantages of regulated approach

- Possibility of substitution of more harmful alcohol and drugs for safer legal highs
- Govt ‘affirmed’ all products meet threshold will be approved
- Attempt to remove politics from assessment and approval of products
Progress to date

- Legislation passed (119 ayes – 1 noes)
- Animal testing largely averted (beagles saved?)
- Down from 200 to less than 46 products
- Down from 3-4,000 convenience outlets to 156 specialty stores
- Code of manufacturing implemented
- Required secondary regulation under development
Do you agree with the new synthetic drug laws? (n=3,220)
IV. A critical appraisal of new regulatory regime
Defining ‘low risk’

- What does ‘low risk’ mean – not in legislation
- ‘low risk to users’
- Individuals different sensitivities (e.g. mental health)
- What scientific tests applied? – not in legislation
- What is recourse if harmed from ‘low risk’ product – who pays?
- Recently added set of six risk principles (‘appeal to vulnerable populations’)
- Some risks can only be determined after approval?
Limitations of clinical testing at identifying ‘low risk’ NPS

- Clinical trials ‘broadly similar to medicines’
- Recommended dose vs. hedonistic consumption
- Dosage in isolation vs. poly drug use
- Healthy trial participants vs. vulnerable indivs (e.g. unsupervised risk taking young people)
- Risky means of administration (i.e. smoking, injection)
- Difficulties of identifying long term harms
The challenge of post-approval monitoring

- Licence holders must report adverse effects
- Challenges of pharmacovigilance (rare side-effects, association other illnesses, long term effects)
- NPS + other drugs producing general ‘hangover’ may reducing reporting
- Notable cases of pharmaceutical companies failing to report adverse effects (e.g. paroxetine)
- Magnitude of profit vs. fines
Impact of legal NPS market on use of other substances

• Testing may reduce per unit harm of NPS products *but* offset by increased prevalence

• Approved NPS products perceived as safer and more socially acceptable stimulate demand

• (i) *Complement* - Greater use of approved NPS increases demand for unapproved NPS and other legal and illegal drugs = more harm?

• (ii) *Substitute* - Greater use of approved NPS reduces demand for unapproved NPS and other legal and illegal drugs = less harm?
How effective will advertising restrictions be?

- Limited to ‘point of sale’ (no t.v, radio, newspaper)
- Other restrictions on physical promotion
- Websites are approved points of sale
- 693 sites selling NPS to Europe in 2012
- Advertising on wider net is prohibited but ability to enforce unclear
- Covert promotion via social network sites and blog
To what extent will the black market for NPS continue?

- Unapproved will be physically identical to unapproved
- Unapproved products may be cheaper, more powerful and more socially attractive
- Conversely, approved products will have legal status, more available and guarantee of safety and quality
- Enforcement required to test products
- Police have power to impose instant civil fine, but additional testing required
Thank you

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